



## FTC The Future of Pharmaceuticals - Tuesday, June 14

Viola Chen:

Welcome. Good morning, good afternoon or good evening, as may be appropriate depending on your time zone in the world. Welcome to The Future of Pharmaceuticals: Examining the Analysis of Pharmaceutical Mergers.

Viola Chen:

On behalf of the Federal Trade Commission and Department of Justice, I have the honor of welcoming everyone today. My name is Viola Chen, Economic Advisor to Commissioner Rebecca Kelly Slaughter, and also a Staff Economist at The Federal Trade Commission.

Viola Chen:

Before we start, let me go over a few administrative details. This event is being recorded. A video recording and transcript of these proceedings will be available on the FTC and DOJ website shortly after the event.

Viola Chen:

Our intent is to create a lasting resource for anyone interested in this important topic. Second, as with any virtual event, we may experience technical difficulties. If these occur, we ask for your patience. We will work to address them as quickly as possible and keep you informed of any significant delays.

Viola Chen:

Finally, please join us on Twitter. Our Twitter handle is @FTC, and we will be using the #FutureOfPharma. Over a year ago, I joined then acting chair, Slaughter's office. Among the many thoughts she had about improving antitrust policy and enforcement, was a notion that we the FTC, needed fresh, new ideas about how to approach pharmaceutical mergers.

Viola Chen:

We had to be proactive. We could not afford to wait for the next big pharmaceutical merger to begin our work. With gracious humility that she did not possess all the answers, with the boldness to say out loud that, "We should convene the best minds and thought leaders on the topic," and with the ... to say

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:

The research and development behind modern medicine has transformed society, and saves or improves countless lives every day. Diseases that were incurable just a few years or decades ago are now routinely treated by doctors around the world.

Lina Khan:

The work of antitrust enforcers can help ensure that companies are facing the right incentives to continue innovating, and to make the fruits of these scientific feats widely available at affordable prices.

Lina Khan:

The pharmaceutical sector is where the life and death stakes of our work as antitrust enforcers really comes to the fore. Just a few weeks ago, trial results for a new breast cancer treatment appeared to indicate dramatically increased survival rates in some of the worst cases. We also saw that the drug may offer an entirely new strategy for treating other types of incurable cancers.

Lina Khan:

These are the types of promising next-generation advances that could extend and improve the lives of millions of people around the world. As antitrust enforcers, it's our job to promote their competition that will help create the right conditions for the next generation of scientific advances, as well as to help ensure that as many people can benefit from these advances.

Lina Khan:

Unfortunately, reports on the state of competition in the pharmaceutical markets in recent years have been troubling and underscored, just how much work there is to be done. For example, just recently a study came out showing that the median list price for new drugs have soared from around \$2,000 in 2008 to over \$180,000 in 2021, an increase of 20% per year.

Lina Khan:

We've also seen empirical reports showing that tiller acquisitions, or acquisitions that are made for the purpose of shutting down potential competitors may be relatively common in the pharmaceutical industry. We've also seen that relatively few leading drugs have been developed within the largest pharmaceutical companies, which are the companies that ultimately enjoy the vast majority of profits.

Lina Khan:

Then, of course we've seen a whole set of lawsuits surfacing, various allegations that companies have been illegally bundling and tying market leading drugs to include competitors for their lesser drugs in recent years. These findings, of course are complex and may arise from a variety of root causes, including the conduct of other actors within the pharmaceutical supply chain.

Lina Khan:

These types of findings really underscore for us, how much work there is to be done. This is why I'm so excited to be hearing from our distinguished panelists today, who will be tackling a whole set of really important questions, including how we can be improving our analysis of pharmaceutical mergers. What types of factors we should specifically consider when analyzing these mergers, beyond traditional concerns around horizontal overlaps, as well as how should remedies, potential for innovation and prior bad acts be incorporated into our merger analysis.

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 terrific program, as well as the panelists and participants for lending us their time. I'm so looking forward to the discussions throughout today. Thanks so much.

Jonathan Kanter:

Thank you, Chair Khan. I would like to start by just echoing your remarks in every respect. Let me begin by really thanking the task force for their heroic work. It's an extraordinarily important issue, an extraordinarily important moment.

Jonathan Kanter:

Commissioner Slaughter has done heroic work, leading this effort, and been a visionary leader in connection with pharmaceuticals and antitrust. We're, literally talking about a market where competition saves lives, and lack of competition can threaten lives. It's more important than ever that, we get this right.

Jonathan Kanter:

Convening this taskforce, being with our colleagues from DOJ, from the FTC, from the State Enforcement Community and the broader antitrust community is an essential step forward so that we can ensure that the antitrust laws are being enforced in a way ... in a manner that all citizens talked about this a lot, so has Chair Khan, is about meeting a moment.

Jonathan Kanter:

We are in a moment, in a moment where we have great demands on antitrust enforcement to ensure that we're satisfying the needs for fellow citizens. This is true in a wide range of areas. It includes areas outside of pharmaceuticals, like technology.

Jonathan Kanter:

In fact, we're even seeing the U.S. Congress work to advance bipartisan legislation that would curb threats posed by dominant platforms. This is about meeting the moment, and we are wholeheartedly in support of that legislation.

Jonathan Kanter:

Today is about meeting a different moment, or meeting the moment of respect to a different issue. That is, one, as I mentioned earlier, is so critical to the health and safety of our fellow citizens. I could not be more pleased to be here today.

Jonathan Kanter:

I'm extremely interested in hearing from all of our experts and panelists, so that we can understand how competitive healthcare markets give patients access to medicine at affordable prices, and hospitals that offer quality care, and choice of doctors. This has never been more important than now.

Jonathan Kanter:

Speaking of innovation, when we think about pharmaceutical industry, we'll talk about access and quality innovative medicine. It's not just medicines that exist today, but it's making sure that competition functions in a healthy, constructive way to make sure that we are solving problems for the future.

Jonathan Kanter:

If conduct, whether its harmful mergers or other kinds of anticompetitive conduct harms the innovative process, harms the ability for our fellow Americans to get access to competitive, innovative drugs at affordable prices, then that is essential for us as antitrust enforcers, to take action. It's essential for the livelihood of our nation.

Jonathan Kanter:

As Viola mentioned, over the past year, both the U.S. and international enforcers have been working together to think about and learn from each other under the leadership of Commissioner Slaughter. This workshop is now a culmination of that work, and it indicates, really a successful intergovernmental collaboration.

Jonathan Kanter:

Today and tomorrow, this workshop will focus on four important areas relevant to pharmaceutical mergers, innovation, concentration, remedies and prior bad acts. I'm eager, extremely eager to hear from our esteemed panelists from today's event, as its event like this, that help us, the antitrust enforcers better understand the industry, particularly as we continue to engage in the process of modernizing the antitrust guidelines for mergers.

Jonathan Kanter:

It allows us to better undertake competition analysis against the backdrop of present market realities, and continue to engage with our partners to ensure that consumers receive the full benefits of competition in pharmaceutical markets.

Jonathan Kanter:

With that, it gives me extremely great pleasure to introduce, again, a visionary leader of this effort, Commissioner Rebecca Slaughter who will give today's keynote address. Take it away, Becca.

Rebecca Kelly Slaughter:

Thank you so much, AAG Kanter and Chair Khan. It's really a pleasure to have you here and to hear your comments. I want to particularly note the fact that we have, both the AAG and the FTC chair at this hearing, reflects an important part, not only of this effort, but of our current agency's collaborative approach.

Rebecca Kelly Slaughter:

People think of pharmaceuticals as more in the FTC bucket, in a lot of ways than the DOJ bucket, but the fact that DOJ has been an eager and willing partner with us on this is really a reflection of how, both Chair Khan and AAG Kanter have prioritized making sure our agencies are working collaboratively together, moving in the same direction, learning from each other and contributing to each other's efforts. I think having the two of you start this off is a perfect way to illustrate that.

Rebecca Kelly Slaughter:

I also want to thank Viola for your incredibly kind introduction, and thank you to the leaders of our partner organizations. Andrea Coscelli at the CMA, Margrethe Vestager at the EC, Matthew Boswell at the CCB, and Gwendolyn Cooley, the Chair of the NAAG Antitrust Task Force.

Rebecca Kelly Slaughter:

I especially want to extend my thanks and gratitude to the staff at The Federal Trade Commission, the DOJ Antitrust Division, the offices of the State Attorneys General, Canada's Competition Bureau, the European Commission Directorate General for Competition, and the UK's Competition and Markets Authority, and our panelists for the extraordinary work that has gone into making, not only today's event, but this entire project a reality.

Rebecca Kelly Slaughter:

The breadth of interest, as you can hear from the different organizations, reflects the fact that this topic is a priority and a concern for, not just the FTC and the DOJ, but enforcers across the country and across the globe.

Rebecca Kelly Slaughter:

I want to express my deep gratitude to each of our partner agencies for deploying your time, your effort and your expertise to participate in the pharmaceutical merger task force. Thank you as well to the members of the public, academics, researchers and others who submitted comments and contributed to our learning and understanding of pharmaceutical mergers.

Rebecca Kelly Slaughter:

One of the byproducts of the COVID-19 pandemic has been the ability to connect with colleagues from around the world with the touch of a button. Being in the same virtual room allows us to connect and enhance collective learning with greater convenience and regularity than we could do with in-person meetings.

Rebecca Kelly Slaughter:

Our new found facility with video conferencing was a bonus that helped strengthen relationships and enhance the taskforce interactions. For the past year, a group of incredibly smart thinkers have taken a fresh look at our approach to merger investigations and enforcement in the pharmaceutical industry, and explored opportunities for growth.

Rebecca Kelly Slaughter:

This collaborative project had several aims. First, we sought to gain a better understanding of the similarities and differences in the competitive environment in our home jurisdictions, and our real-world merger experiences informed by our respective laws.

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:

The FTC is alleged harm to innovation in a number of different cases, including recently in complaints challenging the tie-ups of Lockheed Aerojet and Illumina PacBio, both abandoned, and Illumina-GRAIL, which is pending in litigation.

Rebecca Kelly Slaughter:

In the pharmaceutical context, competition to innovate means competition to bring new drugs to market. It can also manifest this innovation more broadly, in how clinical trials are conducted or how drugs are delivered, for example.

Rebecca Kelly Slaughter:

Competition to innovate can lead to discoveries around platform technologies, such as the mRNA COVID vaccine, which can have vast applicability across different medical indications.

Rebecca Kelly Slaughter:

Even simply, an awareness of the innovation efforts of other firms, information that is often in the public domain, pushes the pace car of research and development faster and faster. Protecting innovation requires us to consider the impact of mergers on, both the incentives of the merging firms, and on what one or fewer firm engaging in R&D in a therapeutic category or particular technology might mean for the R&D race, as well as on non-merging firms.

Rebecca Kelly Slaughter:

For example, the incentives of non-merging firms may be relevant if a merger reduces the number of large firms that are the target sales audience for a new development being innovated by a



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 approaches, keeping our ideas fresh and reflective of market realities.

Rebecca Kelly Slaughter:

Going forward, our individual enforcement and policy work can also inform each other's agendas. For example, in the U.S., we are paying particular attention to the conduct of pharmacy benefit managers as the intermediaries between manufacturers and patients. Last week, the FTC issued 6(b) orders to study the PBM industry and a handful of critical drugs like insulin.

Rebecca Kelly Slaughter:

This will expand the FTC's knowledge and understanding about contracting practices, and pharmaceutical firm pricing, and incentives. The information the commission uncovers in its 6(b) study can and should be presented to the public in a final report. This public-facing work product can help inform policymakers, other government agencies, academics, and many market participants who are working to address punishing drug prices.

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.

Thomas DeMatteo:

With that, Patricia, will you kick us off?

Patricia Danzon:

Thank you, Tom. First slide, please. Do you have my slides visible? Okay. Thank you very much. I am going to be speaking today, about the neglected issue of firm size in pharmaceutical mergers.

Patricia Danzon:

This talk is based on joint work with Michael Carrier and our forthcoming article in the Antitrust Law Journal, as well as my paper that was published last year in Concurrences. Next slide, please. Next slide, please.

Patricia Danzon:

We all know that the standard review of mergers involves looking at whether a merger increases dominance in individual product markets. This is applied in pharmaceutical sector, with divestiture of overlapping products as the standard remedy.

Patricia Danzon:

I would argue, this approach of looking at individual drug markets is important and necessary. There are questions about the efficacy of divestitures, but I am not going to address those today.

Patricia Danzon:

My concern is with the fact that this approach, even if successful in limiting increased dominance in individual drug markets, still leaves the question of whether the merging of two firms to create a larger firm increases the potential for market power from cross-market effects.

Patricia Danzon:

These firm-wide effects are ignored by the standard analysis, yet they are potentially important in pharmaceutical markets because of the role of firms having to negotiate and deal with payers and physician customers who are agents for patients.

Patricia Danzon:

Now, this role of payers and physician customers differs across markets and types of drugs. As I will argue in this talk, the advantages of size are greatest for originator firms. That is, the firms producing on-patent branded drugs in the U.S. compared to these same originator firms in other European markets, for example, or the generic sector.

Patricia Danzon:

Next slide, please. As some suggestive evidence of the importance of size, we point out in the paper, the continued dominance of the same top 20 pharma firms in the industry. If you look over the last decade, or you can go back further, it's the same names, the same companies that have been the leading players, with changes happening mainly due to M&A within that group of top firms, as well as their acquisitions of other smaller companies.

Patricia Danzon:

New firms have entered the top 20, mainly by space being created through mergers within the top 20. Yet this dominance that has just persisted for the top firms is not due to their preeminence in R&D.

Patricia Danzon:

On the country, large firms' share of new active substance, that new compounds has slowly declined to around 20% in 2018. Very small firms are now originating about 70% of these new compounds. There's no evidence that firm size increases R&D productivity.

Patricia Danzon:

The thesis here is that firm size and the continued dominance of these large firms is owed to their advantages in contracting, marketing and finance that enables M&A, and enables their continued dominance. Next slide, please.

Patricia Danzon:

The first area of advantage, of size is in negotiating with payers for reimbursement. In the U.S., we need to distinguish between pharmacy dispensed drugs, which is majority of drugs are capsules, tablets and liquids. These are managed by pharmacy benefit managers, PBMs.

Patricia Danzon:

In the U.S., pharmaceutical firms can set then, this price as free, and then pharma firms compete for preferred position on PBM formularies by giving confidential rebates for preferred position.

Patricia Danzon:

Some of these rebates are passed through to payers, but some are retained by the PBMs. This negotiation with PBMs creates an opportunity for large firms to use their large portfolios, or their must-have, or blockbuster products as leverage in which they can tie access to the portfolio, to the rebates on their main product, to preferred status for all their products across their portfolio.

Patricia Danzon:

This creates this cross-market leverage that can be a major concern. I would argue that this bundling strategy that does arise from increased market power that, comes from size is used primarily, not to raise list prices or to lower rebates, but rather to exclude competitor products.

Patricia Danzon:

The harm is likely to be less access for new products, particularly biosimilar products, but also competitive products in the branded space. Next slide, please.

Patricia Danzon:

There is a similar advantage of science in negotiating with specialty physician customers. These are the specialty physicians who administer most biologics, the infusions and injections

Patricia:

... that are considered part of the medical benefit and are handled by Medicare Part B. And traditionally there's been less role for PBMs in this sector, because the physicians directly buy the drugs, dispense them and then build the payers for reimbursement. So the contracting is traditionally between the

pharma firms and these groups of specialty physicians, maybe in multi-specialty groups or hospital outpatient departments. And again, there is an opportunity for cross market leverage in order to get access to preferred conditions on some drugs, the entire portfolio may be part of the contract and that tends to block access for smaller drugs or drugs from smaller companies. It's possible that there is some real savings from this cross-portfolio contracting, but it's very unlikely that savings is priced on because insurance makes individual patients price insensitive and plans are not choosing drugs on the basis of price.

Patricia:

Indeed, in this particular sector in the US, firms have incentives to compete by raising prices, not lowering prices because the form of reimbursement that adds the 6% margin to the average sales price creates an incentive to raise price, to increase the margin for customers. Next slide, please. So, I've spoken about contracting and negotiation, the next area where size is an advantage is in simply marketing. Next slide, please. Where a firm with a large portfolio can detail multiple drugs on a physician visit and do bundle supply and again, disadvantage is smaller drug companies. There may be some real scale and scope economies here, but again, any savings are likely captured by physicians and firms, not by consumers because insurance blunts the price sensitivity of consumers and firms incentives to compete on price. Next slide, please. The final area that we discussed of where size conveys an advantage is in financing.

Patricia:

Large firms by definition have portfolios of market drugs that generate huge cash flows and retained earnings, and this retained earnings enables large firms to have a lower cost of capital than small firms, that must raise capitals on external capital markets through private and public equity to finance their R&D both capacity, et cetera. And so when large firms acquire small firms, there is a potential for real savings taking advantage of lower financing costs of the larger firms and avoiding the duplication of regulatory marketing and sales capabilities when the smaller firms would otherwise have to pay. So these large, small acquisitions are much more likely to be generating efficiencies, but such efficiencies are not generated through mergers when both firms in the merger already have retained earnings and full capacities. And even though large, large firm mergers do lead to cuts and capacity and personnel, those cuts are not necessarily tied to a merger, they can be done in the absence of the merger. Next slide, please.

Patricia:

So as I have argued, these advantages of size really are specific to the US pharmaceutical market for originator drugs where especially the reimbursement arrangements provide for portfolio wide contracting, which leads to the possibility of these cross markets to lower for effects by contrasting develop markets outside the US. Payers generally set the drug prices of originated drugs using either referencing to external prices or to other products in the same market as the new drug, so-called internal referencing using cost effectiveness analysis and other techniques. And there is no role for portfolio bargaining or contracting to exclude competitive products. So the issue of cross market leverage horizon is much less of a threat in these markets where originator prices are set by regulation. Generic markets in both the US and ex US are characterized by large firms selling to large customers and often to portfolio wide contracting.

Patricia:

But in generic markets, the customers are large, well informed, price conscious pharmacies and wholesalers. And there is a price sensitivity there that significantly limits the potential for competitive firm, firms like these. And so the implications of this analysis for merger review, especially in the US, is that in addition to standard market by market review, we would argue that it's important that in mergers involving two large originated firms were roughly defined as in the top 10 firms by the US sales, there should be a presumption of competitive harm that would shift the burden to the emerging firms to show that merger specific efficiencies exist, that would outweigh the potential for competitive firms.

Patricia:

In the case of mergers involving a large and a midsize firm or two midsize firms, roughly firms in the second, they sell by US sales, there is a strong case for heightened scrutiny, especially if either of the firms has a must have or blockbuster product, which leads to increased risk of uncompetitive strategies with bundling and cross market leverage by contrast M&A involving small firms by large or mid-size firms.

Patricia:

Standard market review is generally sufficient, but with scrutiny if there is a must have or blockbuster product involved. And we believe that although some of these harms that I mentioned could be addressed through other remedies that because these other remedies require on information that is hard to obtain, it's hard to get information about anti-competitive contracting and other forms of conduct that using preemptive stops on potentially harmful mergers is an appropriate addition to the supplemental remedies that of course still would play a role. Thank you very much.

Tom:

Thank you very much, Patricia. Diana, next I'll turn things over to you.

Diana:

There we go, off mute. Thanks very much, Tom. And my thanks to the agencies for inviting AAI to participate at this workshop. We applaud the FTC very much for looking into their merger policy and pharma, and also into pharmacy benefit managers as recently announced in the 6B study. I want to take my few minutes here just to recap AAI's 2020 study on the FTCs history of merger enforcement and pharmaceutical mergers. And of course that study was spurred by asking the fundamental question, what is the role of merger enforcement in what we see now as very high levels of market concentration in pharmaceutical markets and high drug prices? So, I think it's important for context to note that the FTC does actually have a policy on pharmaceutical merger enforcement. And that came out of the 2017, the vestiture study, where the commission noted that it follows a standard approach for evaluating mergers and designing relief.

Diana:

And that standard approach has been to settle virtually all challenge mergers with divestitures. And so I think a rethink is in order and again, we applaud the commission for examining their own merger policy. And that rethink is important because we now have research numerous studies showing a strong connection between high concentration and high end rising drug prices. The CPI for prescription drugs increased at a rate more than double that of inflation. We've had very high profile cases of price gouging, epinephrine, insulin, Duoprim, just to name a few. And then we see very high profit margins for the largest drug makers pushing 20%. And those margins are much higher than a control group of non-

drug companies that have similar R&D expenses. So, that's the motivation for this study. I think more context is also important and that is you can't look at competition and the availability and pricing and accessibility of drugs just in pharmaceutical markets and isolation, they have to be looked at in the context of the bigger pharma supply chain, right?

Diana:

And that's because we have a lot of dominant players and oligopolies with significant bargaining power in other parts of the pharmaceutical supply chain, obviously drug manufacturers negotiate with PBMs for placement on formularies. We have PBMs negotiating with health insurers for prescription drug plans. We also have vertical integration now between PBMs and health insurers, but that's the subject of a very different workshop. So this quest for bargaining power in the supply chain creates incentives for M&A for bulking up to become a bigger, better, more powerful bargainer [inaudible 00:43:48] being your upstream suppliers or your downstream distributors. But the end game in pharmaceuticals is we have a very bottlenecked supply chain in pharma, those are market power bottlenecks, it looks like an hourglass, a very high three firm ratios for generic pharma, 65%. High three firm ratio for PBMs, 75%. For drug distributors, the three firm ratio is 90% and for health insurers, 80%.

Diana:

So let just dive into the major takeaways from the study. And what we did is we examined every single challenge pharma merger at the commission from 1994 to 2020, we will be updating the study soon. Of the 350 reportable deals under HSR, 350, excuse me, were given or granted early termination. And the commission challenged are moved to challenge 67 mergers worth about 1 trillion in value. And what we see over this period of time is that in the early period, 1994 to about 2015 as deals are proposed, not all are reportable, obviously, but if you look at the total number of deals, that tracks upward along with the number of FTC challenges, so you see some alignment in upward tracking of deals and challenges. But post 2015, there appears to be a structural break or a disconnect where M&A continues to track upward, but the number of challenge deals actually falls.

Diana:

So when we unpacked all of these complaints that the FTC wrote in these 67 challenge mergers, we found that most of the markets were highly concentrated and the merger induced concentration was significant. 60% of those markets in those 67 challenge deals were three to two mergers and two to one mergers, 75% were four to threes, three to twos and two to one, so, major... not unexpected takeaway. All of the pharmaceutical mergers challenged by the commission have been highly concentrated mergers. In those complaints on the competitive effects side, the FTC alleged unilateral effects in about a third of those complaints and in about 60% of those relevant markets defined in those complaints, the commission alleged both unilateral and coordinated effects. And importantly, in 75% of those markets defined in all of those complaints, the commission alleged harm to actual and potential competition.

Diana:

So the taking out of small arrivals, which is not a specific to pharma is a theme in pharmaceutical mergers as well. So, just to hit the pause button here, highly concentrated mergers over the past many years reviewed by the FTC, and so that is an important background for looking at now very high levels of concentration. So digging even deeper into the firms that were parties to mergers, both branded and generic, but also the parties that acquired the divested assets in all of these deals that were challenged, we find even more interesting trends and themes. So if you just look at the parties to the mergers

themselves, not other firms that swooped in to buy divested assets, what we find is that 25% of those merging parties engaged in multiple mergers, so they were serial mergers. 45% of merging parties who also bought divested assets in other proceedings were also serial purchasers.

Diana:

So they were going back to the till not only in successive mergers, but they were going back to the till to purchase assets in other challenged mergers. So in total, about 70% of asset purchases in these challenged deals that were made by merging parties, involved parties that were serial acquirers. So, you can already see this group of pharmaceutical firms shrinking and shrinking and shrinking over time. We also found that non merging parties to these mergers were also serial purchasers of divested assets.

Diana:

So in some, what we see is about 20% of merging parties and purchasers of divested assets accounting for a disproportionately large number of transfers of assets, changing hands between the shrinking group of pharmaceutical manufacturers over time. And then in addition, what we see is that post a divestiture in a third of cases, those buyers were acquired within a two year period after they had purchased the assets with a commitment to maintain them and reinject competition. And then of course the FTC's own study, their 2017 study shows that 25% of on market generic drugs that were examined in the FTC study were not sold post divestitures. 75% were sold, 25% were not sold.

Diana:

Okay. So where does this all leave us with this shrinking group of very powerful drug manufacturers? Well, what we see is that antitrust violations in the pharmaceutical industry are pervasive. And what we found is that 55% of the about 70 firms that were parties to mergers and purchasers of divested assets, oftentimes multiple assets and multiple mergers are now defendants in antitrust litigations. So more than half of this group of companies involved in mergers and purchases of divest assets are now have been, or are currently defendants in antitrust litigations, that is an enormous percentage of the number of firms operating in the industry that have been involved in merger activity. That includes generic price fixing conspiracies. DOJ has taken indictments. We have private and state multidistrict litigations alleging conspiracies.

Diana:

We have monopolization concerns pay for delay, product topping, deceptive practices, sham petitioning, our AAI's amicus program is very active in the pharmaceutical area, but suffice it to say that we have a disproportionately large number of these pharma companies that have been involved in M&A, now charged with antitrust violations. And so I think another important takeaway here is of course that because the FTC chose through a standard policy to settle all challenged cases, we really have no judicial record whatsoever on how defendants in those cases would've overcome a structural presumption of... associated with these highly concentrated mergers. We also see that the failure of divestitures really sets an incredibly high bar on taking divestitures, settling challenge mergers with remedies where the burden on the remedy it is extremely high to fully restore competition lost by the merger. So, just to finish up here, we need a new policy on pharmaceutical mergers, absolutely.

Diana:

And the evidence is clear, we've unpacked the FTC's merger policy itself. And so AAI would suggest considering abandoning the standard policy of settling all challenge mergers with divestitures, also



discouraging through public signaling and messaging from the commission leadership by discouraging pharmaceutical companies with deep records of past M&A and purchases of divested assets who are also defendants in cases, discouraging them from engaging in further M&A. And then certainly we need to look very carefully at when deals are settled with divestitures, conditioning those divestitures on the asset, staying with the buyer, but also putting into place all the prior approval requirements. And I will stop there. Thank you.

Tom:

Thanks Diana. Rena, next I'll hand it off to you.

Rena:

Thank you so much. Just waiting for my slides. Thank you. I'm sorry, can you... Yeah, thank you. Thank you so much. Thank you so much for the opportunity to join you. My prepared remarks are going to focus on two themes, competition and transparency, and this is going to go across two related industries, the generic drug market and pharmacy benefit managers. I'll tell you how they're related soon enough. The work that I am going to present is joined with a number of collaborators that include Ernie Burnt, Fiona Scott Morton, Jim Rebitzer, Mike Powell, and Brigham Frandsen at University of Utah. Next slide, please.

Rena:

Thank you. So as you all know, prescription drug spending is high, it's also growing. Drugs consume approximately one out of every \$5 now spent on healthcare in the United States. What is less appreciated, I think is the important role that this industry is playing in access to healthcare. Specifically, the vast majority of Americans are taking prescription drugs and really it's the most commonly used form of mental care in the US currently. Next slide, please. Thank you. The vast majority of drugs that are used and dispensed in the pharmacy, but also in other settings are generic off patent drugs that make up approximately 90 to 95% of total sales, depending on how you count. And really they're part of the virtual circle, where, "Yes, we spend high money or high prices on branded products, but we spend less money on generics when they become available." Next slide, please.

Rena:

The number of generic approvals has increased dramatically at post patent cliff in 2012 and has considerably contributed to price deflation and also spending deflation over the past decade. Next slide, please. It is clear that entry both at the time of patent loss, but also competition between firms on post entry and over time produces downward pressure in prices and other market forces push people to use generics when they become available. Next slide, please. There has been concern raised about competition eroding in generic markets in two senses, the first is related to the evergreening or pay for delay, or other types of behaviors where generic products that we expect to enter don't enter the US market, or are significantly delayed causing consumers and also other payers to pay higher prices than they otherwise would. This is increasingly a concern in the non-traditional small molecule space, but rather in the biologic and biosimilar space. Next slide, please.

Rena:

And really the work that I have done has suggested that not only there should be concern about generic entry and competition upon patent loss, but also there should be increased scrutiny and concern about generic competition and steady state or when after all the entry has occurred. And indeed, as Diana's

already mentioned, myself and colleagues have also found that approximately 50% of all generic drugs markets when controlling for volume are dominated by either monopoly suppliers or duopoly suppliers, and this suggests there's much less competition than a simple count of... and the holders for a given product market suggests. Next slide, please.

Rena:

And just to remind you, because the concentration in these markets, it's these same product markets over and over again that are really acting as monopolist or duopolist in any given product market. Next slide, please. Another thing for regulators and other overseers of these markets to notice is that the median generic drug market actually generates very limited revenue in work that Ernie and I did, we find that the average product market is selling at approximately 1 to 4 million in revenue a year, but more than a quarter are producing less than half a million dollars a year. Those are very smaller markets in terms of revenue and the vast majority of the product markets that we look like would not meet the Scott Hart Rodino thresholds for merger scrutiny at the product level, as Diana already suggested, this is a concern. Next slide, please.

Rena:

This level of competition that's highly concentrated, particularly in study state can engender bad outcomes for consumers and also for payers. This includes price inflation among many important generics, not just as outliers, but in fact, in the work that we have done of more than a quarter of all generic drugs have actually experienced year over year price inflation that outpaces the CPI in recent years. Next slide, please. But also, and perhaps more of concern in terms of promoting consumer welfare have been both ongoing and persistent shortages in some essential drug markets and more recently quality lapses in product markets that are used very commonly to control heart disease and diabetes among other chronic diseases, including the valsartans and also metformin. Next slide, please.

Rena:

In terms of transparency, one thing to really keep in mind here is that while mergers scrutiny has focused on fill and finish manufacturers in the pharmaceutical space, the base ingredient manufacturers and actually the excipient manufacturers are also highly concentrated and sometimes they are forgotten until bad behavior is revealed, and then we have to go back and realize, "Oh, not only are the fill and finish manufacturer's highly concentrated and potentially pursuing anti-competitive behavior," but in some sense, that is related to highly concentrated and also anti-competitive behavior that is being pursued in upstream markets and in the base ingredients spaces. And here, I think the most important thing to notice is that the vast majority of these bulk manufacturers are highly concentrated and they're actually located not domestically. Next slide, please.

Rena:

So in work that we were able to do with colleagues at the Food and Drug Administration, we were able to get a non public data files on the identity of both and the location of both the fill and finish and also base ingredient API manufacturers for the better part of the past decade. Next slide, please. And what we found was that while fill and finish manufacturers tend to be domestically located, API manufacturers are overwhelmingly located in India, China, and Europe and far from our own authorities assessment. And this is a challenge for all regulators of these products in terms of both assessing conduct, but also assessing the quality of these products that are coming into the US market. Next slide, please. We've also found that the API manufacturers in particular are increasingly concentrated

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 companies have gotten into the specialty drug space. Next slide, please.

Rena:

There are clear concerns both for policy makers, but also many actors in the system that this concentration has uncertain impacts on prices and also on patient access, Diana and also Patricia's comments have alluded to some of these concerns. Next slide. And I'll end my remarks by applauding the agency for the FTCs 6B study on pharmacy benefit managers, it's an absolutely critical step. What is also very nice about what has been announced about the scope of the study is that consumer welfare is first and foremost the focus of the investigation and specifically the PBM study is focused on downstream contracts between pharmacy benefit managers and pharmacies, the point of sale for the vast majority of these drugs and upstream contracts with plans.

Rena:

My suggestion is for the agency to not lose focus of the primary relationships that is shredded in much more secrecy, which is specifically the pharmacy benefit managers and these drug manufacturers on generics. We are quite concerned that the relationship between PBMs and the generics might have dual edge on outcomes. In one hand Ernie and I have wondered whether monopoly and oligopoly supply in the generic market meeting monopsony on purchasing in the PDM market is actually keeping prices lower than they otherwise would be given the current market structure of the generic prices or generic supply.

Rena:

But we also are worried about the erosion of competition in this space due to PBM purchasing. On the branded pharmaceutical space, remember drug manufacturers set those prices and they set list prices on reflecting the current market structure of who is purchasing those products. In our work, it is clear that branded manufacturers might view PBM market structure as an endogenous input into the list

prices that they're setting for consumers, and this is key because consumers are actually paying list price at the pharmacy or some portion of list price. So we really encourage the agency to not lose focus of the relationship between pharmacy benefit managers and these drug manufacturers when they're pursuing their current study. And with that, I will say, thank you.

Tom:

Thanks very much, Rena. Lots of great content in all of your presentations today. Next we'll turn to a few questions. First, I'll start with Patricia. Can you explain how staff at the enforcement agencies could practically apply your ideas in the merger review process?

Patricia:

I can attempt to answer that question, Tom. What I would suggest they look at is... as I mentioned, the overall size of the firms that are proposing to merge and where it is

Patricia:

Is a large or a mid-size firm matching with a smaller firm, pretty much business as usual. It really becomes more important to assess the potential increase in market power from the size and the scope of the overall portfolio, particularly in large, defined as within the top 10 by US sales. And they could look at top rankings by global sales, but the rankings are pretty similar and since most of these concerns are particularly to the US market, I would recommend using US sales. And I think that asking firms to provide evidence of real efficiency savings, like a merger specific in these contexts and also as a condition of going ahead but also looking into past conduct of the proposed merger partners in terms of their contracting with PBMs.

Patricia:

Now, this would be the sort of information that could be obtained through discovery, would not be obtainable just general researchers, but looking at to what extent have the merging parties in fact, engaged in cross portfolio contracting with PBMs in their prior business. By definition, these are already large firms with large portfolios and they already have the potential for tying the rebates on their must have products and tying access to some drugs in their portfolio to preferred position of other drugs in the portfolio. And so there should be a historic record of what these contracts have entailed in terms of preferred and particularly exclusive positioning for the firm's products. And some evidence on that can be obtained simply from the facts on, what drugs are in preferred position on PBM formula? Do these firms typically have their drugs in preferred position and particularly exclusive position? And if that is generally the case, I would be suspicious that they are in fact, using portfolio contracting and that the merger is an additional threat to competition.

Thomas DeMatteo:

Diana, anything to add there?

Diana:

No, not much to add other than just an enormous shout out to Patricia and Rena for doing the research that they have done, which really supports an evidence based case for why we need to do a rethink of merger policy in the pharma sector. As far as how the commission sort of retools its policy in pharma, I think that body of empirical work is going to be really critically important but it also has to dovetail with enforcement strategy, which I think flows directly out of AAI report, which is we know that the agencies

under the Biden administration have taken a more aggressive stance on enforcement. At AAI, we would wholeheartedly encourage that and to recognize that the best remedy for a merger is, in many cases, to move to block a merger.

Diana:

The purpose of a remedy, whether it's a conduct remedy or a divestiture remedy is to fully restore competition lost by a merger. We're seeing that those divestitures have not been effective in the pharmaceutical sector. So an agency moved to block a merger in many cases, especially in these very highly concentrative deals where we now have evidence of a failure of past policy is to actually go to federal court and seek an injunction to block a merger and we do need some test cases for that. My own view based on the analysis of all the complaints is that these are not high risk cases. These are not high litigation risk cases if the FTC chooses to go to court. They're highly concentrative mergers.

Diana:

We need an airing through judicial opinion on what efficiencies defendants put forward in the burden shifting process. We don't have any judicial record on that at this point. And it's going to be really important, I think, to get that. And then finally AAI mentions this in our comments on the merger RFI. There really should be a rethink of policy as to who gets to buy divested assets. If a company has a history of antitrust violations, especially criminal violations, as many of the big generic firms have, they should not be considered candidates for purchasing divested assets.

Rena Conti:

I completely agree with Diana's comments and Patricia's. I would add that it's not just end account or end identity that's really important in the generic space, but it's the actual commitment of manufacturing capacity to these products that should be of concern to the agencies. We know from other work that the end account in any given product market appears to be higher than the actual manufacturers entering into these markets and certainly manufacturing these markets over time and contract manufacturing, essentially getting these products off the books of multi-product firms into lower cost on producers is an active area of business strategy now and so it's actually possible that there are even fewer manufacturers of these products than even an actual count of who's registered to make these products would suggest. So really getting into the details of who is making these products and what is the market structure and to what extent mergers might alter that market structure or not is absolutely critical.

Rena Conti:

I think the only other thing I would suggest is that agency focus has largely been on prices and or on consumer access. The quality manufacturing deficits that we are seeing in some critical drug markets is absolutely criminal and American consumers have been exposed on a daily basis to drugs that they use to treat chronic disease that cause cancer. And so, really thinking about quality in addition to price or access is, I think, should be an important focus of the enforcement.

Thomas DeMatteo:

Rena I'm curious what your thoughts are about what has been working well in the pharmaceutical merger review process.

Rena Conti:

Sure. So much and I would say specifically the focus on product markets defined by manufacture molecule formulation pair is an incredibly important thing. And the comments around that of the agencies have made very important, the lowering of the Scott–Hart-Rodino thresholds for a scrutiny, particularly in this space, especially with the small market sizes that we've seen, also very important step forward. And I can't say enough about how excited I am that the agency has decided to take on the investigation of the PBM market.

Thomas DeMatteo:

Patricia, anything you'd like to add?

Patricia:

Yeah. I'd like to come in at the agency for looking at potential entrance so looking at drugs in the pipeline, when they look at accounts of concentration and who are the potential competitors because particularly in the originated space where development lives are long, it can take 10 plus years to bring a drug to market. The drugs that are in the late stage pipeline already are potential competitors. And by the same token, if there is nothing in the late stage pipeline then there really is very little potential for new entry. And so that adding the late stage pipeline to the count of what's already out there on the market is a very realistic and important way of defining markets for these branded pharmaceutical space.

Diana:

Could I just jump in and really agree with first, Rena on the proposal to consider lower HSR thresholds in pharmaceutical mergers. We're seeing the same thing in big tech where all the majority of deals fall below the thresholds and have really contributed to this growth by acquisition model and the platforms becoming so dominant over this period of time so definitely a rethink on HSR thresholds. And I also want to point out that the FTC staff absolutely has an incredible body of expertise in the pharmaceutical sector. I think the analysis of the mergers is fantastic and you see this also in the cases the FTC is brought in pay for delay and other non merger antitrust violations. It's concerning because had we not had so much concentration and consolidation through merger, it's entirely possible that we would've seen a different unfolding of the pay for delay cases and now other methods for squeezing out rivals, product topping and [inaudible 01:18:27] petitioning.

Diana:

So the FTCs expertise is absolutely unquestioned in the staff's ability to unpack these mergers to understand the industry. I think the point of my remarks went primarily to how the commission chooses its strategy on merger enforcement, in terms of now hopefully to move to block more mergers, to enjoying more mergers, to really critically think about the risks of divestitures and the weight and the burden that is placed on a divestiture in these highly concentrative mergers but we are certainly confident that with the expertise that the staff has and a change in merger enforcement strategy and policy, that would be a move in the right direction.

Thomas DeMatteo:

Diana, earlier you mentioned a few recommendations. What additional studies would you like to see conducted?

Diana:

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.

Diana:

And as part of that, I think we see this in food and agriculture as well, where there's high levels of vertical integration and high barriers to multi-level entry. I think the agencies would be well positioned to look into the competitive dynamics between the levels in the supply chain, how bargaining power fits in as a motivation for merger and how to un-bottleneck this very, very important.

Thomas DeMatteo:

Rena, I saw you come off mute. Do you have a few thoughts?

Rena Conti:

I do. So again, I think that the FTC study on PBM behavior and upstream and downstream relationships is absolutely critical. These relationships are contractual. They are hidden from scrutiny and really these relationships determine American access and affordability to these products. So absolutely critical to examine these relationships. I would say there are other critical members of the supply chain that also make money off the high costs and the steering of American consumers to certain products and not others that might be of interest. The first would be group purchasing organizations that are largely the entities that are purchasing pharmaceutical products on behalf of hospitals and clinics. There has been very significant consolidation in the end product or end user space, hospitals, clinics over the past 15 years. They've also leveraged their buying power to contract on drugs.

Rena Conti:

And there have been some significant issues related to pricing but also even more importantly, significant issues related to supply adequacy and quality in those product markets that I think engender some increasing concern and certainly scrutiny. And then lastly, pharmaceutical companies are not the only entities that make money off the high list price of these products, or in buying low and selling high. And specifically hospitals are generating increasing shares of revenue. In my work, we suggest somewhere on the order of 20 to a hundred million dollars a year off the sale of prescription drugs. And so thinking again, about how these prices are endogenously determined by the market structure and by the consumers who are buying these products and how this may actually harm consumers or restrain supply, particularly for these specialty drugs is certainly of concern.

Thomas DeMatteo:

Patricia, anything to add there?

Patricia:

Yeah. I think a couple of things I would like to add. In looking at the PBM sector and I too absolutely command the study, I do think it's important to look at how PBMs have performed in the area of the

pharmaceutical space where they started, which was these sorts of branded drugs that were very similar, the cardiovascular drugs, the anti ulcerants, the antidepressants, where their mechanism of playing off one against the other and choosing a couple to be in a preferred position was a very effective form of competition and it has really broken down in the specialty drug space. And so looking at how PBMs function in specialty drugs versus the more traditional chemical drugs, I think is important.

Patricia:

Final point I would make is yes, we can [inaudible 01:24:32] all these harms to competition, but we need to remember that in this market where consumers are... Excuse me, heavily insured, it is very hard to structure a market based environment that will in fact function efficiently. And so there's always a question of relative to what and if we, unlike other countries, try to just use market competition to control our healthcare prices but in a context where consumers are essentially fully insured, it is a very challenging issue for both the FTC and for the regulators in this market. And I think it has to be looked at in both the regulatory and the competitive structure as how we are going to play in the US healthcare market.

Thomas DeMatteo:

I think we have time for one last question. Patricia, what is your response to criticisms that scale in the pharmaceutical industry is what enables innovation?

Patricia:

All the evidence shows that is not true. As I already said, now around 70% of the new compounds being approved by the FDA come from very small companies. And the share coming from large companies is down to about 20%. And this I think is unsurprising because a lot of the innovation is coming out of NIH funded research that is done at academic institutions and then spun out into small firms. So in a way, the small firms are formed around the innovation and that is a much more effective way of doing innovation than for the large firm to sort [inaudible 01:26:22] scientists doesn't think about the problem. The other point is that in this types of drugs that are now being developed, roughly 50% of the new drugs approved have orphan status. And so the cost of doing the RND is much lower than it was for the big drugs that required huge, long ongoing studies. And so it's much more financially feasible for small firms to do the analysis whereas the very big studies did require large firms in the past.

Thomas DeMatteo:

Diana, Rena, any closing thoughts?

Diana:

Yeah, I'll jump in on that really quickly. I really do think the train has left the station on debunking the conservative ideology that you need scale to be able to innovate. You need the deep pockets to be able to fund big RND programs. We've seen evidence in agriculture, for example, in crop seed showing that high concentration does not beget higher levels of innovation and this is obviously the same case in pharmaceuticals. I think it's also important to consider the importance of parallel path RND. Mike [inaudible 01:27:42] and Bill [inaudible 01:27:43] wrote a very good article years ago about one of the branded drug mergers, emphasizing the importance of parallel path innovation as generating the competition in RND pipelines that's necessary. Again, a lot of parallels on the agricultural biotechnology side, but I think it's really important to note that you get very different innovation pathways from dominant firms than you do from competitors.



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:

If there's a minute more...

Thomas DeMatteo:

Of course.

Rena Conti:

Thank you. I would add not all innovation is the same. And I think it's really important to remember that need to innovation in crowded spaces might benefit some consumers but is a very different type of innovation than breakthrough products and new product categories especially needing unmet need. It's really in those latter spaces where a lot of the smaller spin outs and startups of universities have been focusing their efforts. And I would say we want to make sure that we can preserve that competition area, that innovation and potentially be willing to trade off innovation that is a little bit less innovative, frankly.

Rena Conti:

I think the other thing, just to note here, is that these products can really alter consumers lives. They also come at a very, very high price and so that can restrain access or also erode access in other ways that shouldn't necessarily be the dominant position of our regulatory agencies. I think one last thing is that there's some new evidence to suggest that when regulators alter regulation to insist on higher quality or more supply in these markets, the larger firms [inaudible 01:30:55], whereas the smaller firms innovate to try to meet the new standard. And so we wouldn't want to necessarily engender more political backlash or pressure to reduce regulatory agency effectiveness.

Thomas DeMatteo:

Thank you. I see that we are past 10:30, so thank you all so much for your thoughtful insights today. We really hope that you enjoy the rest of the workshop and this concludes our panel for today. Thanks.

Malinda Lee:

Hello, and thank you for joining us. It is my privilege to welcome you to the Broken Fixes? Remedies in Pharmaceutical Mergers Panel. My name is Malinda Lee, and I'm a deputy attorney general

Malinda Lee:

And the healthcare rights and access sections competition unit in the California Attorney General's office. I have the honor of moderating this panel to discuss pharmaceutical merger remedies. Joining us today for this discussion, our five highly esteemed speakers. We have Professor Robin Feldman with the author, Arthur J Goldberg, Distinguished Professor of Law, the Albert Abramson Class of '54

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 Business Administration at Duke University. We have Professor Arti Rai, who's the Elvin R. Latty Professor of Law and Faculty Director of the Center for Innovation Policy at Duke Law. We also have joining us, Youenn Beaudouin, a Senior Case Handler at the European Commission's Directorate General for Competition dealing with merger control. And finally, we have Synda Mark, who is the acting Deputy Assistant Director for the Office of Policy and Coordination at the US Federal Trade Commission.

Malinda Lee:

As competition concerns are proliferated in the current way of pharmaceutical merger activity, the role and effectiveness of merger remedies to address those concerns garnered significant scrutiny. Historically, the most frequent merger remedy has been divestiture giving rise to questions about the potential role of, and need for other remedies. This panel will consider different, new and underutilized remedies, pharmaceutical murders to address each of the concerns covered in this workshop, including increased consolidation prior anti-competitive conduct and decreased innovation. We'll begin our discussion with brief presentations from each speaker. Let's start off with Professor Feldman to discuss merger remedies in the context of increased consolidation.

Professor Robin Feldman:

Thank you very much. It's a pleasure to be here this morning. In the past 30 years, three waves of mergers have sharply increased concentration in the pharmaceutical industry. Just to give you a couple of small snapshots between 1995 and 2015, the 60 leading pharmaceutical companies merged only 10, but in 2017, just four companies produced more than half of all generic drugs. Now the first two concentration waves were clearly not good for innovation. After those waves, the industry generated fewer new molecular entities each year, compared to pre-merger levels. Merge companies spent proportionately less on research than their non merged competitors. The third consolidation wave, which began in 2010 and continues to this day, is different from the first two, and it reflects a change in the industry structure faced with stagnating innovation. Large pharma firms increasingly source new drugs from startups. The larger firms are then responsible for later stage clinical trials and regulatory approval.

Professor Robin Feldman:

Thus, the bulk of consolidation activity now consists of large firms acquiring smaller startups to bolster their innovation portfolio. Rather than big fish merging with other fish, we see fish swallowing big fish, swallowing little fish. Throughout all three of these merger waves, the tools that competition agencies use to evaluate mergers and mitigate harms fail to capture all of the dynamics of the pharmaceutical industry. So for example, as mentioned before, regulators sometimes require companies to divest certain drugs and particularly those that are in the pipeline. Now to test the effectiveness of this remedy, I have begun examining 56 pipeline drug product divestitures that regulators required as part of merger review. The [inaudible 01:46:01] through the results, although preliminary are not encouraging. Only 36% of the divested pipeline products have an active marketing license today, let alone a meaningful market share. In addition, as a general matter, the pharmaceutical industry poses challenges for market definition, large drug makers can leverage the complex rebate system by grouping together drugs in an attractive discounted bundle.

Professor Robin Feldman:

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 market at the pharma, at the drug level, the compound level much is the way that previous antitrust scrutiny of hospital mergers looked at the hospital market. Those in sense, it was looking at where the hospitals were vis-a-vis patients. The new approaches have simply taken into consideration the important role of intermediaries of insurance companies. I think that's essentially what we need to do here. We need to recognize that pharmaceuticals are not competing against, manufacturers are not competing against each other for consumers, they're competing against each other for space in the formula. In that sense, I would really like to see a development of a two part purchasing analysis for the pharmaceutical sector, much as the FTC pioneered one in evaluating hospital mergers.

Professor Barak Richman:

Now the other thing that I'll emphasize, as it relates to merger remedies, that approach might identify that two somewhat substitutable compounds might present more competitive harm if they were to merge under one roof than a traditional analysis would. Certainly, looking at a game theoretic interplay between what manufacturers do with PBMs, whether the manufacturer owns just one drug or an acquired drug. I think that with the right equations, with the right modeling, we would really be able to understand the competitive harm that's done with a lot more accuracy. Certainly, that might mean that one remedy would be to divest certain firms if we're talking about the world of remedies, so I think it was Anna said the best remedy is to block the merger all together. If we were to have a more realistic understanding of what the competitive harm is because of the institutional framework of how drugs are sold and purchased, we will probably also with greater accuracy, understand how the combination of specific compound under one roof will create competitive harm.

Professor Barak Richman:

The other thing I'll say is this, much like the antitrust approach of product hopping introduces a lot of institutional complexity in the healthcare sector. I think that the role of PBMs does here as well. The reason I brought up this slide is because it's just a very nice visual of how PBMs, and insurers, and manufacturers and suppliers all interact, and how the different bargaining takes place. It's not just about size. It's also about how the institutional structure of the different distribution system, but what different kinds of bargaining practices take place between different parties. And if we were to think of product hopping as a way that a current manufacturer, a current monopolist can basically substitute one generation product for another generation product, without any kind of adequate substitution, we could view that as simply a story about market power, but I think that's the wrong way to look at it.

Professor Barak Richman:

I think a better way to understand product topping is that it is a strategic play that utilizes an understanding of how insurers work, how generic substitution laws work, how pharmacists work and how frankly, doctors also simply make prescriptions. Once you understand all the rigidities of that institutional. That otherwise sounds quite innocuous, continuing one product and beginning another product actually can have a lot of competitive harm. So I'll just stop there. I'll say that much as what was said in the previous panel, we really have to understand the institutional framework of how pharmaceuticals are bought and sold in order both to understand the harms of mergers and also to

understand the possibilities of divestiture. And the second thing I'll say, oh, no. Oh, I'm still on. Oh, great. Okay. I thought I was off.

Professor Barak Richman:

I appreciate that. I don't know where I got cut off. I'll say the first thing I'll say is we have to understand the institutional arrangement when we're both evaluating the potential harm of mergers and also evaluating the potential benefits of certain remedies. The second thing is that all of these are different parts of the puzzle, and I do worry that if competitive harm is the product of a murder, but also a concentrated PBM market, I worry that the emerging manufacturers will blame the PBM market, and I worry that the PBM market attributes, its inefficiencies to the way manufacturers sell their drugs. There really needs to be a comprehensive approach. That also probably means there's comprehensive solutions, but it certainly doesn't mean that we have to allow much as we actually did in the hospital insurer market. One concentrated monopolist or one concentrated market blaming the concentration of another market for all the social ills that they're generating

Malinda Lee:

So much, Professor Richman. We'll now turn to Professor Rai to discuss remedies against the backdrop of competitive concerns of innovation in pharmaceutical mergers.

Professor Arti Rai:

Terrific. Thank you so much. I'm so pleased that the FTC is interested in innovation issues associated with competition in the context of pharmaceutical mergers, it's crucial that pharmaceutical mergers and acquisitions be assessed for anti-competitive innovation effects and that effective remedies be devised. So I think there are at least very two, excuse me, very important anti-innovation effects that can arise in the context of mergers and acquisitions. Professor Feldman pointed out very correctly that in the new wave of consolidation, we are seeing a fair number of acquisitions of the so-called small fish, and I think she's absolutely right about that. So the most obvious anti-innovation effect often arises in that context. It involves the case of the merger between a firm with an already marketed asset. So often a firm that is big and well established and a firm that has an overlapping pipeline asset. So the theory here is that the merge firm has reduced incentive to continue with the pipeline product development because it'll compete with the marketed product.

Professor Arti Rai:

And professor Feldman has done a little bit of work empiricizing that reality. So the standard remedy in that case is divestiture, but there are many problems with the standard divestiture remedy because it is often divestiture of the pipeline asset. The FTC itself has recognized that in the context of complex drugs, the divestiture of the pipeline asset may be impossible in terms of a really ineffective remedy for purposes of bringing that asset to market because of the complexity of manufacturing. And there is, I think in the context of complex drugs, a very specific way you can point to that complexity as being a barrier to entry for a less established firm or a divestiture buyer who is not skilled. I think that even outside the context of complex drugs, the transfer of knowhow to a divestiture buyer can be very difficult for a pipeline asset. By contrast, the merge firm, if it has to divest its asset, may be more likely to be able to continue developing the pipeline asset.

Professor Arti Rai:

So it's easier for the divestiture buyer to market and already develop drug than to successfully bring to market a pipeline drug. However, and this is an important however, if we do focus in some cases, at least on the divestiture of the marketed drug, it's still important to support the scientists associated with the pipeline drug, even if it stays with the more established firm and ensure that they're adequate resources. So post merger investigation to make sure adequate resources are associated with the pipeline drug and ex anti commitments as well to devote adequate resources to the pipeline drug, in particular, supporting the relevant scientists. That's really important because it's often the case that with mergers and acquisitions scientists get put to one side to some extent, and the business types come in and restructure without really investigating what is best for science, and I think that's a really important concern.

Professor Arti Rai:

That brings me to my second important anti-innovation effect that arises, and this can arise even when there is no particular potential for horizontal product overlap, even down the line, and that's the reduced incentive to do R&D, particularly risky early stage R&D in the first instance. There have been a number of econometric studies most recently coming out in 2022 by [inaudible 02:01:44] et al., and then also Kessie and [inaudible 02:01:47] that have shown that you get post merger reductions in R&D expenditure inputs, but also, and perhaps even more relevant, post merger patent output is reduced, which suggests there's less innovating going on. It's important to consider inputs, but I think it's even more important to consider outputs. It's also important to look and as these studies do at what inventors affected by the acquisition do, they're more likely to leave. And that's a problem as well, because these are the seed corn for future innovation.

Professor Arti Rai:

There's several examples I want to highlight here. One actually involves a recent merger between two big fish, AbbVie and Allergan, but nonetheless, as commissioner Slaughter's dissent, in that case, highlighted AbbVie publicly stated its intent to end early stage research at Allergan. That is a remarkable statement, and I think a really unfortunate one that wasn't addressed via the remedies. Another example that we can get numbers behind is another merger of big fish. So kind of the second wave of Pfizer and Wyeth, and basically the merge firm, halved its R&D commitment after the merger closed. So I think we should be very concerned about the claim that these R&D reductions are efficiencies. It seems to me that there's reason to have serious doubt about that because there's real value to these early stage R&D efforts and also claimed innovation efficiencies often involve cutting out parallel innovation, which is really, really important.

Professor Arti Rai:

So it seems to me that in terms of remedies, one new remedy might involve, and this relates to what professor Feldman said with respect to second look, but I think it's probably more ongoing. It's a monitoring of R&D levels and patent output post merger continuous monitoring. Perhaps even in an ex anti commitment to certain levels of patent output and R&D levels post merger. Now that's difficult, and obviously there can be reasons that firms may legitimately reduce their R&D input and patent output post merger, but I think it's really important to have continuous monitoring.

Professor Arti Rai:

Structurally that means in potentially at least supporting the scientists more again, so that if I have one theme from my talk it's support the scientists. So it might involve not just the conduct approach of

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 scientists, and I look forward to questions.

Malinda Lee:

Thank you so much, Professor Rai. Let's now turn to Mr. Beaudouin to share with us insights from the perspective of the European Commission.

Youenn Beaudouin:

Thank you very much. First of all, let me start with the standard disclaimers that the views I will express are my own and do not necessarily reflect the official position of the European Commission. That being said many thanks to everyone for the organization of this workshop and for allowing me to present something that the European Commission has expectancy of experience in assessing namely remedies in particular in the pharmaceutical sector, many among audience members may not be familiar with our practice. So the aim of my introduction will be to present a brief overview of the Commission's practice in terms of remedies in the pharmaceutical sector. By way of background, only a small share of cases reviewed by the European Commission ultimately gives rise to remedies. Since the introduction of merger control in the EU in the early nineties, less than 6% of all cases resulted in clearance decision decisions, conditional on compliance with remedies.

Youenn Beaudouin:

This figure remains relatively constant over time, and the situation is similar in the pharmaceutical sector. The Commission regularly reviews transaction in the industry, only a minority of these giving rise to remedies. A few words regarding our framework, not every remedy is acceptable to the European Commission. Under the framework of our merger regulation, we can only accept remedies that eliminate competition concerns entirely, are comprehensive and effective from all points of view and must be capable of being implemented effectively within a short period of time. The Commission stands on remedy is very clear. We have a strong preference for structural remedies and primarily divestments, which will generally meet the conditions I just mentioned when the divestment covers all the markets giving rise to competition concerns represents a viable and competitive business and where no implementation risks arise. Remedies are also market tested, including by reaching out to customers and competitors.

Youenn Beaudouin:

And this in turn ensures that any remedy is strongly grounded in market reality by factoring in accurately the competitive dynamics relevant to the specific market under investigation. Regarding the pharmaceutical sector, specifically, in the context of mergers, the Commission has the accepted, for instance, the divestment of fully integrated businesses, including manufacturing facilities, the divestment of portfolios of marketed products and such divestment typically covering the applicable marketing authorizations to contract the brands, as well as transitory manufacturing and supply arrangements. Another category of divestment is a divestment of pipeline products, which was mentioned by some other panelists. And when competition concerns arise as a result of an overlap between a pipeline product currently under development, usually at a late stage, meaning in phase two

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:



So the last time that the agency undertook a review of past remedies was in 2015, and in that study, which covered the period between 2006 and 2012, the FTC evaluated 89 settlements, including 24 orders affecting the pharmaceutical industry. Since that time from that study, there have been many changes in the economy and of course, changes across various industries. For example, since the 2015 study began, there have been at least two dozen or so mergers in the pharmaceutical industry that agency staff here at the FTC have evaluated and either conditionally approved or finally approved. And those remedies and consents include a variety of issues that involve settlements, such as consent orders, preserving future competition in two generic drug markets.

Speaker 1:

I'm thinking of the recent ANI Novitium matter. Then also a consent that involved divesting 79 different drug products, and that one I'm thinking back to the Teva Allergan merger back in 2016. So the number of settlements since our last remedy study back in 2015 and the variety of provisions in those settlements is reason in and of itself to consider updating the agency's thinking on remedies as a general matter and the effectiveness of those remedies more specifically.

Speaker 1:

The other thing I'll say is that the goal here is to think about whether remedies are effective in resolving competition problems. And if that goal is to consider different, new and underutilized remedies in the pharmaceutical mergers that we review in ways that could address issues, such as increased consolidation prior anti-competitive conduct as a consideration in our merger review or decreased innovation, then it seems to me that the next best step for the agencies is to consider past practice in our remedies. This is something that I think we can do more of, and I think it's definitely time since that 2015 merger remedy study was issued. It's time for us to review them again, and I'll stop there.

Malinda Lee:

Thank you so much, Ms. Mark. Now that the panelists have set the stage for our discussion, let's dive into some specific questions, which I'll direct to individual speakers, but invite all the other speakers to weigh in on as well. Let's start with professor Feldman. You touched on this in your brief presentation regarding the big fish swallowing, the little fish with respect to the current wave of pharmaceutical mergers. So if you could elaborate on how the current structure of the industry informs how enforcers should view merger remedies first, and then second, what are the ways that enforcers can improve the effectiveness of the traditional divestiture remedy, which in pharmaceutical mergers often involves the divestiture of a pipeline product?

Professor Robin Feldman:

So given that the new industry structure prompts mergers that are for the most part, large fish buying small fish, we need to have different innovation measures that more fully examine the harm that comes from that. So for example, regulators should be able to consider the multiplicity effects of smaller, large numbers of small mergers, as well as the way in which large and disparate portfolios can provide market power through volume rebate. And as professor

Professor Feldman:

Professor Richmond suggested power through the PBM market. But when you talk about traditional divestiture remedies, I'd like to suggest one that might be a little bit different, and that is a type of conduct remedy. There's a difference between new molecules and the creation of evergreen drugs, that

is taking existing products and making minor modification, getting new patents, and then shifting the market to the new drugs.

Professor Feldman:

The type of innovation we'd like to see is the new molecules, rather than the tinkering with existing molecules. What I just described is called evergreening and product hopping. So if evergreening and product hopping are a problem, then one could consider conduct remedies related to that. And I think this follows on Professor [Ry's 02:16:59] suggestion of perhaps asking for divestiture not of the pipeline product, but of the existing product. It's the same type of issue, that is to try to get companies to go back to the bench and invest in creation of new products.

Professor Feldman:

So if you are worried about evergreening and product hopping, perhaps conduct remedies could include not engaging in that behavior. I think that's something that folks haven't talked about much.

Professor Feldman:

The last thing, and again I alluded to this in my talk, is that most law's backward looking, asking whether a defendant breached a contract or committed a tort, but key portions of antitrust law are really forward looking. Regulators have to predict what would happen with and without the merger. And I believe it is important to begin focusing on what actually happens, analyzing what the concerns were, whether the remedies address those concerns and what unexpected consequences unfolded from the behaviors. I think that's critical for developing the new types of remedies that we will need to keep up with the development of the new market strategies.

Malinda Lee:

Thank you so much, Professor [Feldman 02:18:22]. And following on that, I'd like to hone in on the issue of consolidation and how enforcers should approach remedies to address the effects of increased consolidation, such as higher prices and decreased choice. You could speak to that. [inaudible 02:18:39]

Professor Feldman:

Sure. So one cannot address competitive harm without first identifying that harm. And the current merger tools fall woefully short. They're really too atomistic, focusing too much on an individual transaction, an individual market, without considering interactive effects. And in the same vein, again as Professor Richmond raised, you have to think about the consolidated layer of large pharmaceutical companies in the consolidated layer of PBMs. Three PBMs hold at least 80% of the market. If to think about how these two consolidated layers work together to harm competition in the industry. Again, if you're looking at too narrow a slice, one won't see the types of harms that are there.

Malinda Lee:

Thank you so much, Professor Feldman. That's a great jumping off point for my next question, which is directed to Professor Richmond. I think you just heard Professor Feldman reference some of the things that you talked about with respect to PBMs, and also alluded to the possibility of not ... of considering prohibition against engaging in product hopping. So just jumping off from there, what kinds of anti-competitive conduct are exacerbated from mergers and are there conduct remedies to improve merger that could mitigate that competitive harm?

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:

I would be skeptical of that. Monitors tend to be very process oriented, very legalistic. They're under certain instructions to detect certain kinds of behavior, and they do a very good job of that, but they are rarely charged with responsibility to say, make sure that there aren't any inefficiencies injected into the market, or make sure that there isn't anything anti-competitive.

Professor Richmond:

They're not charged with enforcing the rule of reason, and for that reason, precisely because of the complexity, a monitor might be very good to make sure that certain kinds of conduct that are deemed to be anti-competitive is avoided, but they would be ... it'd be much harder for them to determine whether one form of any competitive conduct is being replaced with another, or at least they wouldn't really ... that wouldn't be part of their charge.

Professor Richmond:

So I would be skeptical of that approach, or at least again, pursuing strategies that rely on monitors, I think would also be appropriate to have an appropriate amount of humility.

Malinda Lee:

That's very much appreciated, Professor Richmond. I'm now going to move-

Synda Mark:

Sorry. Could I just interject really quickly with a question to Professor Richmond on this idea that conduct remedies, I'm sorry, conduct in some way should inform our approval process, merger review process in the pharma industry. How do you think the agencies might be able to identify which firms might be more incentivized to engage in any competitive conduct, post merger? If that firm, for example, has not appeared before the agency, or is not one that we might be familiar with in terms of conduct that they have engaged in in the past?

Professor Richmond:

Yeah, I think it'd be very important to develop the appropriate economic models that could really predict that. It took a long time and the courts were very unsupportive and unsympathetic, but eventually the FTC did that in a really wonderful way, in assessing hospital mergers. Hospital mergers are challenged with a set of equations and structural models that are wildly different from how they were used 15 years ago.

Professor Richmond:

That's the FTC and economists really coming up with ... in a collaborative way, actually doing their own research and their own innovation. I think that's what we need in the pharma space also. And I think that it would actually probably be a little bit easier in the pharma space than the hospital space, because we might be able ... we can find out what formularies are, we can have a good sense of what prices are as they relate to consumers, we can follow exact ... we have a better idea of what market definition looks like instead of having a continuous dimension of geography. We have therapeutic areas, which are a little bit easier to measure.

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 protect the scientists. And I'm wondering if you could flush that out a bit, because when firms merge, they often shrink their research and development teams and eliminate pipeline assets. How could merger remedies address that issue?

Professor Ry:

So, as I mentioned, I think that notwithstanding Professor Richmond's skepticism of conduct remedies and independent monitors and the like, I do think that there are ways to get beyond just the process orientation of independent monitors and have those independent monitors actually look to ensure that particular pipeline assets continue to be developed or researched in that area, particularly phase 2a where a lot of the stuff gets killed, because it's expensive, but nonetheless ... well, expensive and risky.

Professor Ry:

Phase 2a is a little more of a bright line kind of designation that can perhaps help the independent monitor get beyond process and where process actually has some implications and some relevance for substance because phase 2a is substantive as well as procedural. So that's one aspect of the issue.

Professor Ry:

I also wanted to note that Professor Feldman raised a really good point about patent output, perhaps including evergreening output, and I certainly would not want that to be the case. So it seems to me that the patent output and/or the new chemical entity output might be ... patents associated with new chemical entities might be the relevant metric there. And again, these are much, I think, more bright lined than some of the other complexities that a monitor might have to deal with in the case of, for example, PBMs and so forth.

Professor Ry:

I think here you can see how much money is being put in, what's coming out. The risk or the challenge here is that science is risky. And so even if you put a lot of money in and genuinely do your best, you may not get the output that you want. And that's the caveat to all of this, that this is not a mechanical process, and the science is risky oftentimes for the most important areas of disease inquiry, for example, neurodegenerative diseases, where we have a huge disease burden already and we'll have more as we go forward. And we haven't really seen any great therapies. In fact, the therapies we've seen have been the subject of much controversy for their lack of efficacy.

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.

Youenn Beaudouin:

I also invite you to attend the innovation panel that will take place tomorrow for more insight into the assessment of innovation in your European merger control.

Youenn Beaudouin:

Now regarding conduct. Now, to date, issues relating to past anti-competitive conduct have not been a decisive part of our assessment of pharmaceutical mergers. We would look at these issues if we investigate markets where we have had, or are having antitrust investigations, such as for pay for delay practices, for instance, or where internal documents of the parties or market participants raise these kind of concerns. But again, these have not been decisive in cases assessed so far.

Youenn Beaudouin:

And in addition to these issues brought up by panelists, which are largely horizontal in nature, the commission also has a track record of assessing non-horizontal effects of merger. And, for example, the assessment of conglomerate effects in complementary or neighboring markets has been relevant in a number of medical device cases. And in cases where concerns related to the interoperability of the products of the parties and products of their competitors, we have accepted interoperability remedies. So as mentioned, these were primarily in a number of medical device cases, and which I will not go into details in light of the time constraints.

Malinda Lee:

Thank you. I'm curious, how have court decisions influenced the European Commission's approach to remedies in pharmaceutical mergers?

Youenn Beaudouin:

Yeah. So as you may know, the role of course in the European system of merger control is primarily to review the legality of the decisions adopted by the European Commission. So it differs from the North American system, or at least my understanding of it, that requires for instance to initiate legal proceedings in front, of course, to challenge a transaction.

Youenn Beaudouin:

So far, there has been no specific judgment by European courts that would specifically discuss remedies adopted in pharmaceutical mergers. However, the Commission's practice, including in terms of remedies, design and implementation, is influenced by court judgments relating to cases and remedies in other industries.

Youenn Beaudouin:

The Commission's remedy notice, which is the published guidance document on remedies acceptable to the European Commission, that aims at providing guidance to merging companies, refers to a number of such precedents from the courts. And there are regularly judgments that are relevant for our purposes. And just a few weeks ago, a judgment in the [Vilan Arubi's 02:36:27] case provided a number of pointers in terms of remedy assessment that can impact the assessment of remedies by the Commission.

Youenn Beaudouin:

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.



Synda Mark:

So again, in terms of what next steps the agency might be thinking about, I think the guidance that we are seeking on our overall merger guidelines is a place to consider. And again, because that points to remedies, and then also thinking about the focus on considering labor markets more systematically in all of our reviews, including review of mergers in the pharmaceutical industry.

Synda Mark:

And I'll turn it back to you, Melinda.

Malinda Lee:

Thank you so much Ms. Mark. It sounds like there are significant developments to come and we look forward to hearing more about as this process unfolds.

Malinda Lee:

The insights from you and the rest of the panelists are greatly appreciated. I'd like to conclude this panel by thanking all the speakers for sharing your views on such important topics for antitrust enforcers, the pharmaceutical industry, and the general public. I also would like to extend a big thank you to the Federal Trade Commission and Department of Justice for hosting this workshop and making this discussion possible.

Malinda Lee:

With that, I'd like to now turn to introducing Anu Sawkar to give the closing remarks for day one of our two-day workshop. Dr. Sawkar is special counsel for intellectual property in the U.S. Federal Trade Commission's Office of Policy and Policy Planning, where she focuses on antitrust and intellectual property policy and enforcement.

Malinda Lee:

She previously served as an attorney advisor in the Legal Policy section and as an honors program trial attorney in the Civil Enforcement section in the U.S. Department of Justice's Antitrust Division. Prior to joining the Antitrust Division, Dr. Sawkar served as a law clerk to the Honorable Sharon Prost at the U.S. Court of Appeals for the federal circuit and to the Honorable Paul Kelly Jr. at the U.S. Court of Appeals for the 10th circuit. She has also worked as a patent agent in private practice. She received her JD from Fordham University School of Law, her PhD from the Scripps Research Institute, and her EA from Northwestern University. Dr. Sawkar, I'll turn the floor over to you.

Dr. Sawkar:

Thank you so much, Melinda.

Dr. Sawkar:

We've come to the end of our first day of The Future of Pharmaceuticals workshop. Thank you all for joining us and a special thanks to our speakers for their insightful presentations and thoughtful recommendations.

Dr. Sawkar:

FTC chair Lina Khan, assistant attorney general, Jonathan Kanter, and FTC Commissioner, Rebecca Slaughter set the stage today by explaining why pharmaceutical mergers matter so much. Given the importance of this topic across the globe, Commissioner Slaughter convened a multilateral task force of enforcers to share thinking and refresh enforcement approaches. This workshop is the culmination of the work of the taskforce partners, but it is certainly not the end of our work to promote competition and innovation in pharmaceutical markets.

Dr. Sawkar:

In today's first panel, we heard from industry experts about concentration trends in pharmaceutical markets. Professor Patricia Danzon suggested that U.S. enforcement agencies should be considering firm size and drug portfolios as a whole, rather than specific drugs in isolation.

Dr. Sawkar:

Diana Moss presented some of AAI's research and analysis on the impact of settling pharmaceutical mergers through divestitures, and the effect over the long-term this has had on market concentration. And Professor Rina Conte focused on the impacts of increased concentration in the generic industry, as well as on increased concentration in the input side, including producers of API and other drug [inaudible 02:43:52].

Dr. Sawkar:

Our second panel built on threads from the first. In our second panel, we heard about the role and effectiveness of diverse divestiture remedies in the pharmaceutical context. Panelists also explored the use of non-divestiture remedies to better address specific concerns. Professor Robin Feldman suggested potential ways to strengthen merger review and improve the effectiveness of remedies, including by using conduct remedies, targeting evergreening and product hopping. Professor [Ardy 02:44:26] Ry explored remedy approaches for preserving competition in innovation and for supporting the scientists. Professor Barack Richmond discussed the difficulty of using behavioral remedies in this complex context and whether independent monitors can reduce anti-competitive conduct.

Dr. Sawkar:

My FTC colleague, Synda Mark, provided an FTC perspective and DG COMP enforcer, [Youann 02:44:51] Beaudoir, provided a European perspective on remedies in the pharmaceutical sector.

Dr. Sawkar:

We'll reconvene tomorrow for two panels, focusing on potential considerations in pharmaceutical merger reviews. The first panel takes a closer look at the impact of pharmaceutical mergers on innovation. And the second focuses on prior anti-competitive misconduct by merging parties. Tomorrow's panels will feature law professors, economics professors, public servants from the United States, the UK and the European Commission and a senior researcher from a think tank.

Dr. Sawkar:

Thanks again to everybody. And we look forward to seeing you tomorrow.