



The Future of Pharmaceuticals - Wednesday, June 15

Viola Chen:

Hi, welcome back to the second day of the workshop. Future of pharmaceuticals, examining the analysis of pharmaceutical mergers. I am Viola Chen economic advisor to commissioner Slaughter and a staff economist at the federal trade commission. Let me begin with a reminder that 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. Second, as with any virtual event, we may experience technical issues. If these occur, we ask for your patience as we work to address them as quickly as possible. We will also try to keep you informed of any significant delays. Finally, please continue the conversation with us on Twitter. Our Twitter handle is at FTC and we are using the hashtag future of pharma. Yesterday we heard from FTC chair, con AAG Canter, a keynote by commissioner Slaughter and two lively sets of panel discussions.

Viola Chen:

The first panel focused on concentration while the second focused on remedies. Participants from both panels urged the FTC to reconsider its historical policy of evaluating pharmaceutical mergers on a product by product basis and of accepting consent decrees based primarily on structural remedies. All of the panelists, which let me note represented a diverse set of backgrounds, offered a long list of additional considerations from firm size to cross market effects and the role of pharmacy benefit managers. These are just a few highlights as I could not possibly do the full scope justice. A great big thank you to all of our panel participants. I am excited for the continuation of the workshop today. Our second and final day. We will first hear from a panel on innovation, followed by a separate panel on prior bad acts. And now I am happy to turn it over to Riccardo Ferrari the moderator for the first panel today. Assessment of innovation aspects and pharmaceutical mergers. Riccardo Ferrari is the assistant director of economics at the UK competition and markets authority. And with that, I will turn it over to you Riccardo.

Riccardo Ferrari:

Good morning. Good afternoon. And good evening, everyone. As Viola said, I'm Riccardo Ferrari and I'm assistant director of economics at the UK competition and market authority. And I'm delighted to be the moderator of this very interesting panel. And I cannot wait to hear what our speakers have to say on one of the most highly debated topics in pharma mergers, which is the assessment of innovation

concerns in merger investigations. To discuss this I'm joined today by fantastic set of speakers. Carmine Ornaghi is professor of economics at the University of Southampton and his research is focused on productivity and innovation with applications in the pharmaceutical industry. Paul Csiszár is director of basic industries, manufacturing and agriculture at their European commissions directorate general for competition. Also from Digicom is Camille Verdon senior case handler. Ellie Yao is director of murderers at the UK competition and markets authority. And last panelist Caroline Holland is attorney advisor to US federal trade commissioner, Becca Kelly Slaughter.

Riccardo Ferrari:

Now one disclaimer that applies to all speakers is that the views expressed in this workshop do not necessarily reflect those of the institutions or agencies they work for. Now, we have that out of the way, we have only one hour to cover a lot of ground. So let's waste no time. We will start with a presentation by professor Ornaghi who will provide some background on innovation in the pharma industry. We will then start a discussion among the panelists on the agency's approach to innovation in pharma mergers. So without further ado, professor Ornaghi, the floor is yours.

Carmine Ornaghi:

Thank you very much Riccardo. I prepared the short presentation show talking about mergers and innovation in the pharmaceutical industry. In the first part of this presentation, I will present some statistics about innovation, then some statistics about mergers and then a brief summary of academics paper that have studied the impact of mergers on innovation. Next slide please. So in this first slide on the left, we see that the pharmaceutical industry, the R&D intensity of the pharmaceutical industry is among the highest comparable to the one of semiconductor and the software. The picture on the right, we see the number of new drugs approved at the beginning of the century. There was a concern about the reduction in the number of new drugs approved. But as we can see on the right of the graph, the number of new drugs approval has increased since 2010. And there has been an important contribution of biological to these increase. Next slide, please. So if we zoom in the last 10 years and we look at the originators of those new drugs, we see that there has been an dramatic change.

Carmine Ornaghi:

In particular, if you look at the left, we see that big pharma in red and small biopharma in blue each contributed with eight new drugs in 2009. Now, when we move to two 18, we see a very different picture because big pharma are the originator of nine drugs. So similar number, but we have a staggering 36 new drugs was originator from biopharma companies. Next slide please. So when we talk about research and development in the pharmaceutical industry, we need to remember that for pharma and like any other industry these are very two very different things. So the R stage is about the creation of chemical and biological compounds that can be then tested in vitro, typically on lab mice in order to investigate pharmacokinetics in order to understand pharmacodynamics in order to investigate toxicity. And then there is the D stage, the development stage that is more about testing the safety first and the efficacy of these new compounds on humans through the clinical trials. So we all know about phase one, phase two, phase three clinical trials.

Carmine Ornaghi:

Now, when we talk about R&D expenditure, most of the R&D expenditure goes to the D stage. In fact, around only 20% of the R&D is spent on the R stage. And when we talk about patenting in the pharmaceutical industry, we mainly talk about the output of the research stage. Next slide, please.

Having discussed some statistics about innovation in the pharmaceutical industry. Now I would like to present some hopefully interesting facts about merges and deposition and other deals. So in this graph, what we see are on the bars, the numbers of merges and deposition while the line show is showing the value of those deals. So if you look at the line, we see three spikes, we have a spike in 2000, then another one in 2015 and the more recent one in 2019. These are driven mainly by some large deals, for instance, in 2000 of JSK. Now, if you look instead at the number of deals, so the bars, we see that the bars are dividing in three groups, the red group refers to large deals, those with a value about 15 million, or relatively large deals.

Carmine Ornaghi:

In Navy, we see the small deals, so those with value below 15 million, and then in light, we see deals for which no value is reported. And these by and large are typically very small deal. So what do we learn from this graph is that the typical deals, merges and acquisition deals that are notified to the relevant competition authority are just a fraction of the total number of deals. Next slide please. So this picture is considering what are the type of deals are consumed in the pharmaceutical industry. In particular this a snapshot of deals done by major pharmaceutical companies in 2015. And we are saying in the previous slide that large merges in the position are just a fraction. Those that are typically notified are a small fraction compared to the total number of merges in acquisition. What this graph is showing is that the merges in acquisition are a fraction of other deals that are consumed in the pharmaceutical industry.

Carmine Ornaghi:

In particular, if you look at all deals, different big companies from Johnson and Johnson on the left, and then we have JSK, Pfizer and all the other big companies, we see that the large majority of the deals refer either to licensing in purple or research only deals in green. Next slide please. Next slide please. So what do we know about the impact of those deals emergence and acquisition in particular on innovation? So research I did many years ago in 2009, found that there was a drastic reduction in patent output and in R&D expenditure. This researcher, the findings of my research have been confirmed in a recent study by [inaudible 00:11:28], and because who find an even in larger decrease in patent output and in R&D expenditure. Now, there is also some studies about the impact of mergers and acquisition on scientists to some of these studies are applied to high tech industries, but then are not specific to the pharmaceutical industry. There is a recent study by Luca, Virginia and [inaudible 00:11:59], which is looking specifically to the biotech industry.

Carmine Ornaghi:

And there is also a recent study that I'm undertaking with my coworker [inaudible 00:12:10], which is also looking at the impact of mergers and acquisition on the scientists turnover. And so the main finding of these studies is that if we have seen a decrease in R&D expenditure and the decrease in patenting, essentially, what's going on, if you zoom in the lab of these pharmaceutical companies, is that you will see also a decrease in the human capital. That is, there is a large turnover, a large number of scientists that move either to other jobs or move to other companies. Next slide. Thank you. So obviously when we talk about the impact of merchants and acquisition on innovation, we need to discuss the recent and very important finding by counting them and quotas about killers acquisition. So the main finding there, as we all know, is that when an acquirer buys a target company and there is overlapping between the projects of the acquirer and the target is more likely that this project is either terminated or delayed and the term killer acquisition and these killer acquisition are more likely when the acquirer has market power.

Carmine Ornaghi:

So there are no other competitors essentially in the market or when this market power is likely to last longer because of patent protection. What the authors find is that around the 5% to 7% of the acquisition can be considered killer acquisitions. And as we've seen before, there is a large number of these deals that essentially are not notified and therefore are under the competition next. So next slide please. So what we find in results of the academic paper is essentially that there is a substantial decrease in R&D expenditure. There is a decrease in the patent output. This is coupled with mirror, by a number of scientists that are leaving the pharmaceutical companies. And there is the problem of Molecules Development that are either terminated or delayed. Now, what about the synergies?

Carmine Ornaghi:

Clearly, it's very difficult to find and to talk about synergies when we are talking about production, even more complex is about talking or finding evidence about synergies in innovation. And so there is no much evidence about the impact of mergers and acquisition on synergies on cross fertilization of ideas. There is no much evidence that, thanks to the merchants and acquisition is more likely that a product will probably reach the market. And so on. Let me stress that essentially these are very difficult issues to investigate. And so the fact that there is no evidence doesn't mean that these are not there. So the lack of evidence is not evidence of lack. And the other things we need to remember when we talk about synergies is that these synergies should be merger specific. And so let's say even more complicated to show that these synergies, this cross fertilization of idea cannot be reached in other ways that is not for in acquisitions. With this I think I've completed my presentation so I'm happy to pass again, the button to Riccardo. Thank you.

Riccardo Ferrari:

Thank you professor Ornaghi. Very interesting presentation and a lot of food for thought, but let's open this up now. So I want to start by asking our speakers from international competition agencies, a quite broad question. How should enforcement agencies assess innovation competition? Are there any specific analytical frameworks that should be used for pharmaceutical mergers? Paul, why don't we start with you?

Paul Csiszár:

Great. Thank you, Riccardo. It's a great pleasure and privilege to be here today with you all. Thank you for giving us the opportunity to speak about the European commission's experience in this field. Before replying to your question, though, on behalf of DG comp, I would like to express my sincere gratitude and appreciation to all my colleagues in this working group, as well as all the third party experts for their outstanding contributions in the past year. And of course today and yesterday as well. As just shown in Carmine's slides, the pharmaceutical sector is one of the most, if not the most R&D intensive sector in our economies, small pharma and big pharma like can point to great achievements in fighting humanities diseases, ease in pain and suffering and extends in human lives. Therefore maintaining and fostering innovation in this sector is of crucial importance.

Paul Csiszár:

And probably it is our collective responsibility while the majority of those hundreds of pharma M&A transactions every year just mentioned a few minutes ago, bring synergies, secure additional funding and have no or low anti competitive effects. Some deals be the traditional merger or the acquisition of a nascent company with promising pipelines may well present some competition problems and thus

warrant close scrutiny by the agencies in Europe. Our clear mandate from our, my commissioner and executive vice president [inaudible 00:18:45] is to help bringing innovative and affordable medicines to European citizens. Therefore, besides preserving price competition that contributes to affordability we also need to focus on dynamic competition in the sector, how to preserve and foster innovation competition, potential competition and future competition. By the way, the importance of dynamic competition, which includes, of course, the preservation of innovation competition has been one of the key objectives of regime for decades as laid down in our merger regulation and related guidelines.

Paul Csiszár:

Therefore putting focus and emphasis on innovation competition in this sector is not at all. So revolutionary as some critics in the sector recently trained in the EU. We intervened the first time in relation to earlier early pipelines. When we reviewed the acquisition of GS case oncology business by Novartis back in 2015. We were concerned that the merger and the result in horizontal overlaps, including pipelines would negatively impact Novartis incentives to continue as before its R&D efforts in an existing joint venture with a third party biotech company. I should add that the JV biotech partner was also very much concerned about such change incentives resulting from the merger. We have cleared the transaction subject to the divestment of its position in the JV to the JV partner and the suitable third party buyer. Those who would look up the history of the case will see that the threatened pipelines placed in the remedy package got developed into a very successful set of drugs.

Paul Csiszár:

By now, in subsequent years, we have developed a four layer analytical framework to assess competition concerns. That includes potential innovation concerns. This analytical framework was set out first in our published decision of the Dow agrochemical case in 2017. Since then we rely on this analytical framework versus innovation competition for all sectors, including pharmaceutical mergers. So what are those four layers very quickly? First, we look at existing products and the effects on actual product and price competition. We assess overlaps between marketed products. The theory of harm here is the elimination of competition between existing products with non coordinated effects on price and product competition. Not very new. Secondly, we also look at potential product and price competition. We assess overlaps involving advanced stage pipelines, typically phase three pipelines that can overlap either with a marketed drug or another advanced stage pipeline drug. Here the theory of harm is loss of potential competition with existing products or between forthcoming products.

Paul Csiszár:

So up to this point, we conduct a rather traditional analysis, but then we also look at innovation competition specific. Our third layer we look at the innovation competition regarding the party's ongoing pipeline. So we assess overlaps between pipeline products, including early stage pipelines. At this level of the analysis, we ask ourselves whether the merger could change the incentives of the combined entity to continue to invest in parallel several R&D programs here. The theory of harm is the risk of discontinuation delay or redirection of overlapping pipeline. I should note that the boundaries between layer two and layer three are not always very clear to some extent, and to some extent overlap cause the delay reorientation or discontinuation of an advanced stage pipeline or an existing drug and keeping the pipeline could also affect innovation competition. Lastly, we also look at innovation competition at a broader level.

Paul Csiszár:

We look at the capability of the companies to innovate in certain therapeutic spaces. We ask ourselves whether this transaction could lead to the elimination of an important innovator or whether there is a risk of a significant loss of innovation competition that may result from a structural reduction of the overall level of innovation in certain therapeutic spaces. Again, I should note here that so far, the European commission has not raised any concerns under this fourth layer of analysis in the pharmaceutical sector here in pharma are the efforts are relatively dispersed among a multitude of players compared to, for example, the agrichemical sector where R&D is in the hands of very few players. Finally, I would quickly mention that in recent years, the commission has intervened to protect innovation competition in a number of merger cases and its recent published decisions of these cases provide useful guidance on how to assess overlaps involving pipeline product at all stages of clinical development. Thank you back to you, Riccardo.

Riccardo Ferrari:

Thank you very much Paul. Ellie, do you have anything to add from the CMA?

Ele Yoo:

Sure. Thank you, Riccardo. And thank you also for the opportunity to speak. I would echo Paul's comments and thanks to all our colleagues on the task force for a very useful project. So I think the importance of innovation as a parameter of competition is similarly to the EC already well established in the CMAs decisional practice, particularly in relation to life science and digital markets. We've also recently reflected more explicitly on the importance of innovation competition in our updated merger assessment guidelines, which were published last year. I think often in a pharma and life science deals more generally, we hear acquirers say that the company they're planning on buying is an innovator, but isn't active in the relevant product market yet and may well not have successfully entered in the future, absent the transaction. I think in the face of that uncertainty, when looking at mergers involving a potential entrant, we tend to look at the loss of competition in two ways.

Ele Yoo:

So one is to look at the loss of future competition, which involves assessing the likelihood and impact of that future competitive entry. And the second is focusing on whether there could be a more immediate loss of competition because existing firms and potential competitors can interact in an ongoing dynamic competitive process. Even before entry actually occurs, driven by efforts to enter or expand in a given market. So I think loss of dynamic competition is more relevant when the investments involved in entering or expanding represent an important part of the competitive process in industries where the process of entry takes place over a long period of time involve significant costs or risks, or our key aspects of the competitive offering are set during the investment phase rather than flexed on an ongoing basis. And farm emerging markets are clearly a key area where investments in new products might involve years of investment in products that may never come to fruition. So we therefore see the process of dynamic competition as particularly important in innovation markets including pharma markets.

Riccardo Ferrari:

Great. Thank you very much. Caroline do you want to add your perspective from the US?

Caroline Holland:

Sure. And I also echo and on thanks for inviting me to join this panel and really my deep appreciation to all of our colleagues on the task force for the wonderful work that we have done together. And finally, I'm also going to reiterate what Riccardo noted at the top I'm here being only on behalf of myself and not any commissioner or the commission. So Paul and Ellie did a great job of prescribing their analytical frameworks. And I think we're well aligned with them in the US. So while I may be a bit repetitive in my answer, to the extent that I am, this demonstrates this alignment on the innovation competition issues.

Caroline Holland:

So your US merger law is well recognized as having the goal of arresting monopolies in their incipientancy and preventing a tendency to create a monopoly. Although the FTC today are in the process of revising the guidelines the agencies have been using the 2010 guidelines and those clearly recognize the harmed innovation competition that a merger may pose. Similar to our counterparts in the CMA and the EC product to pipeline and pipeline to pipeline overlaps and product to product overlaps of course must be analyzed, but in order to thoroughly reach all the potential harm from a merger, we need to consider competition at all stages of innovation and separate and apart from any eventual competition.

Caroline Holland:

Thus, we're looking at competition R&D protecting innovation also requires us... Well it requires us to look at both the incentives of the merging firms, as well as the non merging firms. For example, the incentives of non emerging firms may be relevant. If a merger reduces the number of large firms that are the target sales audience for new innovation being developed by a pharmaceutical startup, this may affect the availability capital to those startups or the merge [inaudible 00:28:55] could gain an incentive and ability to forgo other innovatives thus investment in this space. So I think those are just some ways in which it is important to look at mergers from those standpoints of innovative development process.

Riccardo Ferrari:

Thank you very much. And thanks also that was very clear and interesting, but I think we can all agree that there is a challenge here. So we can apply this framework only to those cases that are under our jurisdiction. So based on the relevant jurisdictional thresholds or on the analytical framework applicable in your respective jurisdiction, how are you confident that you get to review all potentially harmful pharmaceutical merger? Paul, let's start with you again.

Paul Csiszár:

Thank you, Riccardo. Frankly, I'm not very confident or certain to answer your questions directly, but I'm very hopeful that we will be able to do so in the not so distant future. There has been a lot of

Paul Csiszár:

Of discussions in recent years about high value transactions, where the target has no or minimal turnover on the one hand, but has a strong competitive potential on the other hand. And for example, when it has promising pipeline drugs in development, I think everybody recognizes that some of these transactions may, in some cases, result in significant impediments and competition, which is our test. And so we should really not miss their review in Europe. In a nutshell, these deals often fall outside of the EU jurisdictional thresholds. Our thresholds require a meaningful turnover of at least two of the merging parties in Europe, that is, a meaningful turnover from the target as well. At the same time, these transactions, due to the different existing national jurisdictional thresholds, may or may not fall

within the notification thresholds of a specific EU member state who also have general jurisdiction and the right to review these mergers.

Paul Csiszár:

So as you probably know, within the EU at national level, different solutions exist to address this issue of lack of turnover of the target, such as the introduction of deal value based threshold in Austria and Germany or the power to order a notification such as in Sweden at E level. The commission has recently opted for an increased use of the referral mechanism. This mechanism is not new. It's been in our books for a long time. It allows member states to refer potentially anti-competitive transactions to the commissions that do not meet the EU turnover thresholds. These are the so-called article 22 referrals. For many years, the commission has accepted referral from member states only when the member states did have jurisdiction based on its own national merger control rules. A recent example of such referral was the acquisition of [inaudible 00:32:10] by Johnson and Johnson. The transaction had no EU dimension and was referred to the commission at the request of Germany, where the transaction did meet the national merger control thresholds.

Paul Csiszár:

The case was a sort of a reverse killer acquisition. The acquisition of the dominant player, [inaudible 00:32:30], in a given product market by the best placed potential entrant, Johnson and Johnson, hence the reverse killer acquisition theory of harm. Without the article 22 mechanism, we would have missed this case. And after examining the facts, we raise serious doubts in our phase one investigation and the acquisition was abandoned after opening our phase to in depth investigation. In September 2020, in a public speech, my commissioner [inaudible 00:33:08] has clarified that the commission will no longer discourage member states to accept referrals from them, even in those cases where the referring member state does not have jurisdiction over the transaction. In March 2021, along these lines, we adopted a guidance paper, which help companies and practitioners to identify cases that the commission may consider suitable for referral under article 22. Overall, I would say that this new article 22 approach is a necessary and somewhat overdue fine tuning of the interpretation of the commission's existing jurisdictional rules. This is so given that our mandate is the preservation and fostering an even innovation competition in a very wide dynamic sector, where, as it's been discussed, important target companies have little or no turnover.

Paul Csiszár:

The use of this article 22 referral mechanism has obvious advantages compared to drawing fixed deal value threshold line for jurisdiction. This solution brings some flexibility and doesn't require the automatic notification of unproblematic cases over certain deal value. The factors set out in our guidance paper and the filters used by member states, considering referrals, do allow us to focus on the most development cases. As our audience may know, the Illumina [inaudible 00:34:43] merger is the first new article 22 referral that the commission accepted last year, following a referral request made by France. Of course, I cannot comment on the substantive elements of the case, as our phase investigation is still ongoing. The Illumina [inaudible 00:35:03] jurisdiction or referral has been challenged in court. And the judgment from the general court, expected to be issued next month, will rule on whether or not member states could indeed refer transactions to the commissions when they do not need their own national merger control threshold, which was the case in France. One more thing very quickly. I would note that our guidelines make it possible for the merging parties to seek comfort and to consult the commission informally early on to see whether or not the commission would consider the transaction suitable for article 22 referral. We have already been approached on several occasions and have

constructive exchanges around these lines with the merging parties at their advisors. I stop there. Thank you very much.

Riccardo Ferrari:

Thank you, Paul. Just quickly. I'm going to Caroline. Anything to add from the U.S.?

Caroline Holland:

I'll be very brief. I think we're all worried about killer acquisitions and although our staff monitor the industry closely, there are obviously deals that are not public and fall outside of our radar. I do want to note this very briefly that last year, the commission withdrew guidance from the 1990s about the use of prior approval and prior notice in consent decrees, and indicated that remedies would be pursued again. And indeed, the FTC has begun to include in consent decrees provisions that require parties that are settling with us to seek prior approval for prior notice for certain future unreportable transactions. So that can be a small way to maybe identify some of those to the FTC that we otherwise would not have had. But I do think this is an issue that we're going to continue to be concerned about.

Riccardo Ferrari:

And now turning to some applications. So in practice, how do you assess pipeline to pipeline or product to pipeline overlaps? For example, what evidence do you rely on? How do you apply the framework you just described and how early do you start looking at pipeline drugs when assessing innovation competition? So let me start from Ele this time.

Ele Yoo:

Thanks Ricardo. So as mentioned before, I think when assessing pipeline to pipeline overlaps and indeed overlaps between pipeline and existing marketed products, the one applicable analytical framework is through assessing dynamic competition. And when you are thinking about these issues and in particular, the uncertainty of whether a given pipeline product will come to market, we do consider that the uncertainty of the outcome can be the driving force of dynamic competition because it increases the likelihood of new products or innovations. And that in a sense is what we're looking to preserve. So many markets in the pharma sector can be characterized by high switching costs. If for example, patients are reluctant to switch treatments and in practice, that means that incumbent firms have the incentive to compete not only against the products that are already on the market, but also against pipeline products in order to win, for example, as many patients as possible before the pipeline product just commercialized.

Ele Yoo:

So as to reduce the eventual impact of the new product on the incumbent sales. So this type of innovation competition can result in improved competitive offerings from potential entrance and other market participants. For example, as incumbents may be incentivized to respond to these efforts to prevent the future loss profits. That ties in somewhat to what Caroline was mentioning earlier. So I think that's all a way of saying that in our assessments, when we apply it, uncertainty on how the future may pan out, including in relation to pipeline overlaps should not necessarily mean that anti-competitive mergers should be cleared. However, any assessment does of course need to be grounded in evidence. And to that extent, there is a range of evidence we can consider, including the emerging party business plans, internal documents, evidence of steps taken towards entry and expansion. I think taking a few recent examples of CMA assessments in the pharma sector.

Ele Yoo:

So for example, in AstraZeneca Alexian, there was an overlap in a phase one and phase two pipeline to pipeline overlaps for a particular type of cancer. We focused in our closeness of competition assessment on reviewing recent internal documents of the parties and clinician feedback. And this merger was eventually cleared on the basis that we felt the evidence showed there was a strong level of pipeline activity for this particular type of cancer more generally. That would therefore be sufficient competitive constraints on innovation post merger. I think we'll also look at factors like the ability and incentive, as mentioned, of other potential competitors to enter or expand. Thinking [inaudible 00:40:12], which concerned an overlap between a pipeline and a marketed product. We found that there were other suppliers developing a gene therapy treatment and concluded that spark did not offer particulars with advantages of the others and in doing so, placed more weight on forward looking evidence than evidence on past historic performance.

Ele Yoo:

I think just as a final point, [inaudible 00:40:38] also offered some observations on your question, Riccardo, of how far back you should go when looking at pipeline drugs. And one thing we noted in that decision is that pharma markets are obviously characterized by a degree of transparency as to the relevant rivals active in the sector stage of development of arrival firms, pipeline products. And in that context, market players clearly do often begin to react to each other's pipeline products well before commercialization and we made the observation and that decision that affirm at relatively developed stage of R and D for a given treatment is already liable, in some cases, to provoke competitive responses from other market participants.

Riccardo Ferrari:

Thank you, Ele. Camille?

Camille Varcion:

Thank you, Riccardo. I'll probably repeat what Ele just said to some extent, but I will try to give you a practical insight on how the commission assesses pipeline to pipeline overlaps. As Paul already mentioned, we look at pipeline to pipeline overlaps both in terms of potential product and price competition, but also in terms of innovation competition, looking at the risk of discontinuation delay or reorientation of one of the merging companies pipeline drug. I will start to say that there are challenges in assessing pipeline to pipeline overlaps do not apply to the uncertainty Ele mentioned, but this is not a driving factor. And the uncertainty notably is linked to the risks inherent to the development of drugs, but there are also challenges due to the higher asymmetry of information between companies and the commission when it comes to research programs.

Camille Varcion:

That being said, we believe that our current merger control toolbox enables us to assess properly pipeline to pipeline overlaps. And usually we look at several parameters, including the closeness of competition among emerging companies pipeline drugs, but also with competing pipelines. We also look at our promising competing the emerging companies pipeline drugs are, and also the overall number of competing marketed and pipeline drugs available in the market. On this point, I will already say that there is no magic number with respect to the number of marketed and pipeline drugs available in the market that would make us rule out competition concerns. And this will always depend on the disease

concerned and the specifics of the case. That being said, when we assess all these parameters, we rely on several sources of information, including historic market data, but also scientific data.

Camille Varcion:

For instance, clinical practice guidelines, which are very useful for assessment. We also rely on feedback from market participants and notably medical experts, which give us valuable information, notably the features of the emerging parties pipeline drugs, to understand whether maybe best on their mode of action or on the safety and efficacy data available at the time of our investigation. These pipeline drugs would be expected to be used at the same stage of the treatment algorithm or to target the same patient groups. These are of course, very useful information we take into account in our assessment. And we thank medical experts for their valuable corporation in our merger investigations. We also obviously take into account information provided by the merging companies, including the internal documents, which are key to understand the rationale of a transaction, but also the synergies expected by the parties.

Camille Varcion:

And here, I would like to say that the provision of complete and accurate information is actually crucial for assessment, especially when it comes to research programs where maybe some of the information is only in the end of the companies. In the past, the commission has taken a strong stance towards companies not complying with this obligation of providing accurate and complete information. And I'm referring here to Sigma [inaudible 00:45:22] in 2021, which was fined for not complying with this obligation and we will continue to do so in our merger investigations. Then also, and this will probably echo what Ele said. We take into account the time to market and the chances of success of a pipeline drug in our assessment. But these parameters do not determine the scope of our investigation. In the past, we have looked at very early pipeline assets, and even preclinical assets.

Camille Varcion:

And for instance, I'm thinking about the BMS cell gene investigation, where we looked at a preclinical asset following a complaint from a third party, but we also take into account the fact that even for late stage pipeline, there are still many unknowns, notably in terms of efficacy and safety data. And we are willing to make the necessary adjustments when needed. This was, for instance, the case regarding the waiver request, the request to waive the commitments made by Takeda in 2020 regarding commitments he had taken for the divestment of a phase free pipeline drugs. We conducted an investigation following the receipt of this weather request, and we found that actually several developments at effective negatively and significantly the profile and timeline of this pipeline drugs, and we therefore accepted the weather request. So we made the necessary adjustment, taking into account the development, that had occurred with this pipeline drugs. Thank you very much, Ricardo. Thank you.

Riccardo Ferrari:

Thank you very much. So now I have two questions on topics that I'm sure you have encountered many times before, and the first is quite high level. Do you really see a growing risk of concentration of R and D capabilities in the pharmaceutical sector, given the large number of companies with R and D capabilities like big pharma companies, biotech companies, university research programs. So Caroline, I come to you first and then to Camille.

Caroline Holland:

Thanks. So your question, do I see a risk in reduction R and D? Yes. I do see a risk, a potential for a risk and [inaudible 00:47:56] presentation identified some research on that. And while these are not pharmaceutical cases, the FTC has alleged harmed innovation in complaints, challenging the tie ups of Lockheed Martin and Aerojet and Illumina and [inaudible 00:48:14], both of which were abandoned after the commission authorized complaints. This is also an issue in Illumina [inaudible 00:48:21], which is pending in litigation. So I do think this is something to look very closely at, I think the risk is not imaginary, and I give much credit to our mergers one section and economists and the bureau of economics who work to bring these cases that I've mentioned and for looking at, and being on the forefront of these innovation competition issues. And at the risk of being a little bit repetitive, but I'll do so for emphasis, mergers that might reduce the drug research development really can diminish the innovation competition that results in scientific progress. And I think this type of progress that we are trying to protect is very important and the risks of losing that are great enough to really take this seriously and investigate it.

Riccardo Ferrari:

Camille?

Camille Varcion:

Yes. So I will start by saying that I completely agree with Caroline's remarks. But on the commission side, so far we have not seen, as mentioned by Paul, a case in the pharmaceutical sector where the concentration of R and D capabilities resulted in anti-competitive effects. However, as emphasized by all speakers today, innovation is key in the pharma sector. This is a key factor of competitiveness. And so we will continue to look at this aspect very closely in all our merger investigations. So we will continue to request information from the merging companies about their integration plans, their own R and D, but also elements also mentioned by [inaudible 00:50:09] earlier. R and D expenditures from the emerging companies and competitors, number of full-time employees involved in research programs, number of new products launched based on new molecules, but also the ability.

Camille Varcion:

We also take that into account, the ability to enter into R and D partnerships. That being said, in the pharma sector, we didn't have a case so far, but we have applied the theory of harm of sector in the agrochemical sector in the [inaudible 00:50:41] case, also mentioned by Paul earlier. And we have also looked very closely at this theory of harm in the context of a case in the animal health sector, where we saw that there were high barriers to entry to develop R and D capabilities because of the significant investment needed, but also the advantage given to players active in both human health and the crop industry, R and D industry, so which limit even further the number of credible innovator in the space. In the end, we ultimately and conditionally cleared that transaction based on the results of our market investigation, looking notably at all the elements I listed before, but we will continue to look at this aspect closely in all merger investigations in pharma. Thank you.

Riccardo Ferrari:

Great. Thanks a lot. Very interesting. And now to my last question, so don't you think that the systemic review of early pipeline overlaps and the review of acquisitions of small biotech companies we know, or little turnover, could have a chilling effect on investment in innovation in the sector? So let me go to Paul for one.

Paul Csiszár:

Thanks, Riccardo. This is a very good question. Let me first clarify that policy makers and enforcers should always carefully reflect on any possible chilling effects on investments stemming from any action they contemplate, be it a rule making or special specific decisions in individual cases. That being said, however, as it was seen in Carmine's presentation and also known from other sources as well, the pharma medical device R and D landscape is quite [inaudible 00:52:40], fortunately for all of us. Obtaining funding for promising projects, including for startups, are seldom a problem. We should also not forget that reviewing early pipeline deals does not mean prohibiting them. We should keep in mind that the majority of our cases are treated under simplified procedure or otherwise do not require any intervention once they're notified to us. So in the specific context of early pipeline overlaps and acquisition of nascent competitors and possible chilling effect, while our own experience, and several academic studies have shown that the acquisition of nascent companies and other mergers involving overlapping pipelines may well have negative impact on innovation in the sector, the chilling effect allegedly stemming from the merger review process itself claimed by some critics does not appear to have sufficient evidentiary basis.

Paul Csiszár:

As far as we could see. In any event, it is a good practice that sellers and their advisors, when considering their options and choosing their buyer, do take potential antitrust concerns into account so that the merger review filing will go smoothly. I stop there. Thank you.

Riccardo Ferrari:

Great. Thanks, Paul. And I'm interested to hear Caroline, if you have any comment on this.

Caroline Holland:

No, I agree with Paul. I think we can't be blind to risks of a chilling effect, but absent sufficient evidentiary basis for doing so, it's not something that I think I would lose sleep over. Frankly, I think the risks are significantly greater in losing innovation competition if you have killer acquisitions occurring. I think we hear all the time about, we hear from perhaps critics of taking a strong stand on innovation competition. They say that they're very worried about type one error risks, this risk of over enforcement and to be quite frank, I'm much more concerned about type two errors. Under enforcement. And I think we should be particularly attuned to it when innovative drugs are at issue. So I think perhaps the opposite is true, is that we need strong competition enforcement in order to protect the innovation and in order to keep the dollars flowing to innovative companies. So those are my views.

Riccardo Ferrari:

Great. Thanks a lot, Caroline. And thanks to all the speakers here. We have come to the end of this session and it was super interesting. So thanks again. And I would like also to thank, of course, the audience that has joined us online today and will echo again my thanks to the FTC and all the members of the pharma mergers taskforce for their contribution over these day workshop. And also for the work that we've done in the past year. It has really been interesting and I'm sure it will have a long lasting effect on our work. And now I think we can all have a little break and I look forward to the next session on prior bad act, as factors in pharmaceutical merger reviews. Thanks all, and goodbye.

David Lawrence:

Good morning and thank you all for being with us here. This is the last panel, but I think probably the best. I think we've saved the best for last. My name's David Lawrence, policy director of the Antitrust Division. And we're going to be talking for the next hour about prior bad acts as an issue in pharmaceutical merger reviews. And the reason I say I think we're saving the best for last is, we focus so much on the prospective nature of merger reviews, but of course the history of an industry is incredibly important to understanding its future. And so we're going to have a tremendous panel with us to help understand that question today, and to think about those dynamics. Michael Terrier is a distinguished professor at Rutgers Law School, where he specializes in antitrust and IP law. He's co-author of The Leading IP Antitrust treaties, IP and Antitrust Law, and Analysis of Antitrust Principles Applied to Intellectual Property, the author of numerous books and law review articles and chapters, incredibly prodigious academic, and a really intelligent and nice guy.

David Lawrence:

So I think we're going to really look forward to hearing from him on this. Ratsha Kooperam is a senior research assistant at The Washington Center for Equitable Growth. Prior to joining Equitable Growth, she interned at the Federal Housing Finance Agency working with the division of housing mission and goals, and has research interests related to healthcare competition policy and economic measurement. We have Professor Scott Hemple with us today, the Moses H. Grossman professor of law at NYU school of law, and co-director of the Engelberg Center on Innovation, Law, and Policy. Not only because NYU is my Alma mater, we are very pleased, very lucky to have Scott here. He's brilliant, teaches about antitrust and intellectual property as well, and has wide ranging scholarship. And I think brings the sort of interdisciplinary perspective to this that we really need to understand the connection between history of an industry and its future.

David Lawrence:

And we also of course have Gwendolyn Cooley, who is the chair of The National Association of Attorneys General Multi-state Antitrust Task Force, and has been Wisconsin, one of their assistant attorney general for antitrust since 2005. I've had the good pleasure to work with Gwendolyn since she started in her NAG role. And her support of the state relations with the antitrust division has been magnificent. But in addition to helping us build those relationships, she's also a leading light in antitrust enforcement as the lead attorney in state of Wisconsin [inaudible 01:23:19], where she leads 42 attorneys general in their case against the manufacturer of Suboxone, and has a long resume of accomplishments behind that.

David Lawrence:

So that's probably as much biography as the listeners are interested in, but these talented folks have a lot more than that. So why don't we bring them into the discussion. And just to set the stage, I mentioned at the outset, the other panels have focused on aspects of the industry today, or this incredibly challenging exercise of looking into the future, right? And antitrust is not the only discipline where we know that to predict the future, let's look to our past. And I think you the Supreme Court and Brown Shoe tells us, you need to look to the structure, history and probable future. And of course, Brown Shoe is still good law, that line is still good law. It showed up in circuit court opinions routinely even into recent years. And so I guess the question for the panel is, how do we do that? How do we focus on that history piece? And Gwendolyn, maybe you can set the stage for us and sort of underscore some of your thinking about prior conduct as a factor in pharmaceutical merger.

Gwendolyn Cooley:

Yes. So first and most importantly, thank you. To the FTC chair and all the FTC commissioners, and the AEG for antitrust, FTC and DOJ staff, and our international colleagues, this has been a tremendous honor and pleasure to participate in this group, which I think has been a fantastic way for us to have a dialogue about mergers generally, but pharmaceutical mergers specifically. So to conduct, we heard yesterday something like, in the last 30 years over 45% of pharmaceutical assets have changed hands from one pharmaceutical company to another. And something like 55% of pharmaceutical merger parties are also defendants in conduct cases. So that's why we care about this retroactive look.

Gwendolyn Cooley:

And those are cases brought by US DOJ, by the states, by the FTC, and certainly litigation by private parties. Setting that stage for what we're talking about for those of us not in the life of antitrust pharmaceutical land, most of the anti-competitive conduct that enforcers see, relates to carving up a territory or excluding potential rivals. And some of these are part of the way that pharmaceutical markets work in the United States with brand name exclusivity, and then hopefully subsequent generic entry. As you mentioned, I'm the lead attorney on the Suboxone case. So I will of course start there with product topping.

Gwendolyn Cooley:

In that case, we allege that the makers of Suboxone attempted to force the switch from a tablet form that was about to lose exclusivity, to a film form of the drug. And that film form was protected by a patent. Another similar case, Namenda, involved switching from a twice daily pill to a once daily pill. Allegations in both cases were about the removal of that originator drug, that first drug, and its affect on potential generics who would not be substitutable for that patent and protected version. Of course, we have reverse payment cases, which are also called "pay for delay cases," where the branded manufacturer pays the generic to stay off the market for a period of time, ostensibly to settle patent infringement litigation.

Gwendolyn Cooley:

States have been active in this area as well with the Lidoderm case's recent allegation of a months' long delay, as a more recent example. Sometimes the schemes are more complicated. We heard about this a little bit yesterday, and I'm sure that we will hear about it again today from some of our colleagues who this case is near and dear to their hearts, the recent Vyera case, where the makers of Vyera restricted access to the active pharmaceutical ingredient, and then engaged another, what I call "shenanigans," to ensure that there was no supply and no ability for generics to enter the market despite 4000% price increases.

Gwendolyn Cooley:

We see allegations that patent holders misuse the REMS process, which is the risk evaluation and mitigation strategy, I believe, which is the process where generics and brands come together to figure out what the safety mechanisms will be. We see Walker process fraud, which is fraud on the patent and trade office related to their patents. We see misrepresentations to destroy the market. We see patent tickets, which some enforcers have taken a look at, like in Humira where a group of states filed an amicus here in the seventh circuit, expressing concerns about the effect that huge numbers of patents with varying expiration dates would have on competition. And sometimes we see all these things together. Then of course there are the allegations. That was mostly unilateral conduct, but we also see

multilateral conduct, where there are allegations of straight up price fixing or territorial allocation where companies have agreed not to compete to produce generic pharmaceuticals.

David Lawrence:

Thank you. And I wonder Ratsha, you want to jump in? Or others on the panel with thoughts on this intro question of prior conduct?

Ratsha Kooperam:

Absolutely. So I want to add that coordination within the pharmaceutical industry isn't always a bad thing. During the pandemic, we saw companies like Pfizer and Biontech work together to create an innovative vaccine to protect people against COVID-19, but unfortunately this isn't always the case. We don't really see a lot of coordination to bring forth innovation. Rather, we often see coordination to help rake in more profits. Just want to add that.

Scott Hemple:

I'd be happy to jump in here for a minute. When we think about the intersection of mergers and conduct, I mean, I think quite often the causality isn't quite right, but the sequencing is the other way. There's a merger and then there's conduct, right? So there's a merger investigation that uncovers price fixing, and then we go pursue the conduct. Or the merger is temporarily prior to bad conduct. So the Vyera [inaudible 01:29:41] case that has been mentioned a few times, I was the FTC's economic expert in that case and testified at trial in December, there was a merger which then was alleged and shown to be the first stage to the shenanigans that Gwendolyn mentioned. Now here,

Scott Hemphill:

I think part of our focus on this panel is going to be thinking about this in the opposite direction. How conduct, past bad acts might inform merger policy. I think there's two kinds of synergy that we want to be sort of focused on that we can sort of organize our thinking, using a synergy as to inference and a synergy as to effect. So synergy as to inference. Intent, we've understood, at least since Chicago Board of Trade, is indicative of effect an idea that was powerfully reinforced in the Microsoft case. It's not that we are going after folks with evil in their heart. We're going after bad anti-competitive conduct kind of with ill effect, but intent is informative about effect. It provides information about the expectations of parties. What effects do these sophisticated firms think that their conduct will have? And here, I think previous demonstrated bad conduct can be informative of their intent and might therefore inform how we think about a subsequent merger, that that earlier willingness and plan to engage in anti-competitive conduct might inform how we think about the effects of a merger that's in front of us.

Scott Hemphill:

Second, just a synergy as to effect itself, bad conduct, particularly if it has continuing effects, maybe the conduct is continuing, or maybe it has residual effects that haven't been entirely resolved through earlier, injunctive relief, might reinforce. It might amplify the concerns about a merger. So there could be some suppression of competition through some unilateral policy or some contractual restraint, and then that could be amplified or kind of multiplied by an acquisition. So I think these are two different kinds of relationships that we want to be thinking about when we evaluate the role of past conduct in current merger review.

Michael Carrier:

And so let me add just one particular example, which is the merger between AbbVie and Allergan. So much of the anti-competitive conduct that we've heard already in response to this question showed up in just this one merger. So start with AbbVie. You have a pay for delay settlement in which Abbott paid Teva to delay entering the market with a generic version of its testosterone gel. In response, it offered a separate product, cholesterol treating TriCore at below market prices. And the court there said that this was not an independent business deal. And that it was quote, "highly unusual" because Abbott would've lost 100 million in revenues. In addition to pay for delay settlements, Abbott also was found liable for sham litigation. So in an important case, brought by the FTC, the court found that this was objectively baseless and that quote "no reasonable litigant in its position would believe it had a chance of winning".

Michael Carrier:

That's a big deal. It's really, really hard to win sham litigation cases. And the fact that the FTC did so, pretty much shows that this was anti-competitive conduct. And then finally of the patent thicket that we have heard about, in which AbbVie collected more than a hundred patents to delay competition on Humira, there were documents to the effect that it was building in a state to do that the district court issued an opinion that really wasn't supported by the case law. There was evidence of sham conduct here in which AbbVie listed patents that were invalidated with ingredients that weren't in the biosimilar product. And there also were allegations of pay for delay. So you put it all together. And with AbbVie, you have evidence of pay for delay settlements, sham litigation, and thickets, but that's not all because AbbVie merged with Allergan. And so now we get some additional anti-competitive conduct.

Michael Carrier:

We start off with citizen petitions in which Allergan filed repetitive petitions to delay generic competition on dry eye disease, treating Restasis, the FDA, which holds its cards close to the vest, was frustrated with this conduct. In the second response, the FDA said that Allergan quote "should not be surprised" by its response. And then the third response, it said that this quote "repeats many of the assertions already addressed".

Michael Carrier:

And in case we thought we knew the universe of anti-competitive conduct, Allergan, very creatively, came up with a new one, which is trying to transfer its patent to a native American tribe to invoke tribal immunity, to avoid review at the patent office. So at the end of the day, when these two companies merge, you have five forms of anti-competitive conduct that have been pretty much proven in the courts. And why does this matter? You think about the ability and incentive to engage in anti-competitive conduct. And you have that here. You have a heightened ability to engage in the conduct because you have a greater toolkit of anti-competitive tools. And you also have a greater incentive because in many cases they're producing higher monopoly profits, so they have even more incentive to engage in this conduct. So that's one example of how you could use these prior bad acts when thinking about the merger.

David Lawrence:

So let me ask a little bit of a translational question. How do we translate all of the different types of history that were just mentioned into a merger review? So if we take the Supreme Court at its word that Congress wanted to arrest a trend towards concentration in its incipiency and to stop a rising tide of concentration and clamp down with vigor on mergers before the problems arise, what did these sorts of

conduct concerns tell us, and maybe I'll go to you Gwendolyn here. How do you translate them to the modern thinking about merger review that helps us to arrest concentration in its insipidness?

Gwendolyn Cooley:

Yeah, so I think when you see both unilateral or coordinated effects and you've just heard, there's more. You've just heard a sampling of some of the conduct that we've seen. All of it really though, is an attempt to corner the market on a particular drug and maximize profits. From a merger perspective, it's important to look at the history and how that impacts our analysis post transaction. And so I think the conduct matters in terms of what kind of transaction it is. I think that it's pretty clear that if there is head-to-head competition in the molecule-to-molecule space, that is something that is a fairly straightforward analysis. And so for illustration, because it's easier when you're an antitrust enforcer to talk about a hypothetical, I've created a drug, it's called antitrustine, it treats insomnia, obviously. So if generic antitrustine molecule makers wanted to merge, that's pretty clearly head-to-head competition.

Gwendolyn Cooley:

And while it would certainly be nice to go into a court and say, not only is this head-to-head competition, so we should block this merger, but also, they all engaged in all these other shenanigans. Right? I think so that one is pretty clear. Now, if there's nascent competition and you've got name brand antitrustine, wanting to acquire someone who may potentially have antitrustine in the pipeline, right. I think that that's, when you start to really look at the conduct and see what has happened before, right. Is the name brand antitrustine, do they have a patent thicket? Have they engaged in reverse payments to keep that generic antitrustine off the market? But then I think when you get to things that are not molecule-to-molecule, it's a little bit harder, right? Let's say antitrustine wants to acquire the maker of relaxine, which treats anxiety. Is that the same market?

Gwendolyn Cooley:

I mean, if you have less anxiety, then maybe you can sleep better? How do we handle that? Are they in a broader market? We're looking at the whole portfolio of drugs. So I think that's something that we would need to look at more closely. And then of course, remember as David and I know very well when you're in court, it's ultimately the judge that decides this. We need to keep in mind as law enforcers when we challenge cases that ultimately it's the judge who decides whether there's a danger of anti-competitive effects as the result of a merger.

David Lawrence:

So quick follow up. Does prior unilateral conduct to preserve market power or does it indicate that there's market power already in the market that could become sort of the locus of our inquiry in a merger review? Is that helping us with the unilateral effects analysis?

Gwendolyn Cooley:

Is that to me because I would say yes.

David Lawrence:

Yes. OK. I don't know if others want to jump in on this before we move on to the next topic.

Michael Carrier:

Yeah. So it could indicate market power. So in the pay for delay settlement context, the Supreme Court said an *FTC v Actavis*, that when a brand pays a generic to stay off the market, that's indicative of market power. Why else would the brand be paying the generic tens or hundreds of millions of dollars?

David Lawrence:

And let me ask another sort of translational question for the coordinated effects. And I'd throw this out to you Gwendolyn first and then see if others... Does prior coordination in a market, does it test for the same sorts of things that HHIs do, about whether the market already has an oligopolistic structure that should give rise to concern? Is it helping us in that way?

Gwendolyn Cooley:

I think so. I think that if you can show... I mean talk about a more effective way to show that there is a consolidated market that's got oligopolistic effects, then be able to say, look, there are only three antitrust makers in this market and two of them are going to merge, right? And there were all these other coordinated effects already. But as someone who has gone before judges and have won and lost, I think that one is a pretty persuasive one for a judge.

Michael Carrier:

I completely agree. I mean, we're trying to show coordinated effects. These companies are already colluding. And that's it on the silver platter.

David Lawrence:

Yeah. So Michael, what about the size of firms? Should all pharmaceutical companies be treated similarly in merger review and if not, what factors should enforcers consider as they think about the sizes of firms or about whether they're doing branded or generic competition?

Michael Carrier:

I think that the size of firms is something that the FTC should think about. As we heard yesterday, the answer cannot be to only require the divestiture of overlapping products when we deal with pharmaceutical mergers. I think there is a ready-made framework for thinking about these issues. You think about unilateral effects, the effects on these two merging parties. You think about ability and incentives. You look at leverage and cross markets. This is an issue that the FTC is very well able to deal with. And so most of my comments here will come from a forthcoming article I have with professor Patricia Danson at Wharton, and she explained it in great detail yesterday. And so I don't intend to go over it, but let me just pick out a couple points from it. So one of the things that we suggest is a presumption against mergers when there are two large companies that merge.

Michael Carrier:

And so in terms of large companies, we don't have anything scientific there, but you look at the top ten by global sales companies like Pfizer, Roche, Novartis, J and J, Merck, Sanofi, AbbVie, GSK, Takeda, and BMS again, no scientific sample, but that's the type of firm that we're talking about. And they really do have advantages in terms of insurance and reimbursement. When they have a large portfolio of blockbusters, they have a lot of leverage when they're dealing with the PBM and the PBM will feel forced to include these blockbusters on the formulary. And so as a result, the merged entity can exercise its leverage to make sure that its drug is placed on the formulary or in the top tier. And that rivals are

not. So that's just one example. And professor Danson also talked about other benefits here in terms of marketing and financing.

Michael Carrier:

Doesn't seem to be a lot in the way of innovation and efficiencies here. And so that's why we suggest a presumption against a merger between two large firms. Now let's go down to the next level of a large and a mid-size firm or two mid-size firms. We don't offer a presumption here, but we do suggest heightened scrutiny. And the reason is that you think about these firms. And so we call them firms 11 to 20 in global sales, AstraZeneca, Amgen, Gilead, Eli Lilly, Bayer Novo Nordisk, Allergan, Behringer, Celgene, and Biogen. And you look at these midsize firms and they compete with large firms in things like marketing and acquiring smaller firms. And so we go case by case here again, no presumption, but case by case beyond particular markets. So for example, go back to the merger between AbbVie, which is a large firm and Allergan, which is a mid-size firm, here they each had blockbuster products that a PBM would need to include on the formula with AbbVie.

Michael Carrier:

We had Humira that we've already talked about with Allergan, they had Botox. And so a PBM's going to feel some pressure to put these products on the formulary. So you have all that pressure, in the AbbVie Allergan case you also have the bad acts. And so that is something that we need to think about beyond the particular markets. And then finally with generics, let's think about the fact that not every generic is the same. Generics were intended to challenge brand firm patents to bring generic competition to the market, to lower prices for consumers. But in work that I did with professors, Mark Lemley and Sean Miller, we saw that generics were not all the same and that some generics had a significant percentage of revenues that they got from brand firms. And as a result, they were less likely to perform the competition promoting feature that they were supposed to.

Michael Carrier:

So for example, we found that they were less likely to challenge patents, more likely to abandon the challenges and less likely to win them. So at the end of the day, how does this matter? It matters because the FTC should welcome mergers that create pure generics while being a bit more skeptical of those that dilute generics by mixing them with brand firms. And there you could look at certain factors like the shares, the size and things like that. So at the end of the day, I think that size does matter, especially when you have large firms, but also when you have mid-size firms and also generic firms.

David Lawrence:

And when you talk about size in this context, are you talking about strictly market share within a market or are you talking about size by another measure? And if the latter, how would you define that measure?

Michael Carrier:

So I'm talking about the latter. The point here is to go beyond an individual market. And so we just offer the top ten by global sales. As professor Danson said yesterday, you could think about it in terms of US sales, you could do it in terms of the blockbuster products that they have. And so there's no signs here. There isn't an exact line where a firm becomes a large firm, but most generally speaking, it seems like some of the drug firms are large firms, however defined.

David Lawrence:

And so when you're focusing on size in this way, is what we're testing for the ability to engage in the variety of practices that you just went over, that might, even if it's not size within a particular market, be leveraged into anti-competitive effects in a particular market?

Michael Carrier:

So certainly. The existence of prior conduct is relevant. What we focused on primarily were the advantages that uniquely large firms have in terms of the cross market effects of having drugs in multiple markets that PBMs need to include on their formulary. That is a function of how large a company is. And also how many must-have blockbuster products that it has because that increases its leverage when it deals with PBMs.

David Lawrence:

I see. Why don't I open up this question to the broader group and specifically, what is the role of market definition with thinking about the history in a pharmaceutical area and the markets are kind of unfolding or they're evolving, or we're looking to develop a market in the future. How do we connect up these disparate, factual inquiries into trying to understand a market as it evolves or potential markets? I'd love to hear from all of you on this, because it's a great learning opportunity for me. I've been at DOJ, not dealing with pharma for a while, but why don't we start with Scott?

Scott Hemphill:

Yeah, sure. So I guess, I mean my starting point kind of builds on where Mike left off. I'd love to just spend a little bit of time thinking harder about Mike and Patricia's proposal that we should be paying attention to increased bargaining leverage. In some ways this is a new idea. And in some ways it builds, I think on an existing, and I think extremely successful, merger program that FTC has perceived over the last decade. When we think about the hospital merger program over the last decade, the focus there has been on increased bargaining leverage, right? That by combining you could become a must-have with respect to a payer, typically a traditional insurance company and thereby command a higher reimbursement level as a condition of inclusion in a particular insurer's network.

Scott Hemphill:

Now frequently, those, typically, maybe always, those cases so far have been within market in the sense that they were within traditionally defined product markets, but there's important work by economists, making a strong case that even when hospitals are in disparate locations and hence in different product markets, as traditionally defined, that nevertheless there could be the acquisition of increased bargaining leverage that would have much the same kind of harms that the more everyday merger program has been tackling in the FTC. And so what I understand Patricia and Mike to be doing is taking that thinking and bringing it over to pharma and saying, well, just as you could have cross market effects that increase bargaining leverage in hospitals, that could be true over here in pharma. And so we need to take this seriously, need to take a hard look at this. So I just want to offer a minute or two, just think about how might we go about that because healthcare is a complicated business.

Scott Hemphill:

What does it mean to acquire increased leverage? How do we think about the potentially synergistic effects of bundling? If I'm already a must-have, and I've become even more must-have, how does that, if at all, does that affect my bargaining leverage? I think these models get pretty complicated, pretty fast

to the degree that PBMs are passing through their increases to some degree, as opposed to having to sit with it, that probably affects their bargaining in a way that gets complicated. So this is not just that the person, the dispenser doesn't pay for the drug, the usual kind of healthcare issues, but also the specific nature of PBMs in this bargain that I think is important to take a close look at. Now of course the FTC is committed to taking a hard look at PBMs.

Scott Hemphill:

This may already be on the list, honestly, but if I were to give an additional thing to think about, it might be when PBMs negotiate, how, if at all, do they think about, or worry about, joint negotiation over multiple drugs? How, if at all, do they worry about the wake of an acquisition? So I think there's been marvelous work done in other merger contexts about retrospectives and thinking about whether prices increase after a beer merger, let's say, or an airline merger.

Scott Hemphill:

Well y'all could do that here. As long as you're thinking about PBMs in a robust way. One important component here that's I think prompted by the Dans and Carrier program would be all right after a merger, did leverage increase, in fact, from the standpoint of the PBMs? Go ask them, collect data, see how, reimbursement levels changed, if at all, following this. Just asking them whether it bothers them probably is at least somewhat informative, but this is something that we could chase to see whether this theoretical possibility is born out on the ground. And this seems like a good moment to do it, given that PBMs are, as I understand it, due for some scrutiny in any event.

David Lawrence:

Raksha, Gwendolyn, anything to add on this question of how market and market definition relates?

Gwendolyn Cooley:

Raksha, I'll let you go first if you have something.

Raksha Kopparam:

I was actually just going to turn it over to you.

Gwendolyn Cooley:

Okay. Well, so my thought is, I think that's interesting to think about the bargaining leverage, from that hospital experience? If you've got antitrustine and relaxine, what does that actually mean when you're negotiating with PBMs? I don't know that we know the answer to that, but that's something. So to the original question, that's something that's almost easier to look at in retrospect and is a thing that could be done. It's tough to project what that, tough for me to understand since I'm not an economist, tough for me to understand how you would project that in the future, but certainly you could look at that bargaining leverage from the past. When you've got two blockbusters, how does that increase your leverage? I think that's a very interesting question. But then I also think as a litigator, when I go into court, I better be able to show that we can say that this is going to increase prices for consumers or whatever, at the end of the day, not just as an academic exercise.

Michael Carrier:

And I think that supports Scott's very reasonable suggestion for a retrospective and for a look after the fact of what happened. Our assumption was that if you have a combination of must-have products, then you have more bargaining leverage, but Scott makes a fair point, well, you have a must-have to begin with. So the common sense is that when you have more must-haves you have more leverage, but one way to figure that out is to maybe ask after the fact, and that could give you the evidence that Gwendolyn needs when she goes to court.

David Lawrence:

So let me try to focus in on this particular question of imagining there's some evidence of prior bad conduct and maybe go to you Scott with a sort of evidentiary question, which is what kind of evidence do you look to and how would you identify that prior conduct poses a significant risk of post-acquisition anti-competitive conduct? How do you square that circle?

Scott Hemphill:

Yeah, sure. One connection that we've talked about already is worth focusing on and kind of expanding a little bit, which is that the intent of a firm as indicated in documents or in previous conduct can shed light on the expectations of the firm. Right? Is there a project to suppress competition or is it instead to promote it? Now I think one part of the question here, I take it, which is getting away a little bit from the prior conduct question, but also thinking about how to evaluate the merger itself as something I've done some thinking about is how should enforcers think about a merger when the acquirer is willing to pay more than anybody else, doesn't this tell us something important?

Scott Hemphill:

And I think here there's a couple things that we said. One, being willing to pay the most can be a fairly strong indicator of competitive threat. We know that monopoly has higher profits than duopoly. And so the preservation of monopoly, although sequel is a basis for paying a premium in order to get rid of a potential rival. This point applies to current competitors, applies to potential competitors, to nascent competitors. So I have a paper with Tim Wu from a year or so ago, a University of Pennsylvania lawyer that gets into some of these nascent competition questions. Now this is not always necessarily straightforward because clearly paying a premium might have multiple even, alternative reasons. It could be to get rid of a threat. It could also be in order to generate some kind of unique synergy that wouldn't otherwise be available.

Scott Hemphill:

Now, I think it's worth saying here that synergy claims, some skepticism is warranted, agencies in the courts have approached the efficiencies question with some skepticism. I think that skepticism is warranted. Firms have an incentive and an ability to exaggerate or even manufacture efficiencies. Even where earnest, the gains might not materialize. There's of course questions of verification. I think one question here, and if we're thinking about next steps, something to think about doing more work on, I'm always trying to think of six B studies I feel like. So this one might be another one, is to try to think through the degree to which efficiency claims kind of bear out. I think there's a robust tradition in pharmaceutical acquisitions.

Scott Hemphill:

I'm thinking of the big little here. I don't know exactly how that fits into Mike's typology, but where a major firm is buying a set of research projects where I think we frequently see a synergy argument,

which is that the big is in a good position to complete the research or take it through trials, to do marketing that the smaller firm doesn't possess. I could imagine some gains from doing the work to seeing how well that is gone. I don't know one way or the other the answer to that in the mind run of cases. I understand that to be a relatively accepted merger specific efficiency, but this is again a place where further work might be interesting.

David Lawrence:

Yeah. Others have thoughts on the evidentiary question?

David Lawrence:

Michael, you have to get off mute.

Michael Carrier:

Yeah so on Scott's last point, I think that's what makes the mergers between large and small firms or the acquisition of the small firms hard and perhaps harder here than in places, like big tech, because it's not likely, in fact impossible, for a very small company to survive all of the

Michael Carrier:

The clinical trials that you need to do to reach the market. And so I think there needs to be some awareness of that here, there still could be harm, but I think the efficiency claim could be more warranted here than we see elsewhere.

Michael Carrier:

And let me just make a separate point that builds on the pipeline point that we've made throughout. Scott's done great work on [inaudible 02:00:24] competitors. We've heard about killer acquisitions, but I also want to make sure we don't forget about the first inclination or the first, what we called it, of the innovation market thesis. The innovation market thesis got a lot of attention a quarter century ago. A lot of people criticized it and raised concerns that weren't really valid in the pharmaceutical industry, but you think about the FTC's successful challenges at that time 20 to 25 years ago, where you had, for example, [Glaxo Welcome 02:00:54], [Smith Klein Beachum 02:00:54], [Baxter Immuno 02:00:54], [UpJohn Pharmacia 02:00:54], [Glaxo Welcome 02:00:54]. I think these are good challenges. I think that we should not forget that.

Michael Carrier:

And then when you think about the ready made indicator for how likely you are to reach the market, I think that's where pharma really is unique. Where if you're in preclinical studies, you have a one in 4,000 chance of reaching the market. If you're in phase one, two and three, it's 1830 and 57%, that tells you a lot. And one of the concerns with pipeline mergers or innovation markets in general is we don't know how likely they are to reach the market. Here, we know if you're in phase three and you're 57%, that's a lot better than preclinical.

Michael Carrier:

So, that is information that we shouldn't forget about even though it's old, because I think it's really relevant when we're thinking about markets for pipeline products.

David Lawrence:

Can, can I ask a related question, going back to sort of the market definition issue we raised earlier, which is how do we think about prior bad acts, in one market or for one product, as relevant to the pipelines that address a whole different set of products? And maybe I'll start with you here, Gwendolyn. If there's prior collusion in antitrust Z.... Was it antitrust-

Gwendolyn Cooley:

Anything we want it be, yes. [inaudible 02:02:23].

David Lawrence:

Yeah, and maybe it's... Within the portfolios of companies that also have pipelines towards the development of... Towards the development of [relaxer in 02:02:38], right. How do we think... How do we think about that in a merger review? How do we draw those connections? What's the bridge too far and what's the right way to think about it?

Gwendolyn Cooley:

So, kind of to build on Michael's point from just a minute ago, I think really it matters where they are in the stage of production. I think that conduct is always, from my perspective, it's likely, especially in these kind of nascent competitor or non cross market spaces, it's almost always going to be a plus factor, right? One of the things that we look at, right?

Gwendolyn Cooley:

So, if you have someone who is further along in the stages of competition, I'll note the state submitted comments to the merger guidelines. One of the things we, the states who made the comments, talked about was... Yes, those, thank you. We talked about having a presumption for acquisition of [inaudible 02:03:39] competitors, but again, right, that gets to the question of are they doing a research project or are they like fixing to come on the market? So, I think that kind of... Not kind of, I think that probably matters when we're looking at it, but thinking of conduct as a plus factor, unless you've got prior evidence of collusion in that market between the parties where I think that is nearly deposit.

Michael Carrier:

And I like Gwendolyn's calling it a plus factor. That's a good way to think about it. So for example, in our framework, we really focus on it in terms of the mid-size firms. When you have two large firms, you don't really need it. Once you get down to the mid-size firms, we think you shouldn't go market by market only looking for overlapping products and so here's the place we want to take a closer look, there could be competitive harm and maybe prior bad acts are the issue that puts it over the line.

David Lawrence:

I also wonder if this could be a different question at times, when we think about the labor market side of this as well. So, the hiring market, I assume for biologists is somewhat different than for chemists, and even within that many, many sub-fields. On the other hand, prior wage collusion between the same firms with respect to biologists might tell us something about risks for other employment lines as well.

David Lawrence:

And Raksha, why don't we jump to you and sort of thinking about these sort of issues of vulnerable people and economic inequality that we're hearing so much about and that I have to say, we at the department think a lot about this whenever we get into the healthcare industry and thinking about who are the people that price effects translate, not just into a theoretical exercise, but into whether or not you can afford your medicine that day, right? So, should enforcers be thinking about effects analysis and consumer harm in a way that systematically considers economic inequality and vulnerability?

Ratsha Kooperam:

Yeah. So, first I want to thank chair Kahn, AEG Canter, and the pharmaceutical mergers task force for putting this whole workshop together and inviting me to present. It is an honor to be virtually seated alongside such incredible experts in this field. So, thank you so much.

Ratsha Kooperam:

Now to answer your question, yes. Enforcers should be considering the role that merger analysis has on economic inequality and vulnerable communities. So, we're all aware that prescription drug costs have been on the rise in the last few years. In 2020, United States spent around 348 billion on prescription drugs, which is around an increase of around like 15 billion in the previous five years. Arising drug prices affect over half of the US population. A 2019 study found that around 62%... Or sorry. A 2019 study found that around 62% of US adults take at least one prescription drug and now at a time of immense economic volatility, rising drug prices, they just boost the profits of large pharmaceutical manufacturers at the expense of households across the country.

Ratsha Kooperam:

So, the beginning of this year, over 800 prescription drugs increased at an average of 5.1%. Companies like Pfizer experienced a 6% increase in revenue, not considering their COVID 19 products and so as costs continue to rise, people are actually turning to dangerous methods to manage their healthcare expenses. Around 40% of adults responded to or reported not taking their prescriptions as directed by their doctors due to high costs. So, they'll cut their pills in half, they'll skip doses, or even resorts to not filling their prescriptions at all.

Ratsha Kooperam:

So, why should enforcers consider economic inequality and vulnerable communities when it comes to this analysis? When we think of people who need healthcare the most, they tend to be the most vulnerable communities in our society. They are the elderly, they're the sick, people from low income households or people who have been historically discriminated against and while our government has established some systems to help these communities manage their healthcare expenses, these systems aren't as beneficial against pharmaceutical powerhouses. In 2021, the CBO found that out of all major federal programs, paying for outpatient prescription drugs, Medicare part D paid the highest average net prices for branded drugs and so when these pharmaceutical companies merge and continue to gain market power, they're strengthening their ability to set prices at a level that's unaffordable for people already experiencing socioeconomic hardships.

Ratsha Kooperam:

Now, we also have to consider that the enforcement agencies are constrained by resources, and they do rely on prosecutorial discretion when it comes to merger analysis, but when we look at the consumers that are affected by mergers, it is important to understand the makeup of these consumers. Are there

communities that have experienced historic discrimination, which would amplify the harms on them or harms of a merger on them more than on other communities. For example, African Americans are three times more likely to have kidney failure compared to white patients and this is a health disparity that's the result of structural racism and historic discrimination in healthcare, housing and climate policies, just to name a few.

Ratsha Kooperam:

So, patients with kidney failure need dialysis and other expensive medical treatments. However, anti-competitive mergers in this market exacerbates the existing socioeconomic inequalities by making these life saving treatments harder to access and afford. Additionally, we also have to... Or when deciding which merger cases to go after, the agencies should think about the actual harms that may come from the merger. So, a merger between the two largest candle makers in the market, and two pharmaceutical manufacturers, can both have anti-competitive effects in their respective markets, but people don't really rely on candles to survive. They rely on the prescription drugs however. So, this is why enforcement agencies should be considering the most vulnerable people when it comes to this analysis.

David Lawrence:

Thanks. And I was thinking as you're going over that how sometimes we engage in this cost benefit analysis that translates things into price, but if we're thinking about human utility, we've just washed out an awful lot of distinctions among people, a dollar out of someone's pocket can make a huge difference depending on what their overall household budget makes, right. How it actually impacts them.

Ratsha Kooperam:

Exactly. Yeah.

David Lawrence:

So, yeah. And so thinking about this anti-competitive conduct in pharma question Raksha, anything else we should be thinking about in terms of how it affects vulnerable and underserved communities?

Ratsha Kooperam:

Yeah. So, decades of evidence indicates that the increasing presence of anti-competitive conduct in the pharmaceutical industry can contribute to the rising prices that patients face, but these effects are worse for patients who come from these vulnerable or historically disadvantaged communities. For instance, in 2012, a four year patent delay agreement between the manufacturers of Glumetza and as generic competitor resulted in an increase in the drugs price from around \$6 to \$51 per tablet. Now, Glumetza is the extended release version of the drug Metformin, who is commonly a first choice treatment option for patients with type two diabetes. And type two diabetes is an issue that affects people of color at higher rates than white patients. Around 14% of native Americans, 12% of African Americans, and around 12% of Hispanic adults in the United States currently suffer from type two diabetes. While that rate drops to around 7% for white adults.

Ratsha Kooperam:

And additionally socioeconomic differences play a role in diabetes prevalence 14% of adults below the federal poverty line and 13% of adults with less than a high school degree have been diagnosed with type two diabetes and evidence also indicates that specific types of anti-competitive conduct can affect

the access and affordability of drugs that are prescribed to manage diseases that have a high prevalence amongst vulnerable communities.

Ratsha Kooperam:

So, let's take the example of Truvada. Gilead pharmaceuticals is the manufacturer of Truvada, which is one of the most prescribed pre-exposure prophylaxis or prep drugs that can help prevent HIV. In 2014, Gilead entered into a settlement agreement with Teva pharmaceuticals, which is a manufacturing company that developed a generic version of Truvada and this agreement allowed Teva to launch their generic in the fall of 2020. Around the same time, Gilead announced that trial data for an alternative antiretroviral therapy showed signs that it might be safer than Truvada while still effectively preventing HIV. So in 2016, Gilead's new antiretroviral drug, Descovy, was approved by the FDA and then three years later, it was approved for prep and Gilead marketed Descovy as a safer alternative to Truvada and started pushing physicians to prescribe Descovy over Truvada just as Teva's generic was about to enter the market.

Ratsha Kooperam:

And so to compare prices annually, Truvada costs around \$22,000, Descovy costs around \$25,000 while Teva's generic costs only around six to \$8,000. And prep drugs are recommended to over a million gay and bisexual men, transgender women, for people with HIV positive partners. Yet some people, especially black and Hispanic gay and bisexual men, have cited high costs as a reason for not taking prep or discontinuing their existing prescriptions. And now, like in 2021, most insurance plans and state Medicaid programs were instructed to fully cover the cost of prep. However, advocacy groups have actually found that some insurance plans do not offer prep without cost sharing options. So, this further increases the financial barriers based by the LGBTQ community, the bipoc community, and other historically disadvantaged groups. These are just two out of dozens of examples of how anti-competitive practices like product topping and pay for delay settlements, can place extreme financial burden on the most vulnerable communities.

David Lawrence:

And thank you Raksha. And we are quickly running out of time, so I want to get to my concluding question. The reason I have the state comment on the merger guidelines printed out is of course, we at the agencies are knee deep, maybe waist deep, in working through all those comments and thinking about the merger guidelines revisions and I wanted to ask this group, we've been focused on pharmaceuticals, but based on your experience there, and maybe if you could each go 60, 60 to 90 seconds on this, based on your experience in pharmaceuticals, what's the most important generalizable recommendation you would give to the agencies on revising revisions to the merger guidelines?

Scott Hemphill:

Got it.

David Lawrence:

Yeah, go ahead. Go ahead, Scott.

Scott Hemphill:

Yeah. So, I mean, I think we've heard three here that I think are probably the most important. One expanded attention to nascent competition and explicit recognition that even if the success of the

nascent competitor is far from certain, that even in that situation, antitrust has a role to play. Second, you asked about buy side harms. I think attention to buy side harms we've talked... Workers were mentioned explicitly. One could also imagine acquisitions of suppliers, acquisitions of these startups, the fewer big pharma firms there are, perhaps the fewer firms there are to fight over in some therapeutic class, a promising startup.

Scott Hemphill:

So, I think unclear whether in the real world, there's an incremental problem because often there's a cell side harm as well in such a case, but it's something to think about as part of amplifying the discussion of buy side harms. Third, we spent some time talking about bargaining leverage recognizing explicitly that enhanced bargaining leverage is an important form of competitive harm and one in which there might not be a demonstrable output effect. Then we can talk about how there's always kind of an output effect, depending on how you think about it, but making clear that there can be harms due to the weakened position of trading partners, due to the reduction in competition and that output harm is not an essential feature of that issue.

Scott Hemphill:

I think one thing we need to be careful is that the guidelines ought to authentically reflect agency practice. I think as to the three things that I've mentioned, all of which would be incremental on what's explicitly in the guidelines, I think those do capture the kinds of things that rigorous merger enforcement is already taking into account and these three would just be making those more explicit.

David Lawrence:

Sure. Thanks Scott. Michael?

Michael Carrier:

So, following up on Scott's last point, I think leverage is a really important issue. It applies differently in different industries. So we think it applies in pharma, it's not going to apply across the board, but where it does, we think that sometimes it is underappreciated. And then just to put another issue on the table, what does it take to put in the guidelines, a presumption? And so presumptions are all the rage these days, we want to switch presumptions here and there, and that has a significant effect. And so what does it take in order to put in a presumption? And so, Professor Denson and I wanted to be pretty cautious, pretty conservative in switching presumption only for a merger of two large firms and we think that's supported by the pharmaceutical industry, the lack of efficiencies and so based on scholarship and thinking, what does it take to put in a presumption?

David Lawrence:

Thank you, Gwendolyn. And then we'll finish with you, Raksha.

Gwendolyn Cooley:

So I will say, I agreed a lot with what Scott has said. The states have 99 pages worth of comments. So it's pretty tough to summarize them in 90 seconds or less, but certainly we talk about [inaudible 02:18:23] competition, we talk about presumptions and ideas for those, for the federal agencies to consider. I 100% agree that they should reflect our actual practice rather than a hypothetical, but I will say this. One of the things that I heard through this entire workshop is that there are a lot of resources being spent on merger review and looking at anti-competitive conduct generally, and as companies become

ever larger and scoop up increasing numbers of drugs, and this is not just applicable to the pharmaceutical industry, right? They try these strategies in multiple markets, right? If you're doing a reverse payment here, you might try it again in a different markets.

Gwendolyn Cooley:

So, as those cases become more complex and harder to prove, this is one of the reasons why we like presumptions, they're very resource intensive. And I think... I think all enforcers across the political spectrum and around the world, agreed that antitrust needs more resources. If we're going to look at this stuff, we spend a huge amount of time reviewing merger transactions. I know that FTC and DOJ do as well. So, we in the states, would really like more resources and I know the federal government too. So, that's just my one last pitch.

David Lawrence:

You're here. Raksha, can you wrap us up?

Ratsha Kooperam:

Absolutely. So, I definitely agree with the rest of the panelists have to say, and I would also stress that my previous statement on that antitrust forces should understand the demographic makeup of the consumer base and analyze the varying effects by faced by different communities. It is resource intensive work and so to Gwendolyn's point, give the agencies more resources, but weighing the effects of a merger on various historically disadvantaged communities is so important. And this is imperative if the agencies are aiming to stop anti-competitive practices or mergers, and in the long run to help ease the financial burden of prescription drugs. We're talking about product and products and innovations, but in the end, this is about people and how the people are able to get the essential healthcare that they need, so.

David Lawrence:

Thanks and that's such a great note end on because this is critically important stuff to the American people, and we've been so fortunate to have such a great panel helping us with it. So, that'll close out our panel and I think stay tuned for the completion of the event.

Anu Sawkar:

Over the course of the past two days, we've heard from panels reflecting by diversity of experience and thought regarding competition in the pharmaceutical industry. More than half of the panels were women and the panelists provided an international comparative perspective on some of the potential challenges involved in analyzing pharmaceutical workers. The panelists areas of interest include the legal, economic, and equitable underpinnings and implications of pharmaceutical competition. Simply put, we've learned more than we otherwise would have because we were fortunate to hear from such a diverse set of speakers.

Anu Sawkar:

Today, we focused on the relevance and usefulness of two potential considerations in pharmaceutical merger reviews. Innovation, and prior bad acts. While panelists yesterday discussed the role that merger remedies can play in preserving innovation competition, our first panel today took a much deeper dive into the topic of pharmaceutical innovation. Professor [Carmine Arnogi 02:22:26] started us off with a helpful background on innovation in the pharmaceutical industry. Then our UK, EC, and US enforcer

panelists engaged in a lively discussion, comparing approaches used in their respective jurisdictions. They described how their agencies assess innovation competition, including specific analytical frameworks used for pharmaceutical mergers. They considered whether some potentially harmful pharmaceutical mergers are slipping through the cracks due to reporting thresholds. They discuss the risks associated with mergers that concentrate R and D capabilities, and finally, our enforcers confronted concerns about whether systemic review of early pipeline overlaps and the acquisitions of small biotech companies could have a chilling effect on investments and innovation.

Anu Sawkar:

Our second panel considered whether and to what extent past anti-competitive conduct should factor into merger review. State enforcer Gwendolyn Cooley began by explaining why prior anti-competitive conduct be a relevant consideration when reviewing pharmaceutical mergers. She explained how enforcers might approach analyzing both unilateral conduct and coordinated or collusive conduct when reviewing a merger. And then various panelists identified several types of anti-competitive conduct and regulatory abuses that may be more prevalent in the pharmaceutical industry. Professor Michael Carrier revisited and expanded on a theme from yesterday's panels. What impact should pharmaceutical company size and type have on merger analysis? Professor Scott Hemphill identified circumstances under which prior anti-competitive conduct composed a significant risk of post acquisition anti-competitive conduct. He also considered how enforcers should approach a proposed merger, where the proposed buyer is willing to pay a premium and thus may pose a risk of anti-competitive intent, but that buyer also has the potential to generate significant synergies and pro-competitive efficiencies. And finally, Raksha Koppam explained how anti-competitive conduct in the pharmaceutical industry, particularly impacts vulnerable and underserved communities. She suggested that enforcers should take into account these effects in our merger analysis.

Anu Sawkar:

It's been a thought provoking two days, thank you to all of our speakers, panelists, and moderators for sharing their expertise and insights with us. Thank you to all the organizers that made this event possible. The FTC events team and the task force partners, which includes staff from the federal trade commission, Canada's competition bureau, the European commission's director general... Directors general for competition, the UK's competition and markets authority, US Department of Justice's antitrust division, and offices of state attorneys general. And finally, thank you for your time and attention.