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HATCH-WAXMAN AT 40

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WELCOME REMARKS:

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RICHARD G. FRANK: Director, Center on Health Policy, Senior Fellow, Economic Studies, Brookings

PANEL 1: THE ARCHITECTS:

BILL CORR: Principal, Waxman Strategies

STEVEN GROSSMAN: Executive Director, Alliance for a Stronger FDA

HENRY WAXMAN: Chairman, Waxman Strategies

MODERATOR:

WILLIAM B. SCHULTZ: Partner, Zuckerman Spaeder

PANEL 2: LESSONS LEARNED:

MARKUS H. MEIER: Retired, Federal Trade Commission, Health Care Division

BHAVEN SAMPAT: Professor, School for the Future of Innovation in Society, Arizona State University

RACHEL SACHS: Nonresident Fellow, Economic Studies, Center on Health Policy, Brookings

MODERATOR:

JEREMY SHARP: Managing Director, Waxman Strategies

PANEL 3: FUTURE DIRECTIONS:

AL ENGELBERG: Trustee,The Engelberg Foundation

FIONA SCOTT MORTON: Theodore Nierenberg Professor of Economics, Yale School of Management

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MODERATOR:

DAVID WESSEL: Director, The Hutchins Center on Fiscal and Monetary Policy, Senior Fellow,Economic Studies, Brookings

HARRIS: Good morning to everyone in the audience. And to those watching online as this event is being streamed. Welcome to our event commemorating the 40th anniversary. Of the Hatch-Waxman Act. My name is Ben Harris. I'm the vice president and director of Economic Studies here at the Brookings Institution. So today's event is obviously a very important event. I will reflect on four decades of the Act's influence on the pharmaceutical landscape. This landmark legislation, I think, as everyone. In the audience knows, has shaped the modern generic drug industry through a profound impact on patent prices. And pharmaceutical R&D strategies. In the process, saving generating trillions of dollars in savings for consumers. Taxpayers and premium payers. And the bill obviously continues to influence the interplay between state and federal policies and prescription drug markets. Today's event, which is hosted by the Center on Health Policy within the Economics Studies program, promises to offer valuable insights into the Act's past impact and future implications for some for pharmaceutical markets. To delve deeper into the. Act's far reaching effects. We've assembled a series of expert panels. The first panel will feature. The esteemed Henry Waxman, coauthor of the Act alongside other key architects. They'll discuss the bill's conception design and initial implementation. The second panel, comprising leading scholars and government officials. Will analyze the Act's impact on pharmaceutical markets, pricing and innovation. The final panel showcasing scholars and policy leaders at the forefront of the Act's ongoing evolution will address future directions for the regulation of generic drug markets and competition in the pharmaceutical industry. So we're excited to begin this enlightening discussion. And please join me in welcoming our panelists to the stage. Thank you.

FRANK: Good morning. I'm Richard Frank. I direct the Center on Health Policy. And the first panel is really talking about the origins of the act, and it is being facilitated by Bill Schultz. Bill has been around Washington for a few years and he has served as general counsel of the Department of Health and Human Services during the Obama administration, which is where we met. He goes back a long way with Congressman Waxman serving as a counsel to to the congressman years ago in energy and commerce. And he's also been the director of the Office of Policy at the FDA. And so, without further ado, Bill, the floor is yours.

SCHULTZ: Thank you, Richard. And it's terrific you're doing this program. None of us can believe it's been 40 years since Hatch-Waxman passed. The key moment of my career was when I replaced Bill Corr as counsel to Henry Waxman on the Subcommittee on Health and the Environment. And it was a seamless transition. The mailbox said Bill, and we didn't have to even change the name. But I also want to mention before that I was a public interest lawyer at Public Citizen Litigation Group. And I was sort of the consumer representative in the negotiations over Hatch-Waxman. So I got to watch close up Bill and Steve and

Congressman Waxman and Senator Hatch accomplish this enormous feat. So our panel is Henry Waxman, Congressman Henry Waxman, whom all of you know. He was a member of Congress for 40 years. He was chair of the House Oversight Committee and then also the House Commerce Committee. But in 1984, he was chairman of the House Subcommittee on Health and the Environment. Bill Corr was Congressman Waxman's FDA counsel for ten years and his principal adviser during the negotiations over the drug price Competition and Patent Term Restoration Act of 1984, now known as Hatch Waxman. During the Obama administration, he was deputy secretary of HHS, and Steve Grossman was FDA counsel for the Center for Labor, Senate, Labor and Human Resources Committee for six years and was one of Senator Hatch's principal advisers during the negotiations over Hatch. Waxman During the Reagan administration. He was deputy assistant secretary for health at HHS. Now, I want to just give a little bit of background. This is obviously a tremendously important statute, and it was known it was going to be important if it could be enacted in 1984. It was projected in that year that the bill would save $1 billion in drug costs over ten years. Well, the figures are look a little different today. According to the generic Drug Trade Association, in 2022, Hatch-Waxman saved $408 billion in drug costs and saved 2.9 trillion over the previous ten years. Prior to Hatch-Waxman, FDA had no legal basis for approving generic versions of drugs approved after 1962. Oddly, it could. It could approve generic versions of pre 62 drugs. But for post 62 drugs, there was no authority. And by the early 1980s, the patents on those drugs were expiring. So you had a situation where the FDA policy effectively extended the patents for an indefinite period of time because it was so expensive to do the full clinical studies that would be required to get a copy of the drug approved. And so there was a desperate need for a process for approving generic drugs for post 62 drugs, namely in a shortened version of a new drug application which became known as an abbreviated new drug application or an NDA. So let me start with Bill Kau, and I want to ask you to tell us what the landscape looked like in terms of the barriers to creating a vibrant generic drug market.

CORR: You know, there were a few other issues that were occurring at the time. You mentioned the first that there was no legal authority for FDA to approve post 1962 generic drugs without requiring a full set of clinical studies. But there are some other issues just to remind everyone of. Remember the anti substitution laws in the 70s and early 80s where physicians couldn't substitute, I'm sorry. We have pharmacists who are prohibited from substituting generic drugs when physicians prescribed others. Also remember that many states banned advertising of drug prices until 1976 when the Supreme Court said they couldn't do that. But any longer. So the generics were smaller companies. There were major issues they had to deal with where the laws just weren't friendly. And what we tried to do was we started to work on this was to figure out how

do you approach, how do you protect an industry and allow it to grow. But that's part of the story that we'll talk about as we go along here today.

SCHULTZ: Thank you. And so now let me turn to Steven Grossman, who was Senator Hatch's FDA counsel, and ask you about the barriers at that time to pharmaceutical innovation.

GROSSMAN: Thank you. Good to be here. Okay. I think one of the things is that this story is all work is mostly told as David beat Goliath. And that's a legitimate way to tell the story. But it ignores the fact that the the Goliath really needed this. This situation for the industry even then was seen as dire, although not everybody got it. And that you'll hear a lot more about as we talk. So in knowing that Bill was going to do the four barriers to a generic industry, I thought I would do my for barriers to a innovation in the pharmaceutical industry. And the place to start is the question that don't you ever get asked anymore, which is why would drugs not include in Medicare in 1965? And the answer is because drugs didn't matter. They were not all that good and they didn't do a lot. And we now see pharmaceutical care as the heart of treating people. Not so then. So that's the first thing that was still true in the early 1980s. And part of the story is it was starting to change, which is good. So the 1970s was a dreadful time for the pharmaceutical industry. There were few breakthroughs. They had no generic competition. But for medicines that didn't do very much. So, yes, monopolies are good and profitable in the right circumstance, but it doesn't mean that there can't be something better. And I think, as I say, not whole industry, but many parts of the industry understood that. The third was the third aspect of it was innovation was starting. You had Feldstein, which was Pfizer's arthritis drug, which was really, as far as I can tell, I'm not a doctor was the first drug that made any difference in the lives of millions of Arthrex. You have human growth hormone. You start to just begin to see the beginning of biotechnology and seeing that unfortunately, FDA was not making not responding well. They were incredibly slow or overly cautious. FDA still operated in the shadow of Frances Kelsey and wasn't wasn't overly clean about approving anything. So into that, companies were saying, we're finally getting some drugs that matter and which we really believe in, in a way I think we didn't about the others. And the FDA delays are killing us. You know, if you've got an expert in life and, you know, half of it is spent trying to convince FDA to say sort of. Yes. And that was about what it amounted to. So, yes, this is a story of David and Goliath. But let's imagine here as well that Goliath really needed this to work out the right way as well. Thank you.

SCHULTZ: Wonder who was David and who was Goliath? So the landscape is ripe for congressional legislation. But as everyone in this room knows, that's a lot easier said than done in this case. In terms of creating a generic drug program, the powerful pharma industry could be expected to fight any effort vigorously. After all, as long as there is no generic competition, patents were essentially extended indefinitely. So now let's turn to the legislation and how this worked. The key players, Congressman Henry Waxman. And in the Senate, Senator Orrin Hatch, the outside players were the PMA. The Pharmaceutical Manufacturers Association, led by Louis Egmond, who had formerly been the youngest chairman of the Federal Trade Commission and he was now chair of the trade association. Pfizer ends up being key, and they were represented by Peter Hutt, who was a former FDA chief counsel. Very prominent FDA lawyer from Covington Burling. And the reason Pfizer was key is this arthritis drug they had, which was a very big selling drug. The patent on that drug was about to expire and it would have been a very short patent life. And the generic side Bill had Ed, who previously had been an investigator for Bobby Kennedy, and he created a new trade association, the Generic Pharmaceutical Association, which had 5 to 8 members. And the purpose was to be much more active and much more effective legislatively, and it added new energy to the whole effort. And then his counsel, Alfred Engelberg, who I think was the founder really of the institute, that that Richard is now now runs here on the consumer side. Public Citizen was involved representing the consumers, and that's where I worked. So to explore the legislative process, let's start with Congressman Waxman. In the early 80s, Congressman Waxman, you had a very large public health agenda, the Orphan Drug Act, expanding Medicaid, improving Medicare, drug treatment programs, tobacco and so on. But at that time, you started to develop a bill to create a generic drug or NDA pathway to FDA. What got you interested in this project?

WAXMAN: Well, the prices of drugs were quite high, and it just seemed to me that we would be better off if we had some competition from generic drugs. But in the Judiciary Committee, there was a bill that was moving forward just to give a patent extension to drugs. This patent extension, of course, was like giving money to the holders of these drugs because they would not have any competition. So that bill was moving out of the Judiciary Committee and it was about to come to the House floor of what they call the suspension calendar. The suspension calendar is one where a bill is put on for a vote up or down, no amendments. And it required two thirds vote to pass it. And said and Congressman Cason Meyer was going to put this patent extension bill. In fact, he did on the suspension calendar. And when I saw that, I realized if that bill passed, we're not going to get generic drugs because we needed to attach it to any kind of extension of the patent. So it looked like we were going to lose. There was no organized opposition to the bill, a lot of strong support

from PMA. And I talked to the young congressman who was on my committee, who was a very active, eager person to do something. And I said, look, this bill is going to pass. Why don't we see what we can do to get the one third plus one to stop it on the suspension calendar? So Al Gore and I went to Democrats one by one on the House floor, and we were able to stop the bill from passing on the suspension calendar. Now, this was late in the session. I think it was around September. And if the bill fails on the suspension calendar, they have to go and get a rule. Well, the chairman of the Rules Committee at the time was Richard Bolling from Missouri. And he had I did not have a particularly good relationship, but Al Gore and he had a pretty good one because they were they had a lot in common. They were both liberal Democrats from southern states. And Al Gore said, I'll go talk to him. And he talked to him and said, whatever you do, don't give this bill a rule. We're going to be out of session. We could start fresh, but the next Congress comes in. And that's what happened. We prevailed by two votes to get on suspension. And as a consequence, the session ended and nothing had passed.

SCHULTZ: Okay. So let me back up and go to Steve Grossman and and get you to talk about what was going on in the Senate really even before the vote. But in terms of what was Senator Hatch's role in the act, what got him interested in the patent term extension, What got him interested in the generic drug legislation?

GROSSMAN: Thank you. The I think the way to start is it was a very different time and there'll be a theme that comes back again and again. I don't think some of the people negotiating important legislation now are going to be on a podium 40 years later smiling at each other. So Senator Hatch was elected in 1976. He was a part of a new breed of conservatives who felt they could change the world. And the 1980 election swept 12 new Republican senators into the Senate. So suddenly I went from being minority counsel that didn't get to say very much to being majority counsel. It happened very quick.

SCHULTZ: That's a good deal.

GROSSMAN: Yeah. So but changing the world was very much on Sarah Hatch's mind. Changing the law was always on. Senator Hatch is mine. Because that was that was the time that was the mandate he felt he was given. At the same time, and here's the main difference from today, he never doubted that getting a change done included Ted Kennedy and Henry Waxman. And so, you know, people ask, well, what did you do when you worked for Senator Hatch? The answer is I mostly spent time negotiating with Bill. So industry came to him. They were in bad straits. And again, I keep emphasizing that's not was it's not that the entire

industry appreciated that. There were a lot of lot of people with no vision and just a few who did. And he was happy to be there. Advocate he believed in in drugs and the benefits of drugs. And so he started with the patent extensions. And but he was he had the kind of mind that the idea of melding the two together, I don't think was ever a problem for him because that's the way his mind thought. That was the way he went. And again, it's a lot easier to think of that if you realize that he didn't think that was going to be passed without a lot of compromise and a lot of discussion among people of opposing views.

SCHULTZ: Thank you. So just in terms of the timeline, Hatch-Waxman was passed in 1984, but we're in the early 80s. In July of 1981, the Senate unanimously passed the patent extension bill that that Steve is just talked about. And so that led to the question of, well, what about the House? And Congressman Waxman has described the the normal process. You know, when I worked there, the normal process for a bill is that, you know, it goes through committee and then it goes to the House floor. And if it's a noncontroversial bill, as Congressman Waxman described, you can put it on the suspension calendar. The catch there. I mean, there are no amendments. You know, it's a short debate. But the catch there is you need two thirds. And so this event that Congressman Waxman described was absolutely key. If that bill had passed on, the suspension calendar would have been the end. I mean, we would have had patent extensions and Congressman Waxman would have had no way to get the pharmaceutical industry to do anything but vigorously oppose his legislation. And it you know, it may not have been very many good drugs, but they were pretty powerful on Capitol Hill at that time. And so that was a daunting prospect. And so, as Congressman Waxman described after they beat it on the suspension calendar by two votes. So you change two votes and we wouldn't be here today because this bill would have never passed. We would just have patent extensions. And who knows what would have happened to generic drugs. But once they beat it.

CORR: Bill, can I just add one thing there?

SCHULTZ: Yeah, please.

CORR: The suspension vote was two thirds. So. Imagine that at the time we were two votes short of two thirds wanting to give the industry patent extension without the generic drug approval system being fixed. And so it was daunting at that time as we thought about working out well, how can we possibly get the right kind of bill on the floor? But that's so that's when the long slog and hard fought Henry Waxman went to every member. And we until we built up, you know, a better path. But let me I jumped in and a little bit ahead.

SCHULTZ: No, no, that's great. So we end that Congress with no legislation and then the same players come back the next year in 1983 and with a new Congress. And let me let me just turn it over to let me go back to you again, Bill, and and just ask you, you know, what you what you you and Henry, either one. But what were you facing in 1983? I mean, you had won this victory on the suspension calendar. You kept it out of a rule and a majority vote, which you would have lost. But you knew that in terms of patent extensions, you know, things weren't so great. But So what did things look like when you came back in 1983, thinking about this legislation?

CORR: Henry. They looked bleak and they looked determined. We were certainly determined, voluntary.

WAXMAN: Well, what we did was introduce a bill combining the generic approval ANDA and the patent extension. So we had one bill with both pieces added to it, which we hoped and eventually did achieve both sides coming around. But it wasn't so easy as just putting the bills together. We had this bill, we considered it in the House and we passed it in the House. Then when it got to the Senate, different drug companies were say, Well, wait a minute. Feldene got a little bit more time. We wanted to get a little bit more time. And they were standing in line at the door of the Senate and say, we've got a claim for our little patent extension addition that the end of part made a lot of sense because to get a drug approved as a generic, you had to do all the same tests even though you got the same result. You had to prove that the drug was safe and effective. And if you had to do all those tests to get it could take years. Well, and there was an abbreviated new drug application. And the only test was, is this the same drug that's already been on the market? And if it is that FDA was called on to approve it and it could be marketed immediately as a competitive generic.

SCHULTZ: So let me let's back up a minute, though, because you made this sound so easy in that 40 years ago. Not my recollection. So my recollection and I was kind of an outsider, but I was watching this really closely is that you had pharma completely against you in the house and you knew you had to do something. And this is where felting became so important. And my understanding and tell me, you know, if this is right and wrong, is, is that you made a deal with Pfizer and you said you've got very little time left on this drug, but we'll put a provision in this bill that says for anything approved between 1982 and 1984, which happened to include felting, we'll give you ten years, we'll give you a ten year patent extension for any of those drugs. And the reason I remember this well is I was I was a, you know, lobbying for a public interest group, you know, very much on the outside. But but we were you know, we were part of it. And that deal was made and we

were shocked. Why would Congressman Waxman do this and give this this gift to the industry? And so we asked for a meeting and we went in and I'm sure because there and we said, Congressman Waxman, why would you do something like this? And Congressman Waxman's answer was, because I wanted a bill. And that's that's my memory. And so this was a. You know, a huge kind of legislative maneuver to split the pharma industry and start to get some momentum. I don't know if either of you want to come on comment on this or tell me my memories are on.

CORR: Mine as well, Bill. You know, there's someone else here in the room, Al Engelberg, who we should bring into this, because during this period of time when Henry said we've got to stop the PMA from moving forward with just the patent extension stuff, we've got to make the case for we need a generic drug approval system that works. And we spent endless hours, you know, talking with PMA people, talking with people and supporting the generic industry. And now, Engelberg, of course, there's a patent law where, you know, we spent endless hours, it seems like in House Legislative Council, working on every aspect of it, because it was quite a complex bill just to draft. And it's easy now sitting here to say, well, we met, you know, a couple hours a day for weeks on line. But anyway, that was I think one of the most important things was that we had to put together a generic approval system that would work. And those of us knew nothing about how to I mean, none of us did really, and how helped us figure out how do you what is it that generics need in the way of protection to be able to to get through the system and with confidence that they are safe and effective?

WAXMAN: Yeah, Bill, you're absolutely right. I have played an essential role in advising us because he knew all the details of the law and what the legislation could mean. So you were an honorary member of Congress. You may not wanted that title, but you were an honorary member of Congress. And in designing the details of the legislation, we did make it sound easy with the end, but we created a process where drugs that were that weren't interchangeable could rely on the brand clinical studies. And this was section 5O5, B two of the statute. These drugs could be approved only after patents had expired or be declared invalid. So there was a complicated process for resolving patent disputes and we had an 8180 day exclusivity for the first generic. I think that was your idea, but I'm not sure. And that was a way for challenging a patent to create an additional incentive for generics to get on the market. So this is this is where we were where we were working on the legislation and we were doing it in the House before it ever got to the Senate. It isn't that we passed the generic provision and then the House passed the other two. We combined them and sent to the Senate a bill that had all the essential pieces combined.

SCHULTZ: So just in terms of the picture, the you know, the legislative drafting, David Mead was the Legislative Council, so he had a whole staff, but he also did FDA, FDA drafting. And he sat at the head of the table. And he was a very kind of stern person. And then you had the counsel for the Republican and the Democrats and then kind of on the side, you had, you know, Representative PMA, you know, consumer groups, generics. But the problem was the Energy and Commerce Committee was expert on FDA law and health law and so on. That patent law that was written in the Judiciary Committee, that was not their jurisdiction. And this is what Bill said. This is why Al Engelberg, who was a patent lawyer, was so key. And so, you know, Hatch-Waxman is not just a pathway for Andas and other kinds of generic drugs. It has a very unique system for resolving patent disputes. And the idea and the idea was to get them resolved early. But generics were delayed for it was 18 months and then extended to 30 months while those patent disputes are going to be resolved. So there are lots of compromises, as always, involved in this bill, even before it got out of the House, because I. I think the effort was, you know, they wanted a bill that had support not just of the generic industry and the consumer groups, but as much of the prescription drug industry as they could get. So, Steve, Steven, let me turn to you and talk about what this look like from the Senate. You know what the. We've talked mostly about generic drugs, but tell us about patent extensions and how that worked as well.

GROSSMAN: Well, the you know, I'm hoping, assuming that everybody knows more much the details, the five year extension for patent time lost the maximum 14 years. And of course, there were the secret windows in. So that Feldene got something that was important because that's how you made allies. And that was the congressman's brilliance and knowing how to do that, so that when it came over to the Senate, as I said, Senator Hatch was amenable. But I'm pretty sure I don't have a specific memory. I'm sure he fought it for a little while. And so but once it got into the details, you know, there were just masses of people, you know, getting together, dispersing, getting back together again, floating people in and out. And what I remember is that at a certain point, the Senate, Senator Hatch, decided that he was done with the dissenters. And basically and I hope you can imagine that he respected Congressman Waxman and he was amused by Bill Hadad, who was the chief person on behalf of the generics. I, I think he probably I think the fact that he respected you and he was amused by Bill gave him some extra pleasure when he basically told the industry, you know, the remainders, which was a substantial and powerful part of it, that, you know, either you come on board, we'll talk about details, but you need to come on board or otherwise I'm going to feed you to Henry and Bill. And Bill had that. Yeah. Well, there's so many bills in this, but. Yes. And Bill, her dad and I can

imagine, are and having a very chuckle, very great smile as he was telling them that he was going to feed them to Henry. So even on the Senate side, you have your influence.

SCHULTZ: So I just want to make sure nobody's underestimating the importance of this seat in the House. You know, as we said, you know, you can get a bill passed with a majority, but the Senate, as you all know, is much more complicated. And particularly we were coming to the end of the session at that point. It's very easy for a single member of the Senate to stop a bill. And so, Senator, in order to get this bill passed, you really needed to get the pharmaceutical industry not vigorously opposing it. And they obviously really cared about Senator Hatch. You know, he was their their guy. Right. And so when he said to them, look, if you don't go along with this, I'm not with you. I'm sure that sent chills down a lot of spines. And there were a lot of hard conversations because I guess they weren't so sure they were getting a good deal.

GROSSMAN: I don't think they thought they were either. It's you know, one of the things that we all can be proud of who are up here is the combination of the Orphan Drug Act and Hatch-Waxman transformed the industry. And, you know, now they may have less than 10% of the market, but we all have these innovations that have made a difference in our lives. And so, yeah, there was a lot there was a broad lack of foresight that we were combating at all times. And in some ways that's why the critical moment was probably one that amused Senator Hatch more than it was anything else. The idea that he was going to tell these folks that he was going to feed them to Henry, you know, if they didn't get on board. I mean, that was an important moment. Were you want me to talk about Howard Metzenbaum?

SCHULTZ: Yeah. Let's just wait one minute, though. I mean, the other thing I just want to emphasize is the amount of negotiation that went into this and the amount of give. Really on both sides. So the negotiation and it was in the House that really got the bill that then Senator Hatch presented to pharma and said, take it or I'm not with you on that. The end of that negotiation, you know, included things in the current law like patent listing, the fact that the brand companies, when they file a new drug application, have to list all their patents so everybody can see them. The concept of an artificial act of infringement, you know, typically under patent law, you can't really litigate a patent. And until the competitor, the generic in this case actually markets the drug and then is sued and they're, you know, big damages if you if you lose. But this act, you know, very innovative, created an artificial act of infringement. So this could be litigated early and resolved early on. And there's a process where the generic has to certify is a court agree to wait on the patent or doesn't want to challenge the patent. And if it wants to challenge the patent, then there is this 30 month stay

that I that I mentioned. And I think importantly, and I don't know if it was these were seen as so important at the time, but the brand industry got a five year exclusivity for drugs even if they didn't have a patent, if they got a new chemical and a drug that was unpatented, they had five years of of of exclusivity and and for new uses or new formulations, they got three years. So that was the beginning of exclusivity, which, you know, they're now more and more of them. But, you know, I just say this to say, you know, in any piece of legislation and certainly in this piece of legislation, there were sort of a lot of compromises. And you you know, you kind of have to figure out like what is going to be enough both for the industry but also for Senator Hatch, you know, because they had that they had to sell it to him. Congressman Waxman, do you want to add anything now? We'll get to the Senate.

WAXMAN: Okay. Well, I do want to get to the Senate. We finally had reached agreement on all the terms we've made, all these compromises. Some of the compromises turned out to be disappointing. In their effect later, it was difficult to ever change some of those points, but we did on occasion do so. But we got to that final moment where we had to reach an agreement and that two people then showed up, Howard Metzenbaum and our leader Bill Schulz, and they said, Well, we don't know if we like this drug. It's it's too left. It's too upsetting. And they were talking about Senator Metzenbaum using the filibuster to stop it. Senator Kennedy pleaded with them. Senator Hatch pleaded with them. I pleaded with him, and he finally relented. I think he voted no by voice, but out of the conference agreement. But he was a holdout. I think you came before he did. Yeah, but but we it was the perils of Pauline. There was always something new and we didn't expect that involved to show up at the end to be troublesome.

GROSSMAN: Yeah. Yeah. I have a sort of staff level perspective on this.

SCHULTZ: Yeah. Let's hear, let's hear the perspective from the Senate side.

GROSSMAN: I mean, again, context is everything covered. Metzenbaum I wrote down my notes. He was a Bernie Sanders type, but I actually kind of wrote then later I wrote or Tommy Tuberville, you know, they just at a point of principle, there just was no relenting. And it did not matter if 99 people whispered in your ear he wasn't going to move so well. The high level, you know, Kennedy, Hatch, Congressman Waxman, were doing the high level work with Howard. We were working on the staff. And what I remember is that Roche's volume was making about $360 million a year. And every day we would go and visit Metzenbaum staff and

point out to them that every day he sat on this bill, Roche was making another million dollars. And I don't know that that's what he relented over, but that was what we that was the propaganda we were working on.

SCHULTZ: Of course he hated, Roche. I mean.

GROSSMAN: Yeah. Yeah. So I'll say he did this to us on a number of other bills, so I'm not sure how much of it was specific to this because he was just ornery. But anyway, he kept pushing, you know, the end of volumes patent the end of values, million dollars a day until we got movement.

SCHULTZ: So we have a couple of questions here for the panel. The first one is what was the public perception about drug prices at the time that consumers themselves understand why this legislation was so important? So who wants to take that on?

WAXMAN: Well, I think consumers, whenever they're buying anything that cost money, think it's too high. And they were upset about how high the costs of drugs were. They hadn't seen anything by that time, but they were starting to feel the pinch. So insofar as consumers were aware of the legislation, they wanted it and and they wanted competition because they thought they got a better deal with this competition.

GROSSMAN: I remember from that era, the when Feldene was approved and came on to the market, that there was a huge reaction from media, from consumers. And the gist of it was that not just that it was expensive, but that it was going to be taken by patients for the rest of their lives. And at that point, something that represented a 60 to $80 a month bill was money went a lot further than it's true. But we look at what we have now and we just remember that that was shocking that a something that relieved arthritis that made a big difference in people's lives. And it didn't take very much for people to be justifiably upset because that wasn't what they were used to. And from that comes, among other things, the remarkable progress we've made on chronic diseases, which where you take the medicine for the rest of your life.

SCHULTZ: Bill, do you want to add anything?

CORR: Just to say that I think at the time our feeling was drug prices were going to get out of control if the industry could extend their patents. And the basic trade off of patents and generic drugs is one that I think Henry and all of us are really bought into, that if we needed the patents to provide the incentives for the

development of new drugs, but we also needed affordable drugs and we were beginning to see higher prices coming. And, you know, it's a simple thought here, but it was a complex undertaking to think about how do we how do we move legislation that will protect people, get us new drugs, but also protect people who need those drugs and can't afford them. And that that took us back to insurance issues and Medicare and Medicaid issues. But I have to say that over the years that the reason we got as far as we did was because of Henry's commitment to really doing things that benefited the American people. And so I waited 40 years to have the opportunity, Henry, to say, great job. Actually, I told him that the day we won.

WAXMAN: Thank you.

GROSSMAN: From the Senate side, let me add the same. You did a wonderful job. The the Orphan Drug Act and this that transformed the world. I don't think any of us expected that the market generic market would be more than 90% of the market. Of course, I don't think any of us imagined the first million dollar drug either. And I'm pretty sure none of us thought it would be litigated for years. Kept being litigated for 40 years.

CORR: And I'll say thanks to Brookings for giving us the opportunity to reminisce and and repeat 40 years in a in a few moments.

SCHULTZ: And I would say from the consumer groups side, I would thank Henry and Senator Hatch and absentia, we weren't as hard to get as pharma. I don't think we. But what a tremendous accomplishment. And I hope that this discussion is given a sense that it wasn't so easy. Took great. Great skill by members and staff.

GROSSMAN: If I could just add that in the back of the room I have the Slip law version of the original act, which is the first page and the last page. If you've ever noticed in a presidential signing ceremony, there are a dozen pens and a dozen different versions that are signed so that there are souvenirs. I have no idea whether I'm Sarah Hatch's or whether somehow I was blessed by being sent one. But if to the extent this is a sacred event I brought, I brought a relic.

SCHULTZ: So there's a clock here and I can see that we're 30s over. But I've been asked to say there's a break now and that you all will reconvene at 10:30.

SHARP: All right, so the clock says we are started. So thank you all for being here. My name is Jeremy Sharp. I have the distinction of getting I basically worked for the first panel and continue to work for the first panel except Steve. And and I am here on behalf of Waxman Strategies to moderate this panel on lessons learned. And so largely my job is to get out of the way and let these experts talk to you about what we have learned from 40 years of Waxman, Hatch-Waxman being in place. Scuse me old habit. So let me, without any further ado, introduce our panelists. First, we have Bhaven Sampat who is the professor of at the School of the Future of Innovation and Society at Arizona State University. Then we have Rachel Sachs, who is a nonresident fellow here for economic studies at the Center on Health Policy. And then we have Markus Meier, who's the former assistant director of the Federal Trade Commission's health care division and is now retired and blessing us with his experience. So with that, I'm going to hand it off to Bhaven to give our first presentation. And while he's getting set up, let me remind you, there are index cards around the room. If you want to write down a question and pass it up, we will do our best to ask as many questions as we can of this panel.

SAMPAT: And we have decided to stand, at least for our initial gambits here. So. So thanks for. Thanks for inviting me. Thanks for thanks for the introduction. I'm excited to be here. It's it's rare to be at an event with kind of the founders as well as leading academics and leading practitioners. And I've already learned a lot. I really appreciate the invitation. I'm going to just start by quickly summarizing. So I'm an empirical economist by training and disposition, I suppose. And I'm going to start by quickly just summarizing at a very high level just some facts about the 40 years of the Hatch-Waxman regime focused on the patent listing, challenge and restoration aspects of the regime. And I'll be drawing here on some of my old work and also some ongoing work with Scott Hemphill from from NYU Law School. And then based on that, I'll say a few things about lessons at a very high level and hope to continue the discussion when we get there. Okay. So the first thing is, if we look at drugs approved essentially from 1985 to to the present and we look at the number of patents per drug on the Orange Book. So from 1985 to 2020, they've grown sharply. So in the early years, 1985, 1987, there were 2 to 3 patents per drug. Now, on average, there are 7 to 8 patents per drug listed on the Orange Book, four for drugs approved more recently. And that's really I just told you what the average which is increase that's really driven by the right tail of the distribution. There are just if you look at the 75th percentile, it's kind of increased even even more, even more sharply. That growth is driven by a growth in so called secondary patents and different definitions, but patents that are not on the active ingredient, but on more ancillary aspects of of the drug. Secondary patents are controversial, as many people here know, first because they tend to be filed later and issued later than the primary patent, they can extend out patent terms

temporally. Second, because they're kind of viewed by legal scholars as lower quality in the sense that they may have more validity issues, they will more there be more, maybe more questions about whether they're actually relevant to the drug in a context where maybe the patent office could be doing a better job at screening patents ex ante. And the FDA, you know, takes a ministerial stance, I think. Rachel, we'll talk a little bit about that and doesn't really, you know, pay too much attention to what goes on the orange, but they sort of take the brands at their word. Okay, So we have this growth in secondary patenting as well. So essentially maybe 40, 50% of drugs early on had secondary patents 1985 to 1987. More recently, almost all drugs have at least one secondary patent and and some of them as a result of that. You've also had an increase in what Scott and I have called nominal patent term, which is the time from when a drug is approved to when the last listed Orange Book patent expires increased from 13, 14 years in the early days to, you know, 17, 18 years now. This is again driven by secondary patenting. That's the first that's the first sort of set of facts. The second. And I think a lot of that is driven incentivized by the three month stay and other sort of features of the act that were talked about previously. The second. A set of facts is about the paragraph for challenge receipt regime which was also mentioned. So you also have in the Act 180 days exclusivity to the first successful generic challenger of a patent. And you've also seen the sharp rise in paragraph four. Challenges for about 20% of drugs in the mid eighty's to nearly 100% of drugs today and the two are related in a way. First, it's worth saying that paragraph four challenges also have been controversial. They are sometimes viewed as the activities of these rapacious generics exploiting a loophole in Hatch-Waxman to kind of just go after patents on. On high selling drugs. And at least the latter part is right that there are more challenges as you move up the sales distribution. But some of the work that Scott and I did maybe ten years ago at this point suggests that it's actually a little bit more complicated than that. It's drugs with secondary patents that disproportionately get challenged within drugs. It's the secondary patents that typically get challenged and conditional on litigation to completion. The secondary patents typically fall or in some of the generics win. And. And on the primary patents, the brands win as a result of that. So I told you about this, right? A nominal patent term as a result of that, what we call effective market life, which is the time from when a brand drug is approved to when the first generic enters. Has actually not increased so as much. It's actually been pretty stable at 11 to 13 years, kind of oscillated between 11 and 13 years. And I think that goes back, you know, into the 80s, essentially. And so what you have is sort of the second. These challenges playing a sort of restorative role, which is going after and in most cases successfully targeting secondary patents in a context where, you know, the patent office might let them sleep through. So they might be playing a socially useful role in in that regard. And then the third piece of work I'll just talk about before just saying a few lessons and this is much newer work is on the patent term restoration aspects,

extension and restoration aspects of the regime. So as was mentioned briefly under the Act and this this actually is a debate that goes back to the to the to the Keefe hour hearings and the 1962 act. There was concern that clinical trials were eating into patent terms and that disproportionately was affecting, you know, drugs with certain types of drugs, etc., etc.. So you're allowed to extend one patent per per drug subject to a range of constraints, which I won't get into here. A few facts about that. First, when faced with the choice, it's not obvious what firms will do which patent to choose. They typically extend the primary or the active ingredient patent, not not the secondary patents. Second, if you look at just the relationship between the amount of time on that main patent and clinical trial with there remains a distortion in the system in the sense that drugs with long, longer clinical trials still have less time on the extended patent. And that's almost mechanically true. That's just given the formula for restoration. Some of that ends up being blunted by secondary patents. So because you get other patents as well, the line gets flatter. But when you get back to effective market life, the time to first generic entry, that relation, that negative relationship reappears in the sense and what's going on there is that firms typically extend the second the primary patent the secondary at least I patent drugs tend to get challenged and what's left standing is the effective life sustained by the primary patent. And so you have this this sort of negative relationship. Okay. So quickly, some lessons. And again, I'll just say them to a very high level here so we can we can move on to the conversation. I mean, first I just think of methodological point, but also a point for, I think, you know, some of the policy work and journalistic work in this area. I think when we're talking about how much time a how much how much patent time a firm has or a drug has, we have to distinguish between nominal patent term and effective patent life. There's a certain talking past one another. And that goes back actually to the the legislative history of Hatch-Waxman. Second, it seems like the challenge regime sort of works it ratcheting back nominal patent term back to the effective market life that's sustained by the stronger primary patents. But it's a pretty costly way to get there. And there might be lower cost ways to kind of target secondary patents. And I think some of my co panelists will talk about that. But it's also subject to gaming, pay for delay, authorized generics, all that kind of stuff that can sort of break the machinery. And I think that's another issue. Third, on the restoration point, if the goal is, you know, if the goal was uniformity, getting back to uniformity, the system fails in the sense that there still are distortions in the system. And drugs with longer trials tend to have shorter, effective market life, which might be exactly the opposite of what you want. But I think the main lesson for me there first, I'm not sure that uniformity should be the right policy goal, but might be thinking more about using exclusively. It is modeled on the Hatch-Waxman and CE exclusivity to kind of tailor the amount of exclusivity a firm gets, not just to time in development, but also measures of social value, which the current system really doesn't do. So why don't I leave it there and turn the floor over to Rachel?

SACHS: Thank you, Bob, and thank you, Jeremy, for that introduction. And thank you to Brookings for bringing us all together for this very special event. So as we heard a little bit about already this morning, Hatch-Waxman really brought together in many ways the generic and the branded pharmaceutical industry having as these two core elements, the and a pathway and the patent term restoration or extension. And in my view, over the last 40 years, the branded drug industry has managed to shift some of the terms of this essential compromise in its favor by leveraging key terms and provisions within the law itself. So we've just heard about some of the patent lessons learned. I'll be talking about some of the FDA implications and the ways in which executive branch actors are implementing and operationalizing the key terms of this act allowed have allowed the branded industry to shift the terms of the compromise. Also focus on the ways in which Congress and FDA have sometimes, but not in other cases acted to to reshift or to alter the balance of power once again. So I'll provide two sets of examples very briefly of ways in which this has occurred over time. One set of examples where FDA and Congress have not yet fully responded to some of the behavior we might be seeing and other examples where FDA and Congress have worked together to really intervene to alter some of the kinds of behavior I'll be mentioning. So the first example we've heard a little bit about, we'll also hear about it on the next panel is the Orange Book. So the Orange Book itself predates the Hatch-Waxman Act, but the act really formalizes that It requires brand manufacturers to submit information to FDA. It ties generic approvals and applications to those patents and their pendency. But over time, the set of patents that manufacturers have chosen to include in the Orange Book has come under some scrutiny. And recently, in the last year or so, the Federal Trade Commission has actually challenged, I believe at this point, about 400 patents for their inclusion in the Orange Book and the effect of manufacturers actions to list additional patents in the Orange Book makes it more difficult for generic competition to develop. Now, what's FDA's role in all of this? FDA has repeatedly disclaimed a substantive role in monitoring the contents of the Orange Book. It says its role in the process of listing and delisting is ministerial as the term you typically see. And that's certainly a possible interpretation of FDA has legal authority. I would say in some would say it's not the only option if FDA wanted to. It could take a more active role in reviewing whether the patents submitted by manufacturers fall into the statutory categories that are permitted. Some people, for example, have pointed to the regulations FDA already promulgates governing the types of patents that may or may not be submitted. So regulations already provide that process. Patents, patents, claiming packaging, packaging, patents, claiming metabolites and intermediaries must not be submitted to FDA. There's one question of whether FDA could determine whether patents submitted actually fall within those categories. That's a very different question from saying FDA should determine the validity of submitted patents. I'm not asking that

question. But FDA has already developed some expertise in this area that it could be deploying more substantively. Now, I think we'll hear later today there have been some congressional interventions, such as the Orange Book Transparency Act of 2020. Sort of trying to get around the edges of some of these phenomenon. Congress recognizes that there's something going on but hasn't fully responded in the way that it has and some other areas. A second example is product hopping, right? One strategy brand companies may use to delay the development of generic competition. As product hopping, this idea that before the primary patents on a branded drug might expire and a generic competitor enters the market, the branded drug manufacturer can introduce a new formulation, maybe an extended release version, a high concentration version, and work to switch its existing patient population over to the new formulation. So even if you have generic competition entering the market for the initial version, generic entrants will find difficulty establishing a foothold in the market because the patients have largely been moved to the new formulation, which is protected by existing patents, perhaps additional exclusivity and can therefore maintain a longer period of protected time on the market. Now some scholars have looked at antitrust law as having the potential to address this conduct, and that does seem to have been effective in the case of something called the hard switch, where the manufacturer not just introduces the new formulation but pulls the old one from the market. But in cases that aren't quite so strong, where they leave both on the market at. The same time, FDA itself might consider whether additional activities could allow for more support for generic competition. So some academics have argued that FDA could use its suitability petition process to approve generic competitors for the initial formulations of a reference drug as if they were generic alternatives to the more novel formulations as well in other areas. Congress and FDA have worked together to respond to efforts by branded companies to extend monopoly periods. One is citizen petition, so at least some branded drug manufacturers, it was reported, had been seeking to use the citizen petition process with an effort to delay potential generic competitors. And so even where those petitions were denied, the time FDA would spend reviewing and responding to those petitions could delay generic approval, could be highly lucrative for the branded manufacturers. And in the 2007 user fee package and subsequent FDA reports on the topic, Congress and FDA have responded to these various efforts. And it seems like there's been a decrease in that activity over time. It's maybe ongoing at a lower level, but definitely there has been a response. A second area in which there's been a response is the Create Act of 2019. There was a refusal by some branded companies to provide samples to generic firms that they needed to demonstrate bioequivalence. It took a few years to pass, but the Creates Act did include provisions to allow generic manufacturers to ensure that they can get the necessary samples they need to go through the and a process so we can take a step back and think about whether it's possible to draw lessons from these different situations. Some where

Congress and FDA have responded and some in which they have not. So can the citizen petition the sample provision examples? Can they serve as templates for thinking about lessons learned and responding to maybe the Orange Book and product hopping situation? So I'll offer sort of three brief points in response. One is that the process of legislation is a difficult one and it's an iterative one. So many of the post Hatch-Waxman developments could not reasonably have been foreseen at the time the law was passed. And here I'm specifically thinking about advances in science and technology, right? So I haven't even mentioned complex generics combination products where there's a whole range of additional scientific and technological issues that relate to disrupting the paradigm, right? This is not an issue that's unique to the Hatch-Waxman Act, but it may be heightened in the case of legislation and regulation that specifically implicates issues of scientific innovation, as we have in the health care context, and especially in the pharmaceutical context. A second point is that especially with the User Fee Act process, there are these built in legislative vehicles that allow for some of this legislation and policymaking over time. So the other process that it developed after the Hatch-Waxman Act, but it has served as a vehicle for some of these small and moderate changes over time to the ways in which these various pathways are implemented. Perhaps more importantly, and I would defer to members of Congress or agency officials on whether this is the case. But but from the outside, it seems like the process itself also creates the conditions for agency officials to work with members of Congress to build relationships that they would need to surface these issues, to discuss them, to identify solutions and plan ways forward on issues that matter to the agency's work. There are, of course, other legislative vehicles outside the FDA process, right? The Creates Act passes as part of an appropriations package, but the other process itself might be relevant as we think about ways forward and options for intervention at the legislative stage. And then third and finally, in both the citizen petition and the sample provision examples, FDA worked with Congress to take action in response to those activities, but FDA could, in my view, write if it chose to do more with its existing delegated statutory authority. Right. I'm I'm a law professor. I'm very conscious of the ways in which the Supreme Court and including, you know, both Loper bright and corner post from this past term is functioning to take power for the courts away from executive agencies and Congress in ways that might make this task harder. But a number of the statutes that are given to FDA is operationalization and implementation. They have indicia of what Chief Justice Roberts referred to as respect, right for the agency. They use key terms and terms of thinking about the agency engaging in substantive rulemaking, the agency having procedural rulemaking authority in order to implement these various statutory provisions. And FDA acting on its own may be more nimble, may be more able to identify and respond to some of these emerging concerns than can Congress and here. We're we're

thinking about what is the balance of the Hatch-Waxman Act and what's at stake. FDA and Congress really do have more room to exert their authority. Markus.

MEIER: So I'd also like to thank Brookings and for inviting me. I got the call on Friday. I'm filling in for somebody who was supposed to be on the panel. My perspective is going to be a bit different than the policymakers that have spoken, the researchers and the academics, because I served for 25 years, actually for 32 years at the Federal Trade Commission enforcing antitrust law. 25 years of that was involving the pharmaceutical industry. So I am a law enforcer. I stand up in the courtroom. I bring cases. That's the that's the work I do. The views are clearly my own and they are based on public information. So my overview very, very quickly, I'm going to be rushing through this. I'm going to give you a quick primer on the antitrust laws. I'm going to talk about how the antitrust cases all fit within the shadow of three other laws. We've heard about the patent laws. We've heard about the FDA regulatory system. I'm also going to throw out the whole medical medical care system and finance and delivery and how screwed up that is. And and my point is ultimately going to be we have to take those systems as a given when we do antitrust. We don't get to change the way they are. We have to accept the statutes. We have to accept the regulations. We have to accept the case law. But we've been aided greatly. I see one of my colleagues, former FDA official that we used to we used to talk to the FDA all the time, also people at the Patent and Trademark Office. The third thing I'm going to do is identify some of the cases that we actually did at the FTC. And it's been very helpful because a number of these things have already been mentioned by others. And then I'm going to briefly at the end try to share my three lessons learned. So antitrust law. Okay, what the hell is that? Basically, here's the trick. It requires and this is a bit of a a bit of a simplification, but it requires that you prove that there is conduct that unreasonably restrains competition, conduct that unreasonably restrains competition, because there are reasonable restraints on competition like a joint venture could be a reasonable it could have been competitors, but now they're working together instead. So it has to be an unreasonable restraint and it has to be done by somebody or a group of actors, one or more actors who have significant market power or a monopoly. So it's not the act of monopoly that's illegal, but it's the act of monopolization. And it's not enough that what they do harms a competitor. That's simply not enough. Okay, so there's my background. It's grounded in the belief that when we have competition that leads to lower prices, better quality, more innovation, and it's not. And I had to explain this to people in Congress many, many times. It's not a broad mandate to impose our view of what competition should be. We have to be ready to prove cases in court. Now, I would ordinarily explain each of the three systems, the patent system, the regulatory system in the health care system. Don't have to do that because it's been so ably done and given this audience, this

background anyway. But but here's I do want to say just a little bit more about medical care. Antitrust law in economics assumes based assumption that consumers act in their own best interest. They make decisions for themselves and they act in their own best interest. The challenge with pharmaceuticals and health care and medical care is who's the consumer? I loved the question earlier to the panel before it was just assumed, I think, in the answers that I heard, that the consumer is the person who swallows the pill. But in reality, in the medical care area, there's the medical professional who decides what pill you get. You don't even get to choose necessarily. You have to get a permission slip called a prescription. There's the patient who swallows the pill, could be the consumer or there's also the health plan or the payer government or whatever, whoever else that actually decides the formularies and what's on the list and what you can have and what a doctor can prescribe. And the argument that I would make is all three of these are potentially consumers. The consumer function is disaggregated among many different actors. And there's even more than I've just described. And each of them making the thing really complex, the analysis really complex, has different interests and incentives. They're not all lined up. And we have to deal with that too, as we are bringing forward a case. So I said that our cases are brought in the shadow of these three systems just really at a very, very high level. The gaming of the patent system, a couple of types of cases we've had in that area are sham litigation. That is to say, a company has a legitimate. Pat No question. Brand A company has a legitimate patent, no question. But it asserts that patent illegitimately in a lawsuit against the generic to avail itself of the 30 month stay. That's the 30 month stay bring sham litigation. We had a case and we took it up in Philadelphia and. On that one in the Third Circuit on this theory that it's illegal to engage in sham litigation. I've already heard some mention, and most of you are probably familiar, I've heard about pay for delay or what's also called reverse payment settlements. I personally worked on that for 20 years. The basic concept behind that was we have a paragraph for filing that we've heard about where the generic company says to the FDA, says to the patent holder, I want to make a generic and I do not infringe the brands patent either because they're patents invalid or because I've invented around it around a secondary patent type invented around that starts a patent litigation between the two companies. About 30 months later, the two companies are looking at each other, going, What the hell are we doing here? You know, fighting a suit. Why don't we settle? And they settle by the brand company paying the generic not to entry Enter. The reason we call this a reverse payment is because, generally speaking, the putative infringer, the generic company would pay the patent holder for a license to enter rather than the patent holder paying the putative infringer to stay out. And they do this by sharing the monopoly profits that the brand would make, not facing generic competition gaming the FDA regulatory system. We've looked at things like Orange Book listing abuse, we've looked at Rems abuse, we've looked at citizens petition abuse, we've looked at product hopping issues. And on all of

those, I say we have a compendium of every case we ever brought in the FTC in the pharma space, and you can read a lot more about those there. This is the one from October 2023, when I was still the head of the office. I just went online this morning. They've they update this 2 or 3 times a year and I'm no longer on it, but you can find it. But I did want to say one one gaming of the regulatory system that wasn't mentioned. And that's because we so effectively, through working with Congress and the FDA, we so effectively got rid of it. There used to be a thing called multiple, 30 months days. Does anybody remember that? It was when back when the FDA interpreted that every time you file another patent in the Orange Book, you get another 30 month stay, not 30 months for a product, but 30 months for every patent. And so we have the famous picture and an FTC study done in 2004 of Paxil, the drug Paxil, where the 30 month stays add up to 62 months. And we were able to get Congress to fix that in the Medicare Modernization Act and very reminiscent of the discussion in the first panel. Of course, the brand industry didn't want to agree with that, but this was part of the Medicare Modernization Act, Part D, They suddenly got tens of millions of additional paying customers called the elderly people like me soon that I'll be qualified. And and therefore, we were able to get them to get rid of that gaming the medical care system really quickly. One example is my my my favorite litigation I ever did. Right before, shortly before I retired, we went up to New York City. Actually, it was during of a crime spiking in New York City against Pharma bro Martin Shkreli. You might all remember the dollar pill that goes to 750. Well, antitrust can't stop price gouging. That's why they're talking about it in the politics. We don't. A high price by itself is not an antitrust violation. So how did we manage to bring a case against Martin Shkreli and his company? What we did is we we focused on the fact that the way he was able to maintain on an off patent old drug, a $750 price, was because he entered into exclusive arrangements with distributors and he limited the generics ability to get samples of pills. And he bought up all the API suppliers to make it difficult for generic companies to find API suppliers. In effect, he sort of turned an old on patent drug back into a Rems drug with super highly restricted distribution, and therefore he was able to successfully keep the price up. Okay, there's my run through that. Three lessons learned. Three lessons learned. Number one, antitrust enforcement is at best a very second best solution to legislation and regulatory fixes. It's slow, it's uncertain and it's limited. And it's something that I constantly had to talk with my friends at the FDA about, and we had to talk to people on the Hill. We just we don't have this broad mandate to just make everything better. We have to be ready to put cases together. Number two, despite the gaming, as far as I can tell from where I sit and I'm not a researcher and I'm not an academic, I think the Hatch-Waxman Act largely achieved the goals that it set out to do. The United States remains a world leader in pharmaceutical innovation, and U.S. consumers, whoever they are, enjoy some of the lowest generic. Price is among developed countries in the world. Indeed, we've heard the statistic that about 90% of all prescriptions in America are written for

generics, and they only account for about 20% of the cost. Okay. So the other 10% and 80% are the branded drugs. Some credit we've heard also goes to things like the Bayh-dole Act, which which happened around the same time, the Orphan Drug Act. And also the states adopting drug substitution laws. I think this has been massively important and is often overlooked. We heard a little bit about the anti substitution earlier. Well, the FDA working together with the FTC, did a report in the early 80s, developed together a model law, a model state law. And states started adopting this model law to allow for generic drug substitution. So you didn't have to go back to a doctor to switch when there was a bioequivalent generic. A pharmacist could do it. You might say, Why? Why did states have to do this? Because it involves the licensure insurer of pharmacist and pharmacists are licensed by states. And so each state had to adopt this law to allow its pharmacists to do this. It's not a federal law. Third third lesson. Hard to imagine a major legislative fix like we see with Hatch-Waxman. Given today's politics, you know, who knows? Sometimes things happen, but it's hard. Very hard. It's also hard to imagine significant regulatory fixes. Given the Supreme Court's recent decisions, reining in the administrative state. So I finish by saying maybe there's still a role for antitrust, even if it's slow, uncertain and limited. Thank you.

SHARP: Well, thank you to our panelists. That was very helpful and informative. I want to start with a first question, which is perhaps a bit unfair, but you all have spent many years and we've got 40 years of experience with Hatch-Waxman at this point. Now, at this time in the market, in the system, what if each of you had to pick one changeable policy change over legislative regulatory funding something? What is the what is the one thing you would tell policymakers needs to change to increase generic competition to supplement what we know about Hatch-Waxman? And political feasibility does not need to be considered. This is pie in the sky. Okay.

SAMPAT: Okay. The challenge is not political feasibility. It's the it's the one thing. But okay. To me, I think pharmaceuticals is a unique context where you can actually you know what patents matter for a drug by virtue of Orange Book listing. And I think, you know, I talked a little about the challenge regime and how it kind of works, but the costs of it working in some of the gaming, I think, you know, Scott and I are maybe ten and ten years ago said that once something on the order is put on the Orange Book, it should be subject to immediate reexamination. I'm not sure the reexamination process is really used all that much anymore. But essentially you have a unique context where you can do a review of patents at an intermediate stage in a context where the patent office may not be able to intensively do that review ex-ante and the FDA tases

ministerial role. And so that that will be my one proposal if I had to pick one, which I think is actually politically feasible.

SACHS: As a law professor, I'll start by fighting the hypo just a little bit, which is to say that on this panel we've intentionally a little bit siloed our our responses. So Bob is talking about patents. I'm talking about FDA markets, is talking about antitrust, something we haven't really talked about, which is appropriate for the context of the event is is insurance is the role of Medicare and Medicaid and the role of insurers and supporting the development of markets and the development of competition. Many of the very important statutes in that area were passed after the Hatch-Waxman Act, as we already heard on the first panel. But I think I would be remiss if I didn't put that on the table as an area to look for very important policy changes. If I'm restricted to my own remarks and to FDA and ways in which we can think about topics within that agencies remit. I do think lifecycle management and the questions about product hopping and changes in formulations over time are a key area to to really take a look at. The different permutations of it can be very complex, especially as they move into these questions about combination products with devices or formulations and resetting some of those clocks over time as we think about patents and exclusivity terms. I think that's the area where I'd focus.

MEIER: So I obviously didn't have any expertise, again, based on researching being a professor. Instead, I spent a lot of time reading all of your writings and others by Richard Frank. And of course, now I'm blank. I'm sorry, Fiona. Thank you for your own. I think I definitely know you and definitely know your papers. And Marta was in school and many, many others and a while back and I just figured out I don't didn't save this. When I left the FTC, I went I read everything I could and I read every every think tank group and everything that I could find about different ideas about what could be done. Because one of the things we would do is we'd spend a fair amount of time talking with people on the Hill. We'd help them do technical assistance behind the scenes on legislation. And I actually testified on the Creates Act together with FDA Commissioner Gottlieb at the time. And, you know, we would work on this stuff. So I would try to think more than just my narrow area and I would read everything I could. And so I'm going to just take something that's not my original idea. I have no original ideas, but something that I thought was pretty interesting by a couple of professors at the Washington University in St Louis who wrote a book called Against Intellectual Monopoly, and one of their chapters is devoted to the pharma industry. And part of the reason they're doing it is because they're saying the same arguments that they're making that maybe we don't get that much innovation from patents also applies to pharma. Again, I took patents as a given when I was an enforcer, but

it was an interesting idea and actually their focus was more on the brand industry. So rather than as a generic and one of their ideas that I just thought was very, very interesting was the idea that maybe the clinical. All trials, phases two and three are really essentially a public good and ought to be paid for by the public through the NIH. And they propose a process by which you match up drug companies and you match up hospitals and other institutions that want to do the clinical trials, and that you make this information public and available to everybody. Drug companies are still allowed to do their own if they want to. But at the other hand, since there's a lot of important information that kicks out of these things, shouldn't we fund this publicly? And as a result, you lower the patent term, you don't give them quite as much patent and other exclusivity protection. To me, given that 10% of our drugs are brand, 80% of the price is brand to me. I think there's there's more potential gain there than a lot of some of this tweaking around the edges on the generic competition aspects.

SHARP: Thank you for baring with my unfair hypothetical hypothetical there. And as a reminder, there are cards in the bag for people to fill out if they have questions they want us to ask. There's been a lot of increased attention on patent quality. You've talked about secondary patents. Some of you did. To what extent are low quality patents a significant obstacle to competition in the pharmacy space? And I'm emphasizing the quality there in terms of rather than whether it's secondary or not.

SAMPAT: Well, I think they can be if they if they stand, as I mentioned. But I'll say again, I mean, at least for important drugs, typically they get challenged and conditional on challenge. Generally, the generics prevail. I think settlements and all that can interfere with the process. But yeah, I think I think they are, if not challenged, they are a barrier to competition almost, almost by definition, given the linkage system set up by by Hatch-Waxman. I will say, though, you know, a lot of the a lot of the impetus for restriction restricting secondary patents and I'm sort of in that space myself, you know, it's driven by the desire to or the need to bring down drug prices. I think we also have to be realistic about what patent quality type measures will actually do to patent quality type interventions will actually do. I've done some analysis, but the vast like if you look at just top selling drugs, take out biologics because that's a different regime. But if you look at top selling drugs in any recent year, you know what share of them are covered only by a secondary patent. It's maybe, you know, 25%, but it's like 70, 75% depending on what year you look at. Also have a primary patent. And so, you know, reduce patent quality will reduce the duration of of exclusivity. But at the end of the day, I mean, I think a premise of Hatch-Waxman and maybe the reason why we want to think about other policy interventions to support innovation but also balance it with access is that kind of high prices during the

primary patent term are kind of allowed. And. Okay. And that's, I think, a fundamental tradeoff that's that's present in the current regime.

SACHS: And maybe just to add a little bit that the way in which all of these different legal and policy tools interact. Right. We've just heard, you know, how how critical it is to think about patents when the question is how do we get some of these generic competitors on the market? And patents may be a core barrier limiting that kind of competition. But then we've also heard about will you also need to change the anti substitution laws at the state level? And so there's this key role, right, for FDA and FTC, right? You just said that they played and setting out this model bill. And so all of these different steps in the process, this question of approval, it's necessary, but it's not sufficient to respond to some of these issues. And there are more complex federal and state interactions here.

MEIER: If I if I might just add, from from the antitrust perspective and having done 20 years on pay for delay and finally getting a case to the Supreme Court in 2013, almost all of the cases brought either by private plaintiffs or the FTC involved secondary patents. When we had a choice to make between different agreements to look at and to investigate, we would pick ones that had very weak patents, in part because even though the Supreme Court teaches in activists that it is not the patent that counts because the parties have settled, they've stopped that patent litigation. It's the payment that counts. And you have to look at what the payment tells us about the fact that the brand must have thought their patent was weak because why would they be paying otherwise? And we would look for those kind of cases. And maybe my favorite was probably the Cephalon case, where we settled it right before a week before trial for $1.2 billion. And their patent was for the fact that they had a small sized particles, I mean, microscopic sized particles of the active pharmaceutical ingredient that gets taken up. In the bloodstream a lot more quickly. And the generics figured out that we just can put even smaller particles in. And that doesn't come within their patent, their secondary patent. But it also gets the same, you know, FDA bioequivalence hit as the brand as an example.

SHARP: The audience we've got received a couple of different questions around the same issue. But could you all speak to authorized generics and what their current status is and the role is and. Hatch-Waxman And competition. This is an ambush.

MEIER: I'm happy because I can make a pitch. FTC study that issue. Congress had a study. That issue. We did a report. I didn't bring a copy, but you can find it. You know, obviously an authorized generic if you don't

know what that is, it's the brand company. When they're seeing that there's about to be generic competition, it offers its own generic in competition with the generic. And it can either do that by making it itself or it can license somebody else to make it, but it does it under its NDA, its new drug application, and now creates a situation where on day one, when the new generic enters, they're facing competition, competition from another generic. Obviously the generic industry hated that and they thought that was anti-competitive. What we ultimately say in the report is we try to study the short term effects and long term effects. The theory was in the long run, it's going to dissuade generics from trying to enter, because if they have to face competition all the time, it's going to make some uneconomical decisions if you're if you face a brand. On the other hand, we know from studies like Richard Franks and others that two generics make the price even lower than one generic. And so we came out on balance. You know, again, we didn't make any final conclusions, but we found very little evidence that it had any long term consequences. And in the short run, it was a good thing for consumers.

SHARP: The original Hatch-Waxman essentially was a balancing of the perceived incentives of the different stakeholders and the business needs of generic companies. The business needs the pharmaceutical companies, the consumer needs and so forth. Over 40 years, how have those incentives changed or evolved in the minds of pharmaceutical brand name pharmacies, the companies, generic companies and the FDA?

Speaker 5 Well. So one. The first panel was so interesting and it was so wonderful to hear all the thoughts of the architects of the war. But one perspective that, you know, by necessity wasn't part of the panel is the agency perspective. I would love to know more about what agency officials at the time thought about these new opportunities that they had to do, something that they had been actually trying to do and many ways to implement a different pathway for generic drugs to come to market. But also some of the obligations that were now imposed on them. And so one of the questions, you know, I sometimes think about is, you know, from their perspective, did they have all the authority they would have liked to have to enforce the act in these various ways? And what are their relationships with other federal agencies? Even thinking about FDA and PTO, PTO relies in large part I think the term they often use is defer to FDA on these questions of timing for the patent term extension. And they have, say, FDA, tell us what the dates are. Right, how much extension should be given. And so setting up the conditions for the relationships between the agencies is is an incredible part of the story of how things have evolved over the last 40 years. That might not have happened. But for the act, and I think is a really key, key element.

SAMPAT: To answer the question. A bit of a more meta level, I suppose. I mean, to me, I mean, one of the things that Hatch-Waxman sort of naturalize is this idea that fixed patent terms are society's best lever to promote pharmaceutical innovation. And these kind of good market oriented generics are the way we do access. And I think I think that kind of put puts blinders on us to the to the range of policy tools that we have at our disposal, some of which Markus alluded to to promote both innovation and competition and affordability, some of which were kind of left on the cutting room floor, not during the Hatch-Waxman debate, but during key power and kind of debates after World War Two. And I think some of that comes back to haunt us when we when we end up talking about biologics and and the IRA and other things. There's a range of other policy instruments we can use beyond patents and kind of market oriented generics to try to balance or promote both, both innovation and and low prices and affordability.

MEIER: If I could just briefly pick up on a comment that Rachel made, and again, I can't no nonpublic information can't go there, but I can give you I can share at least what I experienced in my interactions with FDA staff. Again, one of the colleagues back in the back of the room at the staff level, staff, two staff, they were very frustrated with a lot of these games that were being played. But remember, the FDA, at the end of the day, their primary mission is to make drugs are safe and effective. They're scientists. They're doctors. They're supposed to make sure drugs are safe and effective. Yet they're seeing all of these games going on and Congress is constantly calling up FDA officials. Why aren't you doing anything about it? And they're saying, but that's the antitrust. People will go talk to them. And so we talked a lot about this kind of stuff. I know that if they had felt that was in their remit to do something about it, they would. And they often participated with us in conversations with people on the Hill with legislative technical assistance behind the scenes. But I guess they also recognized that there really just were some significant limitations on what they could do. This despite the work you're doing and maybe some of the suggestions you can make. And so I'll stop there.

SHARP: I'm going to try to squeeze one quick question in. I was struck by Bill Schultz and Steve Grossman commenting on how PMA did not think Hatch-Waxman at the time was a good deal. I would love to have the panelists quick response on whether or not today is it a good deal for Pharma? Is a good deal for the generics industry and is a good deal for FDA. Has it been?

SACHS: I don't know that I'm ready to go necessarily. So the you know, we also heard that the baseline was this bill was moving on the suspension calendar to just give patent term extension. And so if you were sure

that that was going to pass and having it fail narrowly and then having a several years long process where maybe you didn't get everything you wanted may have seemed like a disappointment. And so I wonder whether that being part of the background is relevant to to the perceptions at the time. You know, I think like Markus, I have a sense that the act really did despite all of our our comments today, it it established the foundations for the modern generic industry and it provided a significant amount of authority to the branded companies. And so from that perspective, it it's difficult for me to see how it could have been too much of a disappointment.

SAMPAT: I agree. It's it's I mean, we sort of as we sort of have talked about some of the some of the gaming and some of the some of the negative lessons. But I mean. Right. I mean, I think it's hard to argue with the kind of just the general trends in terms of the generic industry did exist before. Hatch-Waxman But I mean, that was a big policy win in terms of doing that. But I think there's still room for a lot of improvement on the edges.

MEIER: So broadly speaking, I already think I touched on that, which is it largely is accomplished what at least I believe it was set out to accomplish. Unfortunately, we have extremely high drug prices in this country and we pay an awful lot. And if it was intended to do something about that, then maybe the success can't can't quite claim as great a success for that. I guess in the end, it's part of the same larger problem with our health care and medical care system that maybe in the long run, the the major side effect will be poverty.

SHARP: Well, thank you for being with me. We are just a little bit over. I will remind people we're going to another ten minute break here, I think. And then coming back at 1130, please give this panel a round of applause for their participation. Thank you.

WESSEL: Get you all to sit down, we can get to our third panel. Thank you all. I'm David Wessel. I'm director of the Hutchins Center on Fiscal and Monetary Policy. I had nothing to do with Hatch-Waxman. I've done very little writing or research about drug prices. I am a consumer, so I guess I qualify. I have to tell you that like a lot of people my age and I'm on statins and I went to get the statins and I took out my credit card and they told me at CVS that the price was zero. So I guess I have either an insurance company or Congressman Waxman to thank for that. So we have a great panel here to pick up really where the last one left off. At the far end is Martha Wosińska, who's a senior fellow here at the Center on Health Policy. She's an economist. She's worked at the Federal Trade Commission and the Office of Inspector General, HHS and

at the FDA. So if you have complaints about any of those agencies, she'll take those overnight. Fiona Scott Martin is the Theodore Nierenberg professor of economics at the Yale School of Management, where she's been since 1999. So apparently she can hold a job. She's done a lot of work in the competition space about health care. She spent a couple of years as the chief economist in the antitrust division of the Justice Department. She's told me, though, that since she's solved all the problems in health economics, she's now moving to the challenges presented by digital firms digital competition. And I feel like that Al Engelberg has already been introduced as one of the key players in Hatch-Waxman at the beginning. He is, as was said, a patent lawyer. He was the patent counsel for the Generic Pharmaceutical Association. He later did a joint venture with a generic drug manufacturer to use Hatch-Waxman. And since 1990s, he's been largely a philanthropist, but he can't seem to get away from this question. He has a book coming out in January called "Breaking the Medicine Monopolies." Unfortunately, we don't have copies now, but I'm sure that if you buy one, I'll be happy to autograph it for you when you get it. I don't think we figured out how to do autographs in advance, but we can't do that. So the general tone of the last panel was this all worked pretty well. And I'm reminded of something that Senator Patrick Moynihan Daniel Patrick Moynihan is once said to have said. He was asked when they did the Social Security reform of 1983, he said, well, you haven't fixed the problem for the retirement of the baby boom. And his answer was, it's important to leave some problems for the next generations to address. And so much has happened in 40 years. The explosion of the generic industry driving prices down to really marginal cost. The development of drugs that we couldn't dream of when Hacks Waxman was Hatch-Waxman was formed, which raised an interesting question about whether maybe the incentives for drug development were pretty good under the legislation was passed. And so, Marta, I know you've done a lot of thinking about the generic industry, the production of these drugs. Where is it that we have problems that we want to solve going forward?

WOSIŃSKA: No, I think it's. Now this works. Okay. So what I wanted to talk about is something that hasn't been yet mentioned, and I call it as the dark underbelly of price competition. Or if you look at the numbers and the the low prices that come with generics, I think what we're not really appreciating is that what has happened with price competition is that these drugs have become commodities. And so I wanted to talk a little bit about the consequences of that and where we might be heading. So, you know, Hatch-Waxman provided the foundation for strong price competition. Obviously, other forces have contributed. Marcus spoke about the states substitution laws. We should not also forget about payment systems that incentivize buyers to buy the least expensive alternative. So again, when a generic drug gets approved, it is therapeutically equivalent, which means that you should be able to use any generic version. They're perfect substitutes. So

basically you're creating a commodity. And when you create a commodity, the only differentiating feature between one version and another is their price. And so when you have state substitution laws and when you have payment systems that incentivize buying the cheapest, and you can think, for example, on the hospital side, you can think about drugs where you don't actually even bill separately for drugs. You go get your hip replacement done and you're not going. You get the hospital gets paid just one payment for this. And the drugs that go into it or whatever, you know, saline and whatever else might be used when you get hooked up to an I.V. or the painkillers, that's not going to be reimbursed separately. And the hospital has an incentive to buy the cheapest one for drugs that might be separately reimbursed. For example, you might have in the outpatient setting, ASP plus 6%. It's one. All the generics get counted in the.

WESSEL: One warning. This is an acronym Free zone.

WOSIŃSKA: Sorry. Yes, acronym free zone. Okay. The point is, is that the hospital will have the an incentive to buy the cheapest version. So you have this this context in this context, you know, think about so so you have this great price pressure. So there's a few things that are that are going to happen when you're a seller, when you're a manufacturer. Right? Number one is I mean, you will have to figure out a way to cut costs. One way you're going to do this is you're going to make your supply chain as efficient as possible. Right. And you're going to have no slack. Everything is going to be just in time. There are going to be fewer backups because all of that costs money. Right. So that's one thing that that will go. Another thing is that you will have a strong incentive to move to a lower cost environment. And when you think about sort of what has happened outside of the United States and the manufacturing hubs, let's say in India now, they are called the pharmacy of the world. And the state policies that sort of encouraged us. It is as if you can't even compare what it costs to build a facility in India versus in the United States and also to run it there versus in the United States. So you have seen tremendous shift in the amount of generic drugs, especially the less complex ones like like solid oral dose products that are made in outside of the United States. And then there's also, you know, sort of the third place that goes potentially. And I think that that that that varies company by company, but there's very little room and frankly, very little incentive to invest in upgrades, to invest in people, to have a robust quality oversight function. That's what FDA talks about when they talk about quality culture. And there's great pressure for generics to, you know, sort of not invest in that in that in that quality culture. So and, you know, all of this might work fine, especially on sort of in the quality issue. I mean, the idea is, you know, FDA is going to enforce. Right. They are supposed to keep the standards and enforce quality. I frequently compare FDA to a traffic traffic cop that's that's trying to enforce speed limits. And we all have

places to go. You know what it's like, right? If you know that there's a speed camera, speeding camera, you're going to slow down right there. But what if there aren't any, right? I mean, like, you pass that camera and you speed up again. Right. FDA is not in all the facilities at all places. So that's number one. And then also, what are the consequences of. Egg laying and inspection and whatnot. And I think it becomes particularly challenging for medically necessary products where the risk of shortages is great. This is basically FDA doesn't want to have shortages. None of us want to have shortages. But when the push comes to shove, they inspect a facility and the company says, we're going to shut down for half a year to fix the problems that you're going to say, would you think, is FDA going to say, no, no, no. You need to figure out a way to make this facility work. We're going to help you in all different ways. All hands on deck. We can't have shortages. Can we work something out? This is like basically telling a cop to say only give warning tickets. Right. So you have this kind of a dynamic where in a sense, on one hand, we're like putting basically relying on FDA to hold the line. But the economics really work sort of against this. And what we have basically gotten to a place is that we have since in the last 20 years this has been happening, but especially the last 15 years, and a really a disturbingly large number of drug shortages. Drugs are a lot of them are due to manufacturing quality problems where a facility has to shut down because of GMP issues to address and the market is not resilient enough to ramp up and and produce produce the product. Another piece that I think you know is happening is that experienced, established manufacturers are exiting the market. Two years ago, Teva announced that they are going to do a major reorganization of their business. And I just wanted to read you a headline from from that year. Teva to have slimmed down generic drug business in turnaround effort. The stock is jumping. So it's not a very attractive business to be in. And the established manufacturers are leaving many of the manufacturers that are where in the United States are shutting down facilities where actually and then you'll have more and more facilities opening up in India and China, where FDA oversight is somewhat more limited. And then also, we have had a few reminders about natural disasters, first with Hurricane Maria in Puerto Rico, and most recently last year, there was a tornado that hit a Pfizer facility. And as we sort of think about the the shocks, the potential shocks to supply chains, be it manufacturing quality, discontinuations, natural disasters and and potentially geopolitical threats, that that's becoming a major concern given the very little slack that exists in these systems.

WESSEL: Mara Let me ask you two questions. One came from the audience. So given that a lot of this stuff is made overseas, is is it time to require that the products coming into the United States be tested for quality? Or is it something or do we inspect the plants in India? How does this work?

WOSIŃSKA: Well, the FDA does inspect plants in India. There is a lot of reliance in the US system on making sure that the facility that's operating is following good manufacturing practices. And if you have a system that's reliable, the product should be reliable as well. I would say there is a role.

MORTON: They schedule those inspections in advance so the plant knows when the inspectors.

WOSIŃSKA: That's right. That's part of the challenge with inspecting outside of the United States in that the parties that are being inspected actually have a heads up in advance that FDA is coming. And so recently, we had an inspection where FDA maybe showed up a little bit earlier and they found trucks off of packed with papers and that were being shipped off from the facility and, you know, some other ones being burned to with acid. So you have these issues. But just really quickly to to go back to testing. Testing does potentially have a role. The United States the U.S. FDA has a different approach to it than we have than they have it in Europe. They do a lot more testing for products coming into the E.U. and it's a responsibility of the exporters. I have work forthcoming on this topic, kind of lessons learned around what we can learn from Europe about it. So I'll sort of I don't have an answer for you yet about what's the way to incorporate it, but it's worth it.

WESSEL: Okay. So Fiona, we heard that antitrust is slow, uncertain and limited in effect, but it might be our only option. Markets told us that you can have such a thing as too much competition. So are you worried that we've gone too far?

MORTON: I'm going to be even more depressing than Markus. I'm sorry to tell you that, but. So I wanted to just agree with everything that Marta just said. Generic drugs got so unprofitable that they actually formed a cartel and colluded to raise prices. So given that that made it more profitable, it's not terribly surprising to see a company like Teva, which was a major participant in that cartel, decide to leave some of these markets now that they're not making so much profit. We don't know where the drugs that we consume are made. There is not visibility into the whole supply chain. For some reason, the FDA has decided it does not have the authority to ask for that. So you can't model and the firms and they claim the FDA claims that the firms themselves do not know about their whole supply chain. So that's a little bit shocking and I think is a problem because it means that we can't model, for example, our exposure to a war, a flood, a pandemic, an earthquake, whatever you might want to know about. And if you had drugs, a critical medicine, one version of which was made in India and one made in New Jersey, that's, of course, a lot safer than if all of it's made

in China. And that place could have a pandemic. For example, earlier, I think somebody said, ah, the goal is to bring down drug prices. I actually think the Hatch-Waxman genius is a little more nuanced than that. It's we're going to let you if you invent something fantastic, charge whatever you want. But there's a limit to that at the end of a certain number of years, then there's going to be vigorous competition and you can't stop that vigorous competition. And I think that's the tradeoff that that is attractive to me. And the problem with Hatch-Waxman is that it worked just so well and brought down the generic prices in the way that Marta just described, that that was became very threatening to the brands, that the minute the generic comes in, boom, it's a cliff on my revenues and profits and I get zero after that. So then the brands turn to exploiting the imperfections in our decision making. Just as Marcus described, you've got a PBM as a consumer, a physician, as a consumer, a consumer, as a consumer, that that chain of agency is highly imperfect. And so you can exploit it on top of the FDA and the PTO. Okay. So the first trial was pay for delay, which was the really most obvious thing. I'll just pay my competitor to stay out. Well, split the monopoly rents were both happier and the only party who loses is the consumer and the government. So what Marcus didn't highlight is the FTC started investigating these problems back in 1999, and it wasn't until 2013 that we got a court to decide that maybe in some occasions a competitor paying its rival to stay out could be against our competition laws. I mean, that's quite shocking. And I don't think today's Supreme Court would think that it was a problem for the competitor to be paid to leave. And the great deal of credit belongs to the FTC for persisting for a decade in it to say to courts, no, actually, this is not this is not good for consumers. The second option was let's let's refuse to give them samples so that generics can't actually backward engineer our product because we're going to refuse to give them samples. And there was a legislative fix for that. However, there's a whole bunch more that are still out there. So we had a reference already to product hopping. I don't really like that name because it has a pejorative sound. I mean, I can innovate and maybe the thing I invent is fantastic and maybe the thing I invent is not very exciting. And if I put them to a real market test, if I did that in the market for bread came, my amazing bread would sell and my not very good bread would not sell because the consumer's using her own money. She can evaluate the bread. She's buying it in a very transparent environment. And so we're going to get the right answer. That doesn't happen in drugs. And so product hopping can be abused in that way. And one of the ways one of the big problems is now that we've shut down the ability of the brand to split the monopoly rents with the generic, the brands are now splitting the monopoly rents with the PBM. So you go to the PBM and you say, well, this product that's currently on formulary is about to lose patent protection and go generic and so you lose all your rebates. How about you don't put them on the formulary and put my brand on the formulary instead and I'll give you a big I'll give you a big payout. And that could be switching across brands or that could be, again, the product

top and that works really well. Voluntary Rems strategy works really well with doctors. Okay. If I'm going to. Sorry, a VA, a distribution channel where you say my drug is thank you is really dangerous. And I just decided that last week the FDA didn't tell me it was dangerous. I just decided it was dangerous. So we're going to make this really lock and key distribution channel that doctors have to learn to use and get access to and so on. And now in the generic comes along, I'm not going to let them use my distribution channel. But now the drug has been classified as really dangerous. And so now the generic has to build its own. The doctor doesn't like to switch because they don't know how to use it. So that reduces demand for the for the generic. Another way to to get the PBM not to switch is a disloyalty penalty or a loyalty rebate. So a disloyalty penalty is the generics arrived. People aren't used to it. Some people will switch, but not everybody. So what will do to you? For you PBM is give you the choice of either a reasonable price for this drug. If you buy exclusively from us or 95% from us that the brand or if you switch to either a generic or a rival more often this happens with the me too drug, a rival drug, then you're going to pay a really a high list price for us. And we know that the rival or the generic can satisfy some of your demand, but not all of it. So the rest, the non contestable share, you're going to have to pay a really high price. And that discourages PBMs from switching to entrants. The other thing that brands do is pay their customers to buy their drug with coupons. So it might cost you $10 for the generic $50 for the brand. Well, you get mailed a $40 coupon and so now you can just buy the brand because it doesn't matter to you. It's the same out of pocket cost. And brands are fancier than generics, so people do that. So that's just an end run around The PBMs attempt to steer consumers to the cheaper product. Another option is to create a patent thicket so that you have this endless patents that previous panel talked about that citizens petitions, regular people who object to the arrival of the generic because the. They're worried it's going to offer them evidently low prices and convenience. So all of these things just just build up. And you have the the brands very successfully driving down demand or raising costs for generic entry. And what you get when brands are very successful at doing that is first of all, it's somewhat disingenuous. All these firms want the market to determine price. They don't want price regulation, but they don't want the market to determine price once their patents expired. And so if you manage to control that post patent competition, then and stop it from working properly, what do you generate? You generate the IRA and price regulation. I mean, that's just the natural response of a democratic society where the democracy somewhat works. And and so I don't think it's a surprise that we've arrived. We've arrived at that place. What kind of policy do we need? Ma I'm a big fan of the Biden executive order, a whole of government competition policy. In my view, there are vast swaths of the government who did not receive that memo, like the Department of Agriculture, the Department of Transportation. But the FDA would be a prime example. I'm sure there are people at the FDA who are frustrated by this gaming, but

they're just not doing anything about it. I mean, ask tell firms you need to know where their stuff comes from. And if there's a pandemic and big shortages of medicine, let them complain to the courts and to Congress that they want to keep the origins of their drug secret. I mean, who's on whose behalf is that really? Who's being helped by that behavior? So I think whole of government competition policy would be really helpful to have. And I think instructing some of these agencies that that executive order happened and they ought to move on. It would be helpful. An important thing also to understand is the difference. Rep Yes, my last point distinction between marketing authority and patent authority. Marketing authority is something the FDA controls. If you can't sell a thing into the United States, it doesn't really matter what intellectual property you have.

WESSEL: So Al have an option. You can sit down or stand up right here. Here's what I want to know. I want to know. 40 years have passed. It turns out we're all 40 years younger, including Henry Waxman. Orrin Hatch is back with us. Howard Metzenbaum is not. And they ask you, okay, what should we do to the patent system? How do we end these monopolies that I know you think are causing us economic harm?

ENGELBERG: Well, let me say first thank you, Richard, for the compliment of of of allowing me to speak about the future. Given how long I've been involved in the past, I think I go back now 50 years of dealing with these issues. I want to make it I want to start with an observation, and that is that I think most people would agree that the biggest problem we face today is that drug prices are too high and monopolies last too long. The irony is it's exactly the same problem that we tried to solve in Hatch-Waxman, and it's actually the same rhetoric that was available at the time. And so what do we do to deal with the problem? We created a generic drug industry that now fills 90% of all the prescriptions, as you've heard. But but we we fail to recognize and and we're very slow to recognize that the other the other 10%, which accounts for 80 to 83% of drug expenditures expenditures. One of the reasons we have that situation is that we've had a cost shift. The pharma companies are public companies. They need to make a profit. They need to show growth every year. And and and what we did was completely disrupt the industry as it existed before and in this respect. And that is and it had nothing to do with Hatch-Waxman. Actually, it was one of the impetuses to enact Hatch-Waxman was that the state substitution laws basically ended profitable market within a week. And drug companies, the more successful you were as a company and more successful, your product was the bigger hole you had to fill in the future. When when when that monopoly expired, pharma companies had two choices. At that point, they could either invent their way out of the problem by finding replacement products that would generate the revenue that was gained, the revenue that was lost, the generic competition. Or they

could figure out a way to delay competition. And what we've heard today in terms of the criticism in the last 40 years is that they've done a hell of a good job of figuring out how to delay competition, whether it's basically by manipulating Hatch-Waxman to litigate secondary patents and pay for delay. But more importantly, which hasn't been mentioned today, science has moved past that. The bulk of the and the fastest growing area in pharmaceuticals are biologic drugs, which were never subject to Hatch-Waxman and which are because pharma companies learned the lessons of Hatch-Waxman have none of the guardrails of Hatch-Waxman. They practically take us back to a time of perpetual monopolies, essentially giving drug companies 12.5 years of of of exclusivity, even if there is no patents. And then the right to assert a gigantic patent portfolio, whether it's relevant or not, that can take 8 to 10 years of litigation. And then a market that isn't a generic market because the products are not identical and can't be substituted. So before we get into the question of so how do we how do we fix the system? Obviously what we need to do is shorten monopolies and figure out how to control the price while the monopolies exist. But we have to do that in the context of trying to to protect an innovation system and an innovation system that is completely different. That Hatch-Waxman changed because of what I mentioned at the outset. Pharma companies had to find a new way outside of their own research laboratories to get products in a timely way. And what we have today is a system in which big pharma companies and many, many have disappeared are buying most of the new products. Not all, but most of the new products from venture capital firms who are basically getting those products from biotech startups that are based on government sponsored research. So we have a very odd situation now where the government is the primary sponsor of research and also the primary customer for products that more and more can't afford. So so, you know, what do we do in that situation? I think it was alluded to somewhat in the last panel that we have to move toward some sort of one and done structure. We have to get rid of all the patent games and get rid of. But but recognize at the same time that people that the industry needs a certain amount of time to make its research cause back, including the research on the losers and and a reasonable profit. And interestingly enough, the the patent centric way we did it in Hatch-Waxman Bob and referred to it basically disadvantages the drugs that have the longest clinical trials. And those tend to be drugs in which we have the most need for, for for for for new drugs. And by the way, I should mention that one of the reasons we got to 90% generic substitution is we had a golden era in the first ten, 15 years following Hatch-Waxman of blockbuster drugs that treated ten, 20, 30 million people at a time. And you could make billions of dollars a year charging 4 or $5 for a pill. Today, if you look at the pharmaceutical landscape, we have specialty drugs that are that are consuming, that are that are the fastest growing area. They they are suitable for very small patient population. So even even if even if you charge a very high price for them, which is what's going on, tens of thousands of dollars, you simply can't make you

can't make enough money to replace the blockbuster drugs of the of the past. And and so this is the reason we've had aggressive price increases. So I, I favor something that I've come to call a one and done system when it comes to intellectual property, and that is we have to figure out a way. We tried to do it in Hatch-Waxman based based on the basic patent. And we can go that we can go in that direction. But we have to figure out a way for a monopoly to last for a fixed period of time and then move on. And the patent games have a date certain when it's over, maybe it's 12 years, maybe it's 14 years. There was an attempt several years ago on something called the Modern Cures Act to do just that, to basically set a date. And when that happened, and in exchange for which pharma companies would give up the right to to fully enforce their patents, that has gone nowhere possibly can be revived. And possibly the impetus for doing that is the fact that we have now capped price increases through the Medicare Part D negotiations. And companies may find it in their best interest to know and have a fixed date for for for patent expiration. The other area I think we have to take a strong look at is how the FDA operates in relation to all of this. We've we've gotten we have a the FDA law that basically says that once a drug is approved, you can't change it in any material way. And yet we have something called product lifecycle management, which has been invented by the drug companies in which they make constant changes and patent them and try and build a fence around their product to make it last longer. The FDA and I think we could do this by regulation to some extent, needs to focus on preserving the ability of the generic manufacturer to copy the original product. And lastly, there was a reference to by the Bayh-dole Act. The reality today is that the basic patents on most new drugs are or were our patents that the government paid for. The government paid for the research. The government is licensed under those patents. The government has a right, according to the GAO, to use that license to produce drugs for government programs, which it has never done. And I and and we're going to have to look at very closely the question of what is the premium we are, what is the premium the government and taxpayers are paying? What is the what is the total cost of all this research? What is the total cost of all the drugs? And and would we be better off, as was mentioned, separately, figuring out a way to pay for the research rather than to pay this premium for the capital that's going into the system and create some forms of of public private partnerships that recognize that there would be no new drugs without what's going on in the academic medical centers, which, by the way, in my opinion, is what we're doing now to innovate is far better than what we were doing when the drug companies were in control, because the academic medical center, that money is going to hundreds of young scientists who are chasing ideas not for money, but for this for the sake of public health. And I think we don't want to lose that. But we are now in the danger of telling all these young people that they should focus on meeting venture capital people and and turning their science into money and excel.

WESSEL: So out it come sit down again, because I want to I want to pick up on a point you made and someone in the audience just made it for all three of you. So as I understand it, biologics are the are a problem that we have lots of incredibly powerful drugs. They're very expensive. And we don't have a Hatch-Waxman like system to encourage what's called biosimilars. In fact, where we don't do as well as the Europeans do on that. So what what is the Hatch-Waxman like solution to the biologics.

ENGELBERG: We need of some sort? The whole I think the whole biosimilar drug is not a generic drug. It is more like a me too drug. It's more like Lipitor versus Crestor than than than the generic version of any of those drugs. They are not substitutable under state law. So the question is and I think the FDA is looking at this now, how how do you create a true generic industry so that the generic is a commodity and you compete on price? I would argue, and it's clearly in the public interest that we we should move away from patents, move toward an exclusivity system. But at the end of that exclusivity period, which is now 12.5 years, instead of having a patent free for all, maybe it should be 14 years or 15 years and you get to copy the entire file of the original product so that the product is identical. There's no issue of its identity and we have a date certain on, on, on when when we have a generic. Frankly, you don't even need a generic industry. What you need is a date certain on which the price comes down.

WESSEL: Fiona.

MORTON: Yeah. I think looking at the European experience is really important for understanding biosimilars. So I would differ from Apple here a little bit. There is no clinical, meaningful clinical difference between a biologic and a biosimilar in Europe and the Europeans have lots of them and they switch people. The whole country of Poland moves from one to the other on January 1st and no, nothing has ever happened. So it's really not useful clinically to say that these are differentiated products, but scientifically they are. I also think it's a little difficult to say, well, we just reveal what's in them and let the generic copy it. The problem is right now we don't know how to write down. You can't draw a biologic. It's thousands of times bigger than a small molecule drug. It may be that air gets us to a place where you can model that, but right now those are major barriers. And the Europeans procure biosimilars as if they are substitutes to one another, and that brings down the price.

WESSEL: Marta do you want to weigh in here? Pick a side.

WOSIŃSKA: I will weigh in, but then redirect us, if that's okay.

WESSEL: Okay. But can you refer to what the Inflation Reduction Act did on biosimilars or whether you think that was a good move?

WOSIŃSKA: So Well, actually, I think what what's what's relevant to talk about is what this might do to the to the generics industry. But just just really quickly, you know, if there is a lesson learned from Hatch-Waxman for biosimilars is that you need to be thoughtful about the level of competition that you can unleash. Entry for a generic is, you know, still challenging, but it is in terms of relation to costs to coming on the market. The fixed costs of coming on the market is diametrically different. This is we're talking about several million dollars versus $300 million at this point. And so, you know, if you were to try to drive competition for biologic biologics down to marginal cost, you'll have a problem, right? Nobody will want to come in on the market. So I just want to sort of that that is sort of one one big lesson learned. You know, what's interesting is that of all talked about, you know, in a sense, we're back to where we were before in that we're thinking about how do we get lower prices of drugs. In a sense, what the reason why we have the Inflation Reduction Act is exactly because we haven't really solved it. Someone biologics and still some on the on the small molecule drugs, it has to be old.

MORTON: So they have their biologics, they're old.

WOSIŃSKA: They have to be. They have to be old. That's right. But even there, we're not getting the level of competition that we would expect because of all the games that that have been that have been played. You know, there's a lot we can talk quite a while about sort of the impact on biosimilars and and generics. I will mention, you know, what's interesting on the generics side is that there's clearly at this stage, especially a bit of uncertainty about what is going to be the impact. On the one hand, you know, the Medicare negotiation will lower the prices and will make the market less attractive. At the same time, for the drug manufacturer, there is no better for the branded manufactured. There's no better way to get out of negotiation than to actually allow generic entry. So, again, maybe, you know, there's some interpretation whether whether actually you actually get excluded from Medicare negotiation. If you have the original version being it has a generic competition. What that could change the dynamic is earlier generic entry, but very, very you ready? Product hop. To make sure that you can sort of make that market as small as possible. So, you know, some

of it is, I think, how CMS is interpreting the statute and what actually exempts the product from the market. Some of it is going to be sort of what do we learn about expectations of the potential price drops? So I think there's a lot of lessons yet to be sort of revealed from from the process, but it might have sort of implications for for what plays out how this plays out.

WESSEL: So Al raised what I think is the fundamental tradeoff we face here. On one hand, we all want cheaper drugs and obviously the people who make them don't want cheaper drugs, but we also want to make sure we're providing enough of an incentive for innovation. And and it's not clear to me that we know how much. I mean, if we had longer exclusivity, would we get more innovation? Is it too long? So how do we know how do we weigh this tradeoff between encouraging innovation, which means giving them profits and getting low cost drugs?

MORTON: You asked $1 million question or $1 trillion question. There's a lot of academic research trying to get at this. It's it's definitely a tradeoff. However, I would say that in the United States, the way we handle this is we pay high prices for absolutely anything new. We don't say, how about invent something useful and innovative and then we'll pay high prices for it, which is a lot of how other countries handle something. If it's the fourth meta or whatever, then it has to pass some kind of threshold. So in the United States, we really rely on the market and that's a problem when our markets get broken, as we saw with insufficient antitrust enforcement and the like.

WESSEL: Yeah.

ENGELBERG: Yeah. I think I think the question is vastly different today than it was 40 years ago because the big pharma's gone out of the business of discovering drugs. Not everyone and not across the board, but to a significant extent, the NIH is now spending 50 plus billion dollars and it is admitted by everyone on all sides to be the engine of discovery. So the government's already in in the research business. Then the question becomes, what is the normal profit? We know this from other industries where the profit is some marginal number above the cost of production. And so if you're paying 2 or 3 times that because you haven't because you don't invest the rest of the capital to do the research, we end up in a crazy place.

WESSEL: But you said that the big companies are buying biotech firms, and you said that the scientists are getting lured by venture capital. Isn't that just an indirect way of getting incentives into the system to be to be innovative?

ENGELBERG: No, I think because the the incentive is coming. It's a very, very uneven distribution. The fact. The fact of the matter is, and I h has gotten to this point over a long period of time, it is not in any way, shape or form commercially sensitive. It doesn't distribute that money on on any on any marker that says we're going to give money to this researcher because they're going to discover a new drug. They're generally they're generating science and that that 50 million is generating 15 or 20 million in venture capital money. But that's very expensive money to raise. And I expects a big return now that pharma companies are buying that at premium prices. That's a very expensive proposition. So we have in the name of capitalism and competition, we've created an extremely expensive system that wouldn't even exist without the government's front money. And the government is the ultimate venture capitalist and is not acting and.

WESSEL: Getting a return. Fiona, this is a question from the audience. If Hatch-Waxman sought to balance innovation incentives and payer costs through enhanced competition. What about saying to industry You can opt to receive a longer market exclusivity, but you have to have a price that represents a socially desirable value. Is that a hospital?

MORTON: Because we don't know how to do that. I think that's the the main problem. I mean, I'll say I have a philosophical disagreement with Marta here when it comes to thinking about restricting competition because we're worried about the fixed cost of entry. Okay. We don't do that with cars. We let as many car companies as want enter. And there's a big fixed cost of developing a car and they manage just fine and they don't sell the cars at marginal cost. And that's what would. Even with biologics in my view. So I don't think we need to worry about saying, if we make entry really easy and we make substitution really easy will drive the biosimilar market out of business. We haven't done that with generics either. I do think there's major social externalities with resilience and reliability that no individual firm cares to take into account, And you do need public policy for that, though.

WESSEL: Yeah, my thanks to that. So what you described as a textbook externality, that is that the firms do what's in their interest, but it's not good for the society. They move all their production to the cheapest plant in China and stuff. So what other than raising barriers to entry, what is the public policy that you think would

be wise to make us more resilient? Should we? So we have stockpiles of key drugs the way we do petroleum. What could we do if we don't want to surrender the benefits of competition?

WOSIŃSKA: I think Thanks for this question. I think the number one thing is that what we need to recognize, that if we want to have resilience, we will have to pay for it. There is no free lunch here. And so I think this is what is going to make it politically challenging because we'll need to spend more money on this. I would say there are a couple of things that that are happening that I find very encouraging. They're still going to be hard. I am the number one thing that so most of the shortages that we have experienced so far are generic, sterile, injectable drugs to use in hospitals. And the best way to address them is to really prevent these shortages and prevent the disruptions. And the the the premise here is that instead of reimbursing hospitals and incentivizing them to buy the cheapest is to actually change the way that they place on resilience and have them pay more attention to buying from manufacturers who have more resilient supply chains. So this is not just stockpiles. You still want to make sure that you have a high quality product. And then how much are you going to really stockpile? Right. Drugs expire and whatnot. So inventory can be sort of higher. Inventory is a part of the problem. But I think we want to change the set of incentives and make sure that that that's being done. There is a bipartisan bill in in Senate Finance that I am very excited about. Senators Widen and Crapo have put forward a bill. It is a challenging issue to to get at. I think there's general agreement around the premise. There's a lot of details to be worked out. We still have to get the house on board.

WESSEL: What is the bill do?

WOSIŃSKA: The bill would basically set up a program where hospitals could get paid more if they signed long term contracts with more reliable manufacturers. It creates the ability in the marketplace. It it tries to reward reliability of supply. It also does another important thing, You know, the idea is, you know, where are we paying hospitals? Why are we giving it to manufacturers? It's because it's hard to force Medicare to give money to manufacturers. Right. So they can pay hospitals. And then the premise is, is that by incentivizing hospitals to buy from more reliable manufacturers, they'll be a pass through to manufacturers. So one of the things that the bill also does is eliminates Medicaid inflation rebates for some of these generics that will injectable drugs and other generic drugs. And the idea is, if I am supposed to be investing in quality systems to be more reliable, I better have the possibility of actually raising my price. Right. That's the whole point. I'm kind of differentiating myself on reliability. But Medicaid inflation rebates, not only just through that, but

through the 340 B program means that this is being paid back to the hospitals. So you have to kind of take out that that barrier. So those are the two things that the that the bill does. As you can imagine, a lot of opposition to that on the 340 B side from touching touching that space. So I'm very excited about that, Bill. And I'm hoping that that that it will move forward bipartisan, which is a big thing nowadays.

WESSEL: Right. Well thank you all. I want to call Richard up to give his closing benediction, but I want to just note that we've been at this for three hours and nobody has suggested that tariffs are the answer to this problem.

WOSIŃSKA: I plan to write about that.

FRANK: Well, I have one reflection and a bunch of thank you's. My reflection is that one thing we've seen today is how talent, leadership and a willingness to compromise can actually do stuff. And and so it's uplifting that way. And we don't have enough for those opportunities. And so I'm happy to have had a part in trying to provide that today. I want to thank the participants who've been here and what Congressman Waxman seemed to figure it out, that Steve and Bill and the two bills are just wonderful to go back there. And then this group of experts will mark history jumping into the fray. I really appreciate that. What we want to acknowledge and thank the Arnold Foundation, Arnold Ventures, sorry for supporting us here and their support. That's great all the way down the line for all this work. And then we've had super staff support here. You've probably seen them around the room. It's in Meghan and her bright orange jumper. And and this None of this happens without them. And then just as a note, if you go to our landing page, you'll see above and slides above and was put at an extreme disadvantage because he put together all these cool slides that we refused to allow him to show. And so Bob and slides are all available on the landing page. And as our couple of background papers on the history and the sort of current state of the Hatch-Waxman Act. So thanks all. And I appreciate your sort of sticking with us for three hours.