that, "We are stronger when we work together with our antitrust enforcement partners from the U.S. states and from around the world," sorry, she put her plans into action.

Viola Chen:

Thus, The Multilateral Pharmaceutical Merger Task Force was formed. Over the course of the past year, the task force has convened on a regular basis. Some folks in the task force had to wake up before the sun rose, while others saw that same sun set. To each and every one of you in the task force, thank you for your dedication.

Viola Chen:

The workshop, today and tomorrow is the culmination of the work of that task force. Today, we will hear panel discussions on concentration and remedies. Tomorrow, we will hear about innovation and conduct. The workshop will begin with introductory remarks from FTC Chair, Lina Khan, who was sworn in almost exactly one year ago, today.

Viola Chen:

During her time, one of her priorities has been and continues to be, seeking insights for improving competition analysis. This is showcased by the current efforts of the FTC and DOJ, as they consider all of the public comments on revising the merger guidelines.

Viola Chen:

The discussions we'll hear over the next two days follow those same ideals, of hearing from experts and thoughtful members of the public. Now without further ado, here is Chair Khan.

Lina Khan:

Thanks so much, Viola. Good morning, everybody. It's great to be here with you all today. It's a real honor to speak alongside AAG Kanter, Commissioner Slaughter, our colleagues from the FTC and DOJ, our State Antitrust Enforcement partners, as well as enforcement partners from across the world.

Lina Khan:

I'd like to give a big thank you to the Pharma Mergers Task Force who have done heroic work to put together this event, as well as give a thanks to our distinguished panelists for lending their expertise on these critical issues.

Lina Khan:

I also want to give a big thank you to Commissioner Slaughter and her team, who as we heard, last year, spearheaded the idea of a multilateral task force to focus on pharmaceutical mergers, and have worked tirelessly to convene stakeholders and participants from around the world.

Lina Khan:

I'm so grateful for Commissioner Slaughter's leadership in this area and everything that she and her team, including Viola and Cinda and countless others have done to drive this effort forward. I'm so excited that we'll get to hear from her shortly, through a keynote.

Lina Khan:

Lina Khan:

These are all critical questions at a time when the FTC and other enforcers are reexamining their approaches, and as the broader public is also reckoning with the effects of consolidation across the economy.

Lina Khan:

My deep thanks, again to the FTC staff and the task force members for their efforts to pull together this

Rebecca Kelly Slaughter:

Second, we wanted to ensure that we were working together to strengthen enforcement and align on approaches to common questions with which we are all grappling.

Rebecca Kelly Slaughter:

Finally, with the benefit of our collective exploration of market behavior, incentives and business decision-making, we hope that each agency would be better equipped to tackle the challenges posed by pharmaceutical mergers, collaboratively with fresh thinking and new strategies.

Rebecca Kelly Slaughter:

We have achieved our aims. The task force has strengthened our cooperation, both on big picture and case-specific issues. Casework has always been keyed to our intergovernmental relationships, but this task force was especially helpful, and that this meeting has created the time and space to jointly learn about, contemplate and discuss each other's concerns and challenges outside of the context of specific cases.

Rebecca Kelly Slaughter:

Enhancing these relationships through dialogue, helps to focus our collective lenses on novel and emerging competition issues, and enhances our cooperation on individual matters. Our panelists, over the next two days will highlight a variety of new learning about pharmaceutical consolidation and conduct that is relevant to our merger reviews.

Rebecca Kelly Slaughter:

Before we dive into the first panel, I'd like to take a moment to emphasize why the task force work is so important for constituents across our jurisdictions. Why pharma mergers matter so much.

Rebecca Kelly Slaughter:

First, pharma mergers matter because pharmaceuticals matter. While it's true that many of the industries with which our enforcement agencies engage on a daily basis are critical to people's lives, food, housing, gasoline, for example, pharmaceuticals are especially critical.

Rebecca Kelly Slaughter:

After more than two years of a global pandemic, we have seen up close, the miraculous scientific achievements that resulted in the COVID-19 vaccines and treatments that have saved countless lives. Every day, millions of people depend on pharmaceuticals to treat deadly and serious illnesses, to manage chronic diseases and conditions, and to provide preventative care.

Rebecca Kelly Slaughter:

A competitively vibrant market protects access to existing drugs and promotes new innovations. Access to medicine is already imperiled by untenable costs. In the U.S., spending on prescription drugs has increased from $30 billion in 1980 to 335 billion in 2018. Over that period, real per capita spending on prescription drugs has increased more than sevenfold, from $140 to $1,073.

Rebecca Kelly Slaughter:

This is not only from consumers' pockets, but a sizeable amount of that is taxpayer dollars spent on Medicaid and Medicare drug programs. When mergers diminish competition in pharmaceutical markets, the result is higher prices which can have a devastating effect for patients.

Rebecca Kelly Slaughter:

Enforcement action is necessary to prevent such harms. The FTC has a long track record of investigating pharmaceutical mergers and resolving those investigations with consents that require divestitures of particular products or pipeline products in order to replace the lost competition and prevent harmful accumulation of market power.

Rebecca Kelly Slaughter:

We must not limit our enforcement to existing products and pipeline products. Competitively healthy pharmaceutical markets are driven by the incentive to innovate, to research and develop new and truly innovative treatments. Mergers that reduce drug research and development can diminish the innovation competition that fuel scientific progress.

Rebecca Kelly Slaughter:

When multiple companies are racing to develop new technology, that innovation race in and of itself produces tangible benefits that may be at risk from a merger. The ECs challenge to DowDuPont recognized this loss of R&D, requiring divestitures of R&D assets specifically.

Rebecca Kelly Slaughter:

pharmaceutical startup, which may in turn affect the availability of capital to those startups. The merged firm could gain an ability and an incentive to foreclose other innovators, thus deterring investment in this space.

Rebecca Kelly Slaughter:

Finally, pharma mergers matter because we know that the pharmaceutical industry has a particularly checkered legacy of anticompetitive conduct. In fact, anticompetitive conduct in the pharmaceutical industry is so widespread that, we have an entire division of our agency, healthcare dedicated to investigating and hawking it.

Rebecca Kelly Slaughter:

I want to take a moment to acknowledge important developments led by the healthcare division in rooting out this anticompetitive conduct. Most recently, the FTC in partnership with several states, secured a verdict finding the Pharma Bro, Martin Shkreli liable for jacking up the price of a lifesaving drug for HIV patients more than 4000%.

Rebecca Kelly Slaughter:

The FTC has also made tremendous progress in its fight against branded pharma payoffs to generic drug makers, to delay their competition. DOJ and the states have brought groundbreaking cases around price fixing in drug markets. We do not pretend this anticompetitive activity does not exist when we are considering parties proposing to acquire their competitors, either in the first instance or as divestiture buyers.

Rebecca Kelly Slaughter:

Instead, it is important to consider how mergers might affect the incentive or ability of the merging parties to engage in anticompetitive conduct going forward.

Rebecca Kelly Slaughter:

The workshop this week wraps up the immediate agenda of the pharma task force, but by no means represents the end of our work together. We will continue to work with this exceptional group of partners on, both specific cases and general ap67e pa 5i(s)5(hol)4(ap67)-82-3(bu)4(t)4l[les 311 3nBTh

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Rebecca Kelly Slaughter:

I have no doubt, the knowledge the FTC will gain, will help better inform our pharmaceutical merger investigations. Finally, I'm very excited about the FTC's work with DOJ to refresh the merger guidelines. Our deep dive into pharmaceutical mergers has been a useful exercise contributing to that update.

Rebecca Kelly Slaughter:

With that, thank you, again to the Pharma Merger Task Force members. I just want to note that, I wanted to list off the names of all of the staff who have worked so hard over the last year, to contribute to this.

Rebecca Kelly Slaughter:

I was told that if I did that, it would take the entire 15 minutes, and so I couldn't do it. Know that I know you, I appreciate you. I have seen your hard work, and I'm enormously grateful for it, and I will have a chance to thank you in person. We are really, really lucky to have such excellent people working for us.

Rebecca Kelly Slaughter:

With that, I will turn it over to Thomas DeMatteo from the DOJ Antitrust Division, the moderator of today's first panel. Thank you.

Thomas DeMatteo:

Good morning and thank you for joining us today for our panel on concentration levels in the pharmaceutical sector as part of this two-day workshop, Examining the Analysis of Pharmaceutical Mergers.

Thomas DeMatteo:

I'm excited to be joined today by three great panelists. First, Patricia Danzon is the Celia Moh Professor at The Wharton School, at The University of Pennsylvania. Patricia is an internationally recognized expert in the fields of economics of healthcare, the biopharmaceutical industry, and insurance.

Thomas DeMatteo:

She's a member of The National Academy of Medicine and a Research Associate at The National Bureau of Economic Research.

Thomas DeMatteo:

We're also joined by Diana Moss who's the President of the American Antitrust Institute. Before joining AAI in 2001, Dr. Moss was the Federal Energy Regulator and consulting economist in private practice. She's also affiliated faculty in the Department of Economics and The University of Colorado at Boulder.

Thomas DeMatteo:

Rena Conti who currently serves as the Associate Research Director of the Biopharma and Public Policy for Boston University Institute for Health System, Innovation and Policy. She's also an Associate Professor at the Boston University Questrom School of Business. Her research focuses on the organization, financing and regulation of medical care. She has written extensively on pricing, demand and the supply of prescription drugs.

overseas. Next slide, please. And the fill and finish sites as well are increasingly concentrated overseas. Next slide, please.

Rena:

So and just to pause for a second and say, this work suggests there should be greater transparency into the US supply train, a simple counts of ANDA holders of fill and finish holders who might make the product, does not define competition in the product market spaces. We also have very limited competition or transparency into both who is making these products, but also where these products are made. The statistics that I showed you are the product of foyer releases from the regulators themselves, but actually who makes these products and where they're made is considered a trade secret both by the manufacturers themselves and also the regulators. This is despite 20 years of bad actors, lapses and outcomes when it comes to both prices, but also in terms of quality. Greater transparency would help consumers and payers shop better, and it would also help regulators assess the resiliency of these supply chains over time. Next slide, please.

Rena:

One last note on transparency as it relates to another actor critical to promoting patient access, and consumer welfare in the prescription drug market are the pharmacy benefit managers. Next slide, please. As Diane mentioned, the US PBM market is highly concentrated and is currently highly vertically integrated with plans, and really this includes both for products that are more traditional small molecule generics, but increasingly these compani0 612 nmTJETQq0.00000912 0 612 7(de, pl)4(ea)-22(s)5(e.)] TJETQq0.00000912 0

Sure. So much and I would say specifically the focus on product markets defined by manufacture molecule formulation pa

Well, I think there are a lot of studies out already, obviously, though all the empirical work that has been done by Rena and Patricia and others working in the space. I would offer up that, back to this concept of how the pharmaceutical markets really can't be viewed in isolation, they have to be viewed in the context of the bigger supply chain. I think that's where more work needs to be done. And the 6B study that was just announced on PBMs, I think is the opening of the door into the perspective of how the competitive dynamics in pharmaceutical mergers relate to competitive dynamics in other markets in the supply chain, especially that relationship between drug makers and PBMs, and PBMs and health insurers.

pharmaceutical space where they started, which was these sorts of branded drugs that were very similar, the cardiovascular dru

Diana:

Dominant firms are going to innovate in ways to protect their own market positions. They're going to prevent... They're going to forebear from innovating in areas that cannibalizes their own product lines. It will be a very, very different arc of innovation and not in a way that maximizes consumer welfare or social welfare then you would get, if you have highly competitive firms, duking it out to invest in the next big blockbuster drugs and to invest not only in drugs that will be available at lower prices, but also higher quality.

Rena Conti:

Distinguished Professor of Law Chair and Director of the UC Hastings Center for Innovation. We also have Professor Barak Richman, who's the Katherine T. Bartlett Professor of Law and Professor of

This can help entice the middle players who negotiate on behalf of health plans to disadvantage the firm's competitors. So when a firm acquires small shares of different markets, the acquisitions won't trigger regulatory review in any single market, despite the combined market effects. In other words, pharmaceutical companies can amass volume and breadth of products and the power that comes with that without ringing any antitrust alarm bells. Most important, the modern industry structure in which large companies buy up small companies, poses particular challenges for merger evaluation. Acquisition of a startup is not intrinsically negative in that it can incentivize formation of startups and new research. However, any startup can become capable of challenging incumbent firms, not only by developing competitive products, but also by allowing the startup to gain familiarity with regulatory pathways and establish relationships with regulators. Thus, when the big fish swallow up all the little fish, it ensures that no little fish can ever grow into a challenger.

Professor Robin Feldman:

Unfortunately, antitrust tools do not sufficiently capture these concerns, a big fish buying a single small fish is unlikely to trigger regulatory warning signals, even if it is only one of many transactions. So I'd like to close with a couple of thoughts on strengthening merger review. First, I'd like to suggest that regulators should adopt a robust second look policy. Rather than relying on crystal ball predictions of what will happen after a merger competition agencies should establish a system of post merger review to ensure that past decisions had the intended results and to improve future evaluations. In addition, competition measures should be adjusted to consider the power of volume across different markets, as well as the impact of repeated small mergers. When a pharma company buys a small startup, the probability that the particular startup might have displaced the monopolist could be small, but if a monopolist buys a hundred startups, the chance is far greater that competition has been restrained. When we focus atomistically on individual purchases and individual markets, we risk missing the forest for the trees. Thank you very much.

Malinda Lee:

So much, Professor Feldman. Now let's turn to Professor Richman to discuss emerging remedies in the context of prior anti-competitive conduct.

Professor Barak Richman:

Thanks Malinda, and thanks for having me. I have some slides, but I'm not even sure they're really necessary. In part, one reason is because much of what I'll be. Okay, well here they are anyways, it's fine. And you can just skip, go ahead to I think what is the third slide. Much of what I'm going to say is I think is a bit of an elaboration beyond, actually Robin referred to it also, but really what Patricia said in the previous panel. So the kind of conduct I look at in the pharma space is conduct that is enabled by the dominance or the presence of PBMs.

Professor Barak Richman:

And I like everybody else in the previous panel and this panel, I'm very grateful and excited that the FTC has decided to look at PBMs in particular. I don't want to necessarily vilify PBMs, even though they do control a very significant amount, as Diana said in the previous session, that is a highly concentrated market. It is actually in many ways, its own bottleneck, but I think is most important is to understand the institutional role they play in the distribution system. We can go to the next slide.

Professor Barak Richman:

I can go to the slide after that.

Professor Barak Richman:

So the kind of approach that I think is really necessary is an approach that the FTC pioneered, not that long ago. Current antitrust treatment of pharmaceutical or merger pharmaceutical firms looks at the

monitoring what's going on, but specifically setting up early stage research as a group that has autonomy within the larger firm. I think that might be a specific way to continue keeping the R&D intensity and the flavor of small firm research within the larger firm and ensuring that adequate resources are devoted. So thanks for listening to my remarks on supporting the scientist

or phase three of clinical trials, and another pipeline product or a marketed product of the other emerging parties, then remedies can involve the divestment of such pipeline product.

Youenn Beaudouin:

In old cases involving divestment. The Commission also ensures that whatever divested business is purchased by a suitable purchaser that will maintain or even strengthen the viability and competitiveness of the divestments. And elements to identify suitable purchaser include generally three standard criteria, which are that the purchaser be independent of the parties, that it has the financial resources, expertise, ability, and incentive to maintain and develop the divested business as a viable competitive force and third that the acquisition of the business by the proposed purchaser must neither be likely to raise competition concerns in itself nor give rise to risk of implementation of the commitments being delayed, including in relation to potential regulatory processes.

Youenn Beaudouin:

On top of these specific criteria may be added depending on the case. In some instances, they may relate to the type of purchaser that would be suitable. And some cases we could require for instance, that an established generic supplier would be the purchaser or linked to the purchaser's local presence requiring for instance, an existing presence in Europe or in specific European countries. In addition, in very specific circumstances, the Commission may also accept non divestiture remedies and these would in particular be the case when the transaction raises conglomerate concerns linked to interoperability, that is when different products offered by the merging parties need to interact between themselves and third party products. Thank you.

Malinda Lee:

Thank you so much for that. Great overview, Mr. Beaudouin. Now let's turn to a Ms. Mark for the perspective of the US Federal Trade Commission.

Speaker 1:

Hi, good morning, and good afternoon. Thanks Malinda. And as Youenn did, I will also start with my standard disclaimer that our remarks are my own, and I am not necessarily speaking for anyone at the Federal Trade Commission or any of the Commissioner. So I will try to be brief. First, I think it's important to focus our attention on the mission of antitrust enforcers at the FTC. For example, one part of our dual mission is to protect competition, and one of the ways that we protect competition is to ensure that any remedies or settlements are effective in resolving competitive concerns effectively in fully preserving the existing competition.

Speaker 1:

With that idea in mind that remedy policies and practices are also critical to enforcing antitrust laws. I think a step in the right direction is to think about the effectiveness of our merger remedies. If we are to consider, give consideration to the settlements that we are taking in the future, by looking at the settlements of the past. Similar to the ongoing review of analysis of mergers in the pharmaceutical industry that we're discussing here today and the review of our merger guidelines, more generally that the federal agencies have undertaken. I think a review of our mergers merger remedies is something that we need to consider. This is something that Professor Feldman mentioned in her remarks.

Speaker 1:

Professor Richmond:

So, to some degree maybe I'm on the wrong panel in the sense that my honest inclination to answer the question is that first of all, all conduct is ... all negative conduct is exacerbated after mergers and conduct remedies really are a disfavored remedy. So I'm inclined to say everything and nothing, as an answer to your question.

Professor Richmond:

A little bit more seriously, I do take very seriously what both Professor [Dans 02:20:57] and then Professor Ry said about the efficiencies of scale and that there really are very ... maybe no or very hard to measure efficiencies as it relates to the research side. And in that ... as far as innovation, and in that sense, the thumb really has to be very firmly on the side of really questioning whether a merger should be approved at all, precisely because so many different kinds of conduct are exacerbated by market power. And it's not just market power in particular therapeutic areas, it's not just market power overall. To the degree that the healthcare delivery system is complicated, there are multiple nodes of ... or multiple opportunities to create bottlenecks.

Professor Richmond:

Uwe Reinhardt describes us as a war of attrition, and there's a lot of truth to that. I think we need a lot of humility in thinking that certain conduct remedies really can solve the problem that we're concerned about, in large part because avoiding one kind of conduct often just invites pursuit of another kind of conduct. With complexity comes opportunities to create inefficiencies.

Professor Richmond:

So having said that, with ... bearing in mind that I think there's a lot of reason to be very skeptical of the efficacy of conduct remedies, precisely because of the kind of institutional complexities that we're identifying in the marketplace.

Professor Richmond:

I do think that there's something to be said for another thing that Professor Feldman just said, which is if you can really get a sense of what the competitive harm is, the source of competitive harm, then you might be able to design a certain remedy in particular, that is particularly designed to that. Typically when we think of inefficiencies, market harm that's caused by certain contracting strategies, one thing we do is we simply prohibit that particular kind of contract. We have now done that in many states for MFN clauses. I think it's a little simplistic. I think it hasn't really stemmed harm significantly, but so long as we are constantly monitoring what the industry's doing and we can act somewhat nimbly, then I think it'd be appropriate to come up with ... to really expand the number of arrows we have in our quiver of conduct remedies, and just be very attentive to what the market is doing.

Malinda Lee:

You mentioned the complexity in many conduct remedies. Is there a role for independent monitors to ensure compliance with those types of remedies, as well as the ability to monitor how behavior from firms may evolve over time?

Professor Richmond:

And I think with the right structural modeling, you would really be able to rely on reliable equations that would not rely on the kind of things, Synda, that you're describing, which is have we seen these people before? Are they good people or are they bad people? Can we trust them to engage in certain conduct or not?

Synda Mark:

No, thank you. That's helpful. Sorry, Melinda.

Malinda Lee:

No worries. Thank you for the question, and I invite others to weigh in.

Malinda Lee:

So that leads me to move to Professor Ry. In your earlier remarks you mentioned that your theme, your one theme would be protection. Sorry, Melinda.

Professor Ry:

So keeping that all in mind that inputs don't equal outputs necessarily, at least we can monitor inputs and try our best to support scientists in terms of having that research budget to do the risky phase 2a, for example, research.

Malinda Lee:

Thank you, Professor Ry.

Malinda Lee:

I'm going to move to direct a question to Mr. [Beaudoir 02:31:10] and ask for you to share some of your insights on ... from the perspective of the European Commission, so that we can get a cross-comparative perspective.

Youenn Beaudouin:

No, thank you. If we look at the issues that were raised by the various panelists on consolidation, innovation and conduct in term and how we address them, but regarding consolidation, this is the standard theory of harm in most pharmaceutical mergers involving competitors, where competition concerns arise. And we have, for instance, assessed cases in the field of generics or consumer health products, which raise concerns linking to consolidation, in particular where the transaction created or strengthened a dominant position. Here, the remedies, when a case raises concerns relating to horizontal effect in the pharmaceutical industry, as in any other industry, a standard remedy is a divestment. And this covers the bulk of remedies that we accepted in the pharmaceutical industry over the years. Regarding innovation, this is an aspect that we assess, particularly when both companies are active in R&D. Our focus has been mostly on late stage pipeline products, but we also look more broadly at innovation efforts in broader fields. So for instance, in a AbbVie Allergan, we looked at the innovation efforts in autoimmune diseases as a whole.

Youenn Beaudouin:

What remedies are there when we have innovation concerns? Well, these are also horizontal in nature. So divestment with the ... is a standard remedy to concerns relating to innovation. Innovation concerns due to overlaps resulting from pipeline products have been remedied by the divestment of such pipeline products. That was a case in AbbVie Allergan or Takeda Shire.

Youenn Beaudouin:

And there are specific challenges in terms of remedy implementations with the divestment of pipeline products due to the inherent risks of development of these products. And in 2020, the commission waived remedies entered into by Takeda to secure its acquisition of Shire, in particular due to the negative scientific studies and unforeseeable difficulties relating to the conduct of clinical trials of the divested pipeline product.

Youenn Beaudouin:

In addition to the divestment of pipeline products, the divestment of all R&D operations in a specific field of research could also be a suitable remedy if broader concerns arose in terms of innovation efforts. And as was the case, for instance, in the agrochemical field, in the DowDuPont case that Commissioner Slaughter brought up in her earlier remarks.

Without going into the details of the case, it refers to a transaction in the corporate products market, which the European Commission prohibited in 2019. Here the parties had offered divestment remedies which included a number of carve outs, and it needs judgment of may. The general court of the European Union clarifies in particular that the Commission can assess the viability and competitiveness of carved out assets proposed by the parties when assessing remedies, and that it cannot accept remedies that would not fully eliminate concerns because a key asset is missing.

Youenn Beaudouin:

The judgment for this specified that a divestiture remedy has to be viable in itself. And so the Commission does not have to take into account the resources of a presumed purchaser to ensure the viability of the divestment.

Youenn Beaudouin:

The court also specified that when remedies are market tested, more way has to be given to customers' replies as opposed to competitors', since they are directly impacted by the merger, whereas competitors could benefit from price increases. This case is only the most recent example of how poor decision shapes the Commission's approach to remedies, or in this case confirms it.

Malinda Lee:

Mr. Boudoir, it's very interesting to hear how our international partners are managing the same challenges that we face here in the U.S. market, pharmaceutical market.

Malinda Lee:

In my remaining time, I'd like to turn to Ms. Mark to provide some thoughts from the Federal Trade Commission, the U.S. Federal Trade Commission, and specifically I'd like to ask what next steps the Federal Trade Commission hopes to take in regards to new approaches, different approaches, to pharmaceutical merger remedies.

Synda Mark:

Yeah. Thanks again, Melinda. So I'll start by again just pointing to some of the recent engagement that the FTC has done with respect to our remedies, excuse me, with respect to our merger guidance rethink project more generally, and just talk briefly about what the agency plans to do, which I think is to take a more holistic rethink of all of our processes and practices here. And I think that includes remedies.

Synda Mark:

So if you take a look at the request for information that went out with the rethinking of the merger guidelines project, that the agencies ... the DOJ and the FTC submitted back in January, you'll note that there is a specific call-out in that RFI for consideration of remedies, the remedies practice and policies. And so I think, obviously that issue is on the table.

Synda Mark:

One of the questions that I think we should also be considering is whether, and to what extent, a consideration of labor markets, more systematically, and the follow-on consideration of remedies in labor markets, might also be on the table.