FORDHAM UNIVERSITY SCHOOL OF LAW
FORDHAM COMPETITION LAW INSTITUTE

47TH ANNUAL CONFERENCE ON INTERNATIONAL ANTITRUST LAW AND POLICY

ANTITRUST ECONOMICS WORKSHOPS + NETWORKING SESSION WITH HEADS OF AUTHORITY

Wednesday, October 7, 2020

Morning Session Sponsored by Edgeworth Economics

Welcome and Opening Remarks

James Keyte
Fordham Corporate Law Institute Director and Adjunct Professor, Fordham University School of Law;
Director of Global Development, The Brattle Group

MR. KEYTE: I want to thank everybody for attending Fordham's first virtual conference.

First, I want to wish everybody's families and colleagues the best of health and safety. These are, of course, very difficult times for everybody, but we'll get through them. Again, I hope everybody is safe and well.

In the meantime, going virtual in the business world and the antitrust field has been for

some a challenge; for others, just interesting; for me, of course, as a Luddite, a bit of a nightmare, a little bit of which I have already experienced today.

With this conference and going forward, we at the Fordham Competition Law Institute are going to create a platform for ourselves to have a virtual family, do some additional conferences during the course of the year, leading up to the annual live conference, which we will certainly do every September or October.

Today is our traditional Workshop Day. We have two economic panels coming up, one put on by Edgeworth Economics, the other put on by The Brattle Group. We hope everybody participates in those. There may be some time for Q&A at the end of those, so be ready to look for those.

In between those two workshops we are going to have a Heads of Authority Q&A session. Typically, in the live Workshop Day, the heads of authorities have their own meeting, a private meeting, that goes

on. What we are doing this year, being a little creative, is having seven key heads of authority from Europe and the United States do a question-and-answer session with me addressing tech tools, sustainability, and antitrust in the time of pandemic. It should be quite interesting, and we will certainly want questions from the audience.

We will also have instant surveys that we will do leading up to some of the panels. We hope everybody participates in those too.

Thank you very much.

Morning Session I
Conflicting Decisions in Pharmaceutical Class Certification Workshop

Moderator:
George Korenko, PhD
Partner, Edgeworth Economics

Panelists:
Jeffrey C. Bank
Partner, Wilson Sonsini

Justin Bernick
Partner, Hogan Lovells

Danielle R. Foley
Partner, Venable LLP

Tram Nguyen, PhD

Principal Consultant, Edgeworth Economics

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DR. KORENKO: Good morning. Thank you for attending the panel. I'm George Korenko. I am a Partner at Edgeworth Economics, an antitrust economist, and I regularly testify in matters involving antitrust, commercial damages, and other areas. I have done a lot of work in the pharmaceutical industry throughout my career, so this is going to be a very interesting panel for me.

We've got a great panel discussion for you today. We have four distinguished panelists. Our topic is the conflicting decisions we have seen in recent years in pharmaceutical class certification cases.

When we talk about some of these cases — whether it's *Nexium*, *Solodyn*, *Lidoderm*, *Asacol*, *Intuniv*, now with *Lamictal* and *Niaspan* — it may be difficult to interpret where we are in this landscape of cases in terms of what it takes to certify a class in a pharmaceutical class action case. Fortunately

for us today, our panelists are going to provide some insights into where we stand with respect to some of the critical issues that seem to be in conflict in these cases.

Our first panelist is Danielle Foley. She is going to discuss the issue of what constitutes a *de minimis* number of uninjured members of a proposed class. Danielle is a Partner at Venable LLP. She is a trial lawyer with extensive experience in complex class actions and multiparty litigation involving antitrust, false advertising, breach of contract, business tort, and unfair competition claims. Danielle has defended clients against both the Federal Trade Commission and private plaintiffs. She has defended pharmaceutical companies as a trial counsel in three reverse-payment jury trials held under the United States Supreme Court's landmark decision in *FTC v. Actavis* as well as numerous others.

Our second panelist will be Jeff Bank, who will discuss how courts have come down on the use of

averages in pharmaceutical class certification matters. Jeff is a Partner at Wilson Sonsini Goodrich & Rosati where he practices antitrust litigation and counseling particularly in the pharmaceutical industry. Jeff is an experienced litigator representing both plaintiffs and defendants. His work has ranged from complex multidistrict litigations and global cartel cases to actions against competitors. He has successfully defended pharmaceutical, technology, and media companies against class actions and has experience in all aspects of litigation from discovery through appeal. He regularly counsels clients on merger clearance issues and business practices. He has represented a diverse range of clients before the FTC, including companies from medical device, pharmaceutical, and media sectors. Jeff was recently named a Rising Star for 2020 by Law360.

Third, my colleague at Edgeworth Economics Tram Nguyen will provide an economic perspective on

predominance issues in some of these recent decisions. Tram is a Principal Economist at Edgeworth Economics. Since joining Edgeworth, Tram has worked on a range of antitrust, labor and employment, and public policy issues. She has particularly experience applying economic research and analysis in numerous antitrust matters within the pharmaceutical industry. She has coauthored papers on economic topics and legal developments in the U.S. pharmaceutical antitrust cases. She specializes in quantitative economic analysis and modeling within the context of industrial organization and antitrust, labor and employment, and firm management, and she has extensive experience with analyzing large and varied datasets as well as expertise in machine learning and statistical tools.

Finally, last but not least, Justin Bernick will close out our panel with a discussion of causality issues in pharmaceutical class certification. Justin is a Partner at Hogan-Lovells. Justin defends clients in antitrust lawsuits in state

and federal courts and has participated in some of the nation's largest antitrust class actions. He has experience in multidistrict and multijurisdictional litigation and consumer class actions. He has represented companies in the Department of Justice, Federal Trade Commission, and state antitrust inquiries, including merger and conduct investigations. Justin litigates a wide range of antitrust and competition issues pertaining to mergers and acquisitions, allegations of price fixing, market allocation, vertical and horizontal agreements, and monopolization. His work spans various industries, including life sciences and pharmaceuticals. Recently, Justin was named a Rising Star Under 40 by Law360 and was also named in the Legal 500 U.S.

That is our distinguished panel.

With that, I will get us started with Danielle.

MS. FOLEY: Thank you, George, and thank you all for joining us today.

I am Danielle Foley from Venable. As George mentioned, I try a lot of antitrust cases. Fortunately, I have tried a number of them in a number of years, which can be hard on the schedule but great for the experience.

One thing I have learned is that the technology always fails just when you think you need it to work, so we're just going to roll with it. Thank you, George, for recovering my slides and helping us out today.

I am going to talk about the concept of *de minimis* in the antitrust pharmaceutical class action space. This is an issue that has been hotly contested in cases for a number of years. It really asks a central question — that is, whether the number of uninjured class members is too many for the class to be certified. To understand this question you really have to think about two major questions: (1) why does it matter that there are uninjured class members?; and (2) whether there are just too many uninjured class

members.

The question of "Why does it matter?" really stems from two things: (1) the nature of the class certification tool in the requirements of the Rules of Civil Procedure Rule 23; and (2) the nature of the pharmaceutical's distribution and payment chain, which creates unique situations and unique questions for the antitrust pharmaceutical space.

If you think about the nature of the class certification tool, class certification, as we all know, is the exception in our system to the rule that litigation should be conducted by and on behalf of the individual named parties. That is why Rule 23 sets out a number of requirements in order for a case to proceed as a class action.

As the First Circuit said in *In re Asacol Antitrust Litigation*,[1] "The proper treatment of uninjured class members strikes at the heart of the competing considerations for Rule 23 certification," and really the question is under Rule 23 whether there

are too many uninjured class members can affect all of the elements of Rule 23.

In particular, they can affect predominance, which is the question: "Are there too many uninjured class members or common issues" — in particular, you see this with antitrust injury — "to predominate?"

You also see it with respect to ascertainability: Are there too many uninjured class members to be able to identify them and separate them from the injured class members in a reasonable and administratively feasible manner?

And then manageability, which is really the question: Are there too many uninjured class members to allow the plaintiffs to present all of their evidence and all of their elements in a way that protects the defendant's Seventh Amendment and due process rights?

If you think about the antitrust and the

[1] 907 F.3d 4251 (1st Cir. 2018).

pharmaceutical distribution cases, when you think about the pharmaceutical chain, you have to think about these cases are not the simple case where there is one defendant selling one product at one price directly to consumers. Instead, in all of these cases you have a brand company with brand products, you may have one generic or you may have multiple generic companies all selling different generic products, you have insurance companies, you have pharmacy benefit managers, you have wholesalers, you have retail stores and retail pharmacies of varying sizes, you have health and welfare benefit plans, and you have consumers, and they are involved in a web of different contractual arrangements.

What that means is not everyone in the potential classes are affected in the same way and not everyone is injured. How does this play out in these antitrust cases in the pharmaceutical space is that you will have different categories of uninjured class members.

We see this play out largely in the end-payor classes. That's not to say these issues do not arise in the direct purchaser classes, but you see them predominantly in cases involving end-payors, which are the third-party payors and consumers.

For example, what you see in cases alleging the delay of entry of generic products are arguments about brand-loyal consumers, and those are consumers who, even if a generic had been available earlier, would not have switched, they would not have paid a lower price, and thus they are not injured. You will similarly see it with respect to consumers who pay a flat co-payment for their insurance — if they have the same co-payment for the brand as they would have had for the generic, they have no overcharge, and thus no injury. You see these types of issues arise in these cases.

Now the question is: How many is too many? That is really the question of *de minimis.* Where did this concept of *de minimis* come from? It first arose

in the First Circuit's decision in *In re Nexium Antitrust Litigation*[2], which was a reverse payment case.

The timing of the class certification decision is a little unique and odd because the First Circuit issued its opinion after the jury trial was completed. I represented one of the generic companies. After a six-week jury trial, there was a full defense victory. The defendants asked the First Circuit to withdraw the appeal, but the First Circuit wanted to weigh in on this issue, and so the First Circuit proceeded with the *Nexium* decision. What the First Circuit said had a couple of key lessons and takeaways.

First, it is okay for a class to be certified with some number of uninjured class members as long as it's a *de minimis* number. Now, the First Circuit did not define what *de minimis* was; instead, the First Circuit said, "It will be a functional test." Really, what the First Circuit said was: "Is

[2] 177 F.3d 9 (1st Cir. 2015).

the number of uninjured so large that it renders a class impractical of improper? — that could be more than *de minimis*." "Is the number of uninjured so large that it causes non-common issues to predominate? — that wouldn't be *de minimis*." "Is the number of uninjured so large that it violates the defendant's Seventh Amendment or due process rights? — then it might not be *de minimis.*" But it gave no hard-and-fast rules and it left it clear as mud in that sense.

The other takeaway is that parties would need to come forward with evidence to support the calculation of the number of uninjured class members. The court concluded that it had not been shown that there was more than a *de minimis* number of uninjured class members. Really, if you drill down on the decision, what you see is that there wasn't enough evidence to take the number of prescriptions of Nexium — for example, the number of prescriptions that might have stayed on the brand product — to the number of class members, and that was a critical issue that the

First Circuit had. You see in the cases that followed *Nexium* real battles between the experts and the parties about trying to take the number of prescriptions and turn it into the number of uninjured consumers.

What happened after *Nexium*? Not surprisingly, there are conflicting results and scrutiny of the economic evidence. For example, there were some decisions, including one that came out right after *Nexium*, just a few months later, the *Vista Healthplan v. Cephalin, Inc. (Modafinil)* case, where the court in the Eastern District of Pennsylvania said: If it is more than 5 percent — that's what the evidence was, more than 5 percent uninjured — then that was not *de minimis*; that created problems across the range of requirements for Rule 23 that affected either the ability for the class be ascertainable, for the plaintiffs to prove predominance and some manageability — so the class was denied.

On the other end of the spectrum, we saw

some courts grant certification where there was a range of uninjured class members from 5 percent up to 10 percent. In *In re Lidoderm*, for example, even where the plaintiff's expert conceded 6–7 percent of the class members were uninjured, the class was certified.

In re Solodyn is one at the high end of the spectrum. There was a District of Massachusetts decision following *Nexium* that really leaned heavily on the *Nexium* decision. There the court certified the class even though the plaintiff's expert conceded that possibly 10 percent of the class was uninjured, and even under some scenarios put forward by the plaintiff's economist that 19—37 percent of the class was uninjured. But, with the guidance of *Nexium*, the court certified the class.

The takeaway from all of these cases was a real battle between the experts at class certification about how many class members were uninjured and how do you identify them.

That takes us to where we are now. Really, you see that there continue to be challenges to certifying classes in the antitrust pharmaceutical space, and particularly challenges with in the consumer class.

In 2018 the First Circuit went back into the fray, as I like to say, of this class certification issue in the *Asacol* decision. There the First Circuit walked back the reach of *Nexium* and did look at the unique facts and circumstances of that case. In *Asacol* the court denied class certification where at least 10 percent of the class was uninjured and the court recognized this was likely thousands of uninjured class members. As we will hear from some of our other panel members later on, this created real issues. *Asacol* recognized with predominance an antitrust injury, which has become a real focus point in a number of other cases that followed.

As one court has described the *Asacol* decision, "It is likely the death knell of

pharmaceutical antitrust class actions brought by indirect purchasers."

Following *Asacol*, we have seen again increased scrutiny and real difficulty certifying classes, in particular, that contained consumers. So, shortly after the *Asacol* decision, the District of New Jersey denied class certification where there were 10 percent uninjured class members, right in line with *Asacol*, and frankly calling into question the earlier decision of *Solodyn*, which had followed the *Nexium* decision.

You see other cases, particularly in the First Circuit, where there have been a number of these cases percolating, where class certification was denied, and in particular for consumers. For example, in the *In re Loestrin* case, the court denied certification to a consumer class with 6.7 percent uninjured class members but granted certification to the third-party payers; so you saw a split of the traditional end-payor class there.

In re Intuniv was denied class certification.

In *Asacol* on remand, interestingly, class certification was denied. Even where the plaintiffs had offered to jettison the consumers and just focus on the institutional payers, the court denied class certification.

So there are cases where on the margins, when you are down in the 5 or 6 percent range, you may still find some courts certifying classes with that number of uninjured class members, but it is harder. Courts are continuing to grapple with how many uninjured class members are too many and what level of scrutiny they need to bring to the economic evidence. In order to have your class certified you need a strong economic analysis that is backed up by a strong testifying expert, frankly. There is still no bright line by the courts to say, "This number is the magic number," but we see if it is greater than 5 percent there is trouble; if you are at 10 percent,

you are very much in trouble of getting your class certified.

I think one of the takeaways that we have seen and we will continue to see will be fewer consumer classes will likely be pursued and certified, with a likely larger focus on the institutional members, such as third-party payers, because of the real problems that you see with consumer classes and the problems present in these cases.

I will pass it back to you, George.

DR. KORENKO: Thank you, Danielle.

I have one question for you. You mentioned there is no bright line in terms of when you have too many or when you don't have enough to cross that threshold of *de minimis*. But when the economists of the plaintiffs and defense disagree and they are on opposite sides of those 10 and 5 percent, how do you see the court resolving those issues?

MS. FOLEY: You see the court really delving in and conducting the rigorous analysis that is

required and has been required since *Hydrogen Peroxide*. There are often competing *Daubert* motions filed against the experts and the courts consider those at class certification. The courts look for concessions by the testifying experts and look for places that they can put a real hold on it and say, "Okay, this is the bottom number; this is the lowest number the plaintiffs will concede exists," or "this is the highest number that they will concede exists." It is truly a battle of the experts at that point and the court making a factual determination.

DR. KORENKO: Thank you for your discussion. I think it's really interesting.

With that, we will move on to Jeff Bank to discuss the use of averages.

MR. BANK: Great. Thanks, George.

Hi, everyone. It's nice to see you here. I wish we were in person, but thanks to James and Fordham for organizing this.

Standard disclaimer: My views expressed

today do not necessarily reflect those of my firm, colleagues, or clients.

I am going to talk today about the use of averages and recent case law on the subject. Some of my colleagues here today will likely address some of the same cases that I am going to speak about but I think will be coming at it from different angles.

Before we get to when are averages used in class certification analysis, I want to take a step back and see how we got where we are.

There have been a number of Supreme Court cases over the last decade and numerous appellate courts have also taken up the question of how a court should evaluate class certification motions.

At the Supreme Court level, the *Dukes* case, the *Comcast* case, and the *Tyson Foods* case laid out some standards and some guidance for the lower courts in terms of evaluating class certification motions that I think are particularly important when it comes to the question of whether the use of averages is

appropriate in class certification analysis.

The Supreme Court has said that the lower courts must conduct a "rigorous" analysis; that analysis may overlap with the merits in some circumstances; the court should act as a gatekeeper regarding expert opinions offered in support or against certification; the expert analysis has to actually fit the theory of liability. The Court has held and endorsed the use of some statistical evidence as a means of showing common proof among class members — and we are going to really dig into that in terms of the use of averages.

The Supreme Court has stressed, though, that whether and when statistical evidence can be used to establish class-wide liability really depends on the purpose for which the evidence is being introduced and the elements of the underlying cause of action. It becomes very fact-specific very quickly.

Based on some of those Supreme Court rulings, the Third Circuit has described the district

court's responsibility as the following: "The district court is supposed to determine that the requirements of Rule 23 are met with any factual determinations made by a preponderance of the evidence. The district court is to resolve all factual and legal disputes relevant to class certification, even if they overlap with the merits, and the district court is to consider all relevant evidence and arguments including expert testimony offered by the moving and opposing parties."

So how does that get us to averages? Well, Rule 23(b)(3) requires that the plaintiffs show predominance in order to certify a damages class. Specifically, they need to show that questions of law or fact common to class members predominate over any questions affecting only individual members.

Whether a class might contain dozens of members or thousands or more members, the plaintiff's expert will need to develop a methodology that can be used to show that the class members were harmed, and that they were harmed in a sufficiently similar way,

by the conduct alleged to be unlawful. Assuming all of that can be shown via common proof, the expert will also need to show that damages can be calculated through a methodology that does not require individualized inquiries.

Experts have a number of possible methods to use to show that plaintiffs can meet their burden. One method is to show that an overcharge can be determined by looking at average real-world prices compared to average but-for prices.

The question for us today is: When is the use of averages sufficient to meet the standards of Rule 23? We are going to look at some of the cases in the last couple years that have really focused on this.

In re Niaspan (E.D. Pa. Aug. 13, 2019) is a really interesting case out of the Eastern District of Pennsylvania. It is one of the reverse payment cases. There were motions for certification by both the direct purchasers and the end-payors and,

interestingly enough, the court found one way for the directs and one way for the end-payors.

For the directs, the court found that there were very few uninjured customers, so the direct purchasers' expert's use of averages to show injury and harm across the direct purchaser plaintiffs was accepted by the court. The court looked into whether there were significant differences between the direct purchasers and did not find sufficient differences to justify denial of certification. The court also found that the defendants' insistence that the court focus on actual prices was flawed because the experience of customers in the real world was not necessarily equal to their experience in the but-for world. It was a fairly straightforward decision.

However, on the end-payor side the court found that the expert's use of averages in the common impact analysis simply did not suffice. The court held that the use of averages generally is controversial and found that courts have "come down on

both sides of the issue at the class certification stage."

The district court mused that the use of averages may be somewhat suspect, but not necessarily fatally flawed, and highlighted a theme of what I think will run throughout all of the cases that I will discuss, that the courts really need to conduct a rigorous analysis: they need to look at the specific drug product at issue; they need to look at the particular class that is being proposed for certification; and they need to look at real-world market factors that relate to that class and that particular drug. In doing so the court really needs to focus on differentiation among the data between particular plaintiffs in the proposed class and whether there are indicia that the averages being proposed by the experts are concealing or not concealing certain outliers within the proposed class.

For the end-payor class in *Niaspam* the court eventually concluded that the use of averages simply

does not show whether an individual class member was injured; that it masked uninjured proposed class members, going to the problems that Danielle just spoke about; and that it masked large variations in class members' purchase prices. Now, of course, there may be some variation in purchase prices that is acceptable in a common impact analysis, but where the variation is so large as to cause individualized inquiry to be necessary, then it may be that the class is unsuitable for certification.

In this case, the end-payor plaintiffs (EPPs) also really provided no means to identify uninjured class members — such as brand loyalists, coupon users, and flat co-payers — and we will see how that is different in another case in a little bit.

Some of the other panelists will talk about the *In re Lamictal Antitrust Litigation* case (3d Cir., Apr. 22, 2020), so I am going to just focus on a few high-level observations here.

The Third Circuit overturned the district

court's certification of the class in this reverse payment case. I think the decision can fairly be read to mean that the courts really need to undergo and conduct a rigorous analysis when looking at the Rule 23 standards and it is not enough to just do so on a superficial level.

Here the lack of rigorous analysis strongly colored the Third Circuit's holding, maybe even more significantly than the Third Circuit's criticism of the use of averages. The Third Circuit emphasized the rule that factual matters must be determined at the class certification stage if they are necessary to determine whether certification should be granted.

Here the parties had put forth evidence regarding complex pricing strategies and machinations between the brand and the generic — they were very complex — and the Third Circuit essentially chided the district court on not conducting enough analysis on the impact of those pricing strategies.

The court also reiterated language that

every plaintiff must be able to show antitrust injury, kind of bleeding into the analysis that Danielle talked about, about what percentage of uninjured plaintiff members may be too much. The district court said, "Every plaintiff must be able to show antitrust injury through evidence that is common to the class," and it cited to an earlier case, *Hydrogen Peroxide*: damages may not be susceptible of measurement across the entire class. The Third Circuit really dug in here on the difference between showing injury versus showing damages, and I think that does get conflated in some of the district court opinions that we are discussing today.

On the substance of averages, the Third Circuit found that there was a very high presence of potentially uninjured customers, and that really sank the plaintiff's expert's use of averages here. Up to a third of the proposed class paid no more or less for the generic drug than they would have absent the defendant's supposedly unlawful agreement. So 33

percent potentially uninjured class members was too much here.

There are three other decisions that I want to talk about today.

The decision in *In re Loestrin 24 Fe Antitrust Litigation* in the District of Rhode Island came down in July 2019. There it was a mixed theory by the plaintiffs as to the allegedly unlawful conduct. They alleged that the brand had obtained its patent through sham; they alleged that the brand had conducted a practice known as product hopping, where it allegedly unlawfully transferred the market from one product to another to avoid generic entry; and the plaintiffs alleged a reverse payment between the brand and the generic to delay generic entry.

The court acknowledged that the complicated facts and legal theories really make it challenging to figure out the but-for world. For example, what if one of the theories from the plaintiffs was eventually proven true but the other two were not; how should an

expert figure out what the but-for world would look like in that context?

If the plaintiffs were able to show that all three types of conduct were actually unlawful, what would the but-for world look like in that context? Would each proposed class member be harmed in a similar way as a result of all the different methods of alleged unlawful conduct, or were some class members harmed by one type of conduct but not another?

The court acknowledged those questions, acknowledged that they were complex and difficult, and the court focused on the direct purchaser's expert's use of averages, particularly in the purported context of damages. The court noted that the methodology put forth by the expert incorporates the variation across class members in the actual prices they paid and in the prices they would have paid, and the court said that providing averages correctly summarizes the combined effects of all of these class members in a single class-wide overcharge measure. The court said

that aggregating damages in this way is well accepted.

The defendants focused on trying to show differences between the proposed class members: those purchasers who had been purchasing the brand product but would still continue to purchase the brand product; those purchasers who had been purchasing the brand product but in the but-for world would have switched to the generic product; and those purchasers who only purchased generic products and alleged harm. At the end of the day, the court said that the model works for them all.

I think one of the keys here, though, is going back to the point that this case really involved multipronged alleged unlawful conduct. The court noted that "defendants had not earned the benefit of the doubt when the very reason we cannot know the answer to that question is because of their alleged wrongdoing" and cited to the *Namenda* case. So the court essentially put the burden back on the defendants to overcome the fact that the alleged

conduct was so complex.

In re Restasis Antitrust Litigation (E.D.N.Y. May 5, 2020) is similar. There it was an end-payor class that sought certification. It was another complicated case with an alleged multiprong scheme to delay generic entry.

The expert used a "yardstick" approach, comparing what the but-for world would have been had generics entered earlier for Restasis. The expert looked to another similar drug product to see what happened there in the real world and then used averages to calculate damages.

Notably, the expert in *Restasis* did identify and exclude proposed class members that were flat co-payers — government entities and fully insured through their health plans — so the expert took steps to identify and exclude potentially uninjured class members from the analysis, which I think makes a difference. To Danielle's earlier point, the experts are really going to have to dig in and do a much more

in-depth analysis to identify those uninjured class members and try to exclude them early on in the analysis.

Similar to the *Loestrin* case, the court pointed to the complexity of defendant's alleged wrongdoing as the cause of any uncertainty in the class certification analysis. The court said, "If the plaintiffs cannot prove their damages with precision, the most elementary conceptions of justice and public policy require that the wrongdoer shall bear the risk of the uncertainty which his own wrong has created."

Interesting that at the class certification stage the court is essentially holding the defendant out as the wrongdoer and placing the uncertainty on them there, before really any finding on the merits, and even in the class certification proceedings the court did not make any finding on the merits that the defendant was in fact a wrongdoer and yet held them to a heightened standard.

In *In re Zetia Antitrust Litigation* (E.D.

Va. June 18, 2020) there was a direct purchaser class in the Eastern District of Virginia. *Zetia* came after the *Lamictal* decision. The defendant cited *Lamictal* and said, "The plaintiff's use of averages in *Zetia* was improper and that the court did not conduct enough of a rigorous analysis on the plaintiff's expert."

The court did acknowledge that under *Lamictal* the use of averages may be inappropriate in some circumstances, however the court distinguished *Lamictal* noting the unique contracting strategy involving a nuance in the particular anti-epilepsy drug market that was at issue in *Lamictal*, and the court acknowledged that the defendant's real-world pricing strategies may impact whether averages can be used; you have to look at the market factors. But ultimately, the *Zetia* court found that the defendants failed to put forward evidence that the Zetia drug was marketed in the same way Lamictal was.

So the burden does shift to the defendants to come forward and show that real-world market

factors, nuances about the particular drug, unique circumstances about payers and purchasers in a particular drug market, differences between channels (whether through wholesale, retail, institutional) — that those really make a difference and foreclose the use of averages.

So where does that leave us today? It is pretty clear that the courts all acknowledge that they have to conduct a rigorous analysis, that the merits may come into play and may really matter at the class certification stage. It also has emphasized the battle of the experts that will occur at class certification even before the battle of the experts at the merits stage, becomes a precursor to that, and in some ways may limit the analyses and arguments that can be put forth at the merits stage depending on what the parties put forward at class certification and depending on the court's holdings at the class certification stage.

Sophisticated econometric analyses are

absolutely necessary in class certification, particularly in end-payor cases where you have distribution chains in the pharmaceutical industry that are incredibly complex. To try to show that common proof can be used to prove impact and damages for those end-payors at the bottom of the chain really requires significant and substantial analysis, and *Daubert* motions are going to become even more common at the class certification stage than they already were.

It is also important to keep an eye on the non-pharma cases. Of course there was the *Tyson Foods* case that I talked about earlier; the *Aluminum Warehousing* (S.D.N.Y. July 23, 2020) case in the Southern District of New York; the earlier cases on rail freight and hydrogen peroxide. I think the use of averages is going to become a hot topic in numerous industries and looking outside pharma is going to be important.

I do think, though, that pharma is unique in

many ways. There have been rapid and significant changes in the industry over the last ten to fifteen years — consolidation horizontally and vertically; growing power of pharmacy benefit managers to influence pricing and supply at multiple rungs in the chain; the difference between a generic product, a brand product, a specialty product is blurring more and more so competition between pure brands and generics looks different now than it did ten or fifteen years ago in some circumstances; complex insurance agreements that may require individualized inquiry; growing use of rebates and discounts to compete for particular customers or channels.

All of these complexities weigh against the use of averages because it really becomes a question of whether it is possible to show that any pharmaceutical purchaser at any level is truly "average."

George, back to you.

DR. KORENKO: Thank you, Jeff. Very

interesting.

I do have one question. You talked a lot about the merits issues coming up more and more at the class certification stage. In my experience, a lot of times the courts are reluctant to address at least some of the merits issues. Do you see this changing as we go forward given some of the recent cases we have seen?

MR. BANK: I do. I think, especially with the *Lamictal* decision, the courts are really under fire to dig into the facts, figure out the particular nuances relating to a specific drug, figure out what the competition in the marketplace was, figure out what it would have been in the but-for world. So I do think the merits are going to become more and more important, which has important implications for the litigation overall.

I know in the past in some cases we have tried to bifurcate class certification discovery versus merits discovery. I think it is going to

become even more difficult to bifurcate that. It means that you may not be able to do class certification proceedings as early in the case as plaintiffs or defendants might want and class certification may have to wait until the end of fact discovery.

Third-party discovery is, of course, critical in pharmaceutical antitrust cases, and beginning that process of sending out subpoenas to those third parties as early as possible is going to be critical.

I think the merits findings at the class certification stage will also accelerate the litigation. There will be fewer novel issues to address at the summary judgment stage, and you may start seeing settlements and resolutions come earlier in litigation than they would have otherwise.

DR. KORENKO: Thank you, Jeff. Very interesting.

Next we will turn to Tram to talk about the

economics of predominance.

DR. NGUYEN: Thank you, George.

To continue the discussion I am going to cover the economic analysis of predominance and, in particular, I will talk about some of the direct purchaser cases and end-purchaser cases from the angle of antitrust injury and damages, and then I will review some recent court decisions on the issue of damages and on the issue of uninjured customers.

First, let's talk about the economics of class certification. From the perspective of economics, when we talk about the requirements of class certification, it usually hinges on two fundamental questions.

The first question is: Can plaintiffs show with common evidence common injury to the entire class? This means can all or nearly all class members be shown to have suffered antitrust injury from the conduct — for example, can the plaintiff show with one regression model that all class members have suffered

an overcharge?

Once the first question is established, then the second question becomes: Can plaintiffs also rely on the formulaic approach to calculating damages?

In economics we define a customer to have suffered injury when the actual price that he or she paid is higher than the but-for price absent the conduct, and damages is then the difference between the two prices.

For an individual inquiry regarding the use of averages, let's review a specific direct purchaser case. In general, a lot of cases that we see today have a common formula where the plaintiff's experts would rely on average prices to show common proof of injury to the class. What the plaintiff's experts usually do is to calculate one average but-for price for all class members and also, in a similar fashion, what is the average actual price for all class members. If the average but-for price is below the average actual price, then the class is considered to

have suffered injury.

In some of these cases, the defendant's experts might point out that for some class members the actual price that they pay might be below the average but-for price and therefore they are uninjured by the conduct. But if the number is small, as Danielle explained before, the courts have concluded that a small absolute number of uninjured class members might be picked off in a manageable manner and that would not hinder class certification.

In the case of *Lamictal*, as Jeff explained the background of the case before, this is a case where the court actually went in the opposite direction. In April of this year, the court of appeals vacated and remanded the class certification decision by the district court.

Lamictal is an interesting case where the facts of the case made the use of averages become inappropriate and we can take a closer look at why that is the case. In this case the brand manufacturer

GSK, instead of competing with the generic on introducing an authorized generic product, competed on price. That means GSK then had negotiations with purchasers or had strategic pricing, and that in turn caused Teva, the generic manufacturer, to also lower its price preemptively. The defendant's expert actually showed that twenty-five out of thirty-three generic-only purchasers likely paid less in the actual world than absent the conduct. This leads to the situation where we have a large percentage of the class being uninjured or likely uninjured by the conduct and there is a need for individualized inquiry to look at individual circumstances and study whether an individual class member was actually injured or not.

To demonstrate how this works we can look at a simple example where there are only four wholesalers in the class and each one has an actual price that they pay per pill and the but-for price. The actual price here is the blue bar and the but-for price is

the orange bar.

If we follow the plaintiff's theory of injury, the plaintiff's expert would compute the average actual price (the blue line) and the average but-for price (the orange line). As long as the blue line is above the orange line, then there is injury to the entire class, and this is true in this example.

However, if we look at the individual data, Wholesaler 2 and Wholesaler 4 did not suffer any injury because the actual price is below their but-for price, and they make up 50 percent of the class. This is an example where averages actually mask individual differences in prices and there is a need for individualized inquiry into the question of injury.

Next I will cover the issue of identifying uninjured class members. As Danielle has mentioned, it is common to have uninjured class members in a class. But when does it become an issue to class certification?

In the case of *Asacol*, as we have heard

today, the plaintiff proposed a similar mechanism to *Nexium* where in this proposal the claims administrator could rely on an unrebutted affidavit from putative class members to identify who was injured or uninjured by the conduct. But the First Circuit in the case of *Asacol* actually held that if these affidavits could be rebutted, then the approach is no longer appropriate.

But in the case of *Asacol* there is a generic delay and also a product hop, which means the brand manufacturer in the case switched the product from one formulation to another and forced consumers into a hard switch before the generic became available. The goal is to retain market share for the branded product before the generic entry.

Both sides in this case, the plaintiff's and defendant's experts, estimated approximately 10 percent of the class would be uninjured by this conduct. Because of the nature of the case, we might have brand stayers; we might have consumers who purchased the old formulation and have stopped

purchasing the new formulation altogether before the generic was available; or there could be consumers who are insensitive to price because they have the same co-pay for brand and generic products, so they would also not be injured by the conduct.

The problem becomes how we identify these members in the class from the data. In the case of *Asacol*, identifying these uninjured class members became an infeasible task. The plaintiffs proposed no other mechanism besides following *Nexium* to identify and remove uninjured members from the class. And, because this is an end-payor case, 10 percent of an end-payor class is not "a small absolute number" that can be removed before trial, so the court did not certify the class.

But what is interesting with Asacol is also there is another wrinkle on top of the issue with uninjured class members. The plaintiffs in the case also proposed an approach where the plaintiff's expert, Dr. Conti, proposed a class-wide proof of

injury by estimating that the generic drug would take up 90 percent of market share when it became available and they could use this probability to prove that all or nearly all class members were injured. But the court concluded that in this case if we use the 90 percent market share to show that an individual consumer would likely purchase the generic, and therefore be injured, it would lead to the wrong conclusion that everyone was injured by the conduct.

We can dissect what this means, but first I want to point out that the district court's opinion on 90 percent of market share means that 90 percent of the class being injured is also misleading because we are talking about a market of a product, which doesn't really mean an individual only consumes one product or one pill in the market.

But even if we assume that 90 percent of the market will convert to the generic, that can be used as an approximation to the probability that a person will purchase the generic, it still does not mean that

this is going to be proof to show that the entire class is injured because if we look at a simple example with paying consumers in the market, we know that nine out of ten will purchase the generic and the other one will purchase the brand, for simplicity.

But if we look at a given consumer, we do not know whether in the but-for world that given consumer will still purchase the brand or the generic, and therefore is uninjured or injured by the conduct. If we go ahead and assume that everyone is likely to consume a generic and that therefore they are injured, we will arrive at the wrong conclusion that ten out of ten consumers here will purchase the generic. But the data show that in fact there is one person who is uninjured, so probability methodology is not a deterministic approach for class-wide proof of injury.

Now if we combine both the problem of the use of averages and uninjured customers in an end-payor case, we arrive at *In re Niaspan Antitrust Litigation* (MDL No. 2460, 2020).

The use of averages, in the view of the *Niaspan* court, is that it is a common approach and can be acceptable as long as differentiation in the data being used to compute the average prices is not so large that the average becomes misleading or, in the facts of the case, allow that the averages do not conceal the true story behind the data. *Niaspan* is again a generic-delay case where there is an end-consumer class including the third-party payors and end-consumers who purchased Niaspan or the generic version of Niaspan.

In this case, the plaintiff's expert relied on an average overcharge model that relied on several assumptions, the literature on generic market substitution rate and price discount, and the plaintiff's expert also used the rise in quantity from the Niaspan product and the yardstick product to calculate a yardstick model. There are several issues with this approach.

First of all, the yardstick model is not a

model to show class-wide injury and there is large variation in the data regarding restriction costs to third-party payers and consumers. Specifically, from the data, third-party payers might pay anywhere between zero to $100 for the prescription, and similarly consumers can also pay between zero to $250, so immediately the average will mask all of these large variations in the data.

But the issue also lies with the assumptions that the model is based upon. If we use the literature to approximate the generic substitution rate, the literature is based on a variety of drugs that might not be specific to the drug at issue or might not have the same characteristics as the drug at issue. We can think, for example, of a lifesaving drug, a psychoactive drug, might have very different characteristics, and therefore consumers might be less likely to switch to the generic, so the generic substitution rate is not the same as what the literature says.

Similarly, the yardstick products also might not have the same characteristics as the product at issue. But, most importantly, the plaintiff's expert's model in this case is an average overcharge model, and that is what it means — it computes an average overcharge. At best, it can calculate the overcharge across all class members on average but does not really prove whether an individual class member, PPT or consumer, actually suffered an injury.

So the court in the case of *Niaspan* concluded that the use of averages in the yardstick model is not a proof of class-wide injury; it masks uninjured class members; and also large variations in the data. Also, as Jeff mentioned, the end-payor plaintiffs in this case also provided no means to identify uninjured class members. They could be brand loyalists who will continue to purchase the brand even when the generic was available; or consumers who use a coupon in their purchase and therefore do not pay a higher price; or flat co-payors who have the same co-

pay for the brand and the generic. This became an important issue in this case even when the EPPs proposed to use third-party data to identify the uninjured class members.

We can think of the issue with flat co-payors. Even if we have third-party transactional data to identify a flat co-payor in the data, we would have to observe the same consumer who purchased both brand and generic at different points in time and under the same insurance management structure. But, in reality, we might only observe the consumers who purchase only the brand or only the generic; or, even if they made a purchase of both, they might have switched from one insurer to another insurer over this period of time; or their insurance plan structure might have changed and therefore their co-pay structure changed. So it became quite impossible to identify the uninjured class members from the class even if the plaintiff proposed to exclude flat co-payers from the class definition.

In conclusion, the issue of common proof of injury becomes an important factor, continues to be an important factor, in class certification decisions where, in particular, an average overcharge model, which is often relied on by plaintiff's experts, is not a common proof of injury, especially when we see that there are large variations in prices in the data and the use of averages cannot mask individualized inquiry.

Also, plaintiff's and defendant's experts, even if they focus on assessing subgroups in the class that might be uninjured, the issue of identifying who these uninjured customers are becomes important. If it is complicated to identify and remove uninjured class members from the class, this might become a problem for class certification.

Last but not least, probably the approach is not a deterministic approach and cannot be used as common evidence for class-wide injury.

Thank you, George.

DR. KORENKO: Thank you, Tram. Very interesting.

I want to pick up on one thing that you mentioned. You talked about probability is not deterministic and how the 90 percent probability of switching to a generic does not tell you that necessarily 90 percent of the class is injured. Can you explain a little more why a probability does not tell you the same thing as the fact of injury?

DR. NGUYEN: The answer is twofold.

First of all, if you look at a market as a whole, we are looking at transactions or the number of products being sold in a market, not the number of consumers in a market because the same patient might refill their prescription a few times or buy multiple products at once. So the 90 percent market rate does not translate to 90 percent of the class purchasing the generic or the brand.

On top of that, this is the average probability for the entire market, but each individual

will have a different probability of purchasing the brand or the generic depending on their insurance plan or their personal preferences or their doctor's preferences for the drug. So we cannot just apply the same rule of thumb, 90 percent probability, to everyone in the class. We have to look at their individual circumstance to determine whether in their but-for world, given all of their individual factors, will they purchase the brand or the generic.

DR. KORENKO: Great. Thank you, Tram. I appreciate that.

With that, we will turn it over to Justin.

MR. BERNICK: Thanks, George. Thanks, everybody, for listening and for having us here to speak with you today.

I am going to take a little bit of a step back here. We talked a lot about lack of injury, uninjured consumers, using averages, proportions of uninjured consumers. I am going to look at little bit at the question of "Why?" — underlying those

determinations that there may be uninjured consumers in the class, what is the underlying causal reason for that lack of injury or the injury itself?

Just speaking for myself as an impatient trial lawyer, I like to ask, "Well, what is the core issue in dispute here?" Often, these pay-for-delay cases hinge on some underlying factual predicate. To what extent can a court grapple with that at the class certification stage, or should the experts just assume that the actual predicate is true and defer that calculus to later on down the road for a merits decision at summary judgment or trial? There are some cases that go in different directions on that.

I think the first predicate to keep in mind is that it is pretty well established under Rule 23 that it requires an evidentiary showing, meaning facts or some sort of common proof. We talked a lot about the economic models that plaintiffs put forward to attempt to satisfy that burden of common proof of harm or impact to the class members.

We have talked a lot about how that economic model, that common proof that the class might put forward, could mask individuals who are not injured to the point where common questions no longer predominate under Rule 23 and a class should no longer be certified.

But again, there is this closely related question here about the factual or causal predicate to the alleged injury — what actually causes this proportion of injured class members that could defeat class certification at the end of the day? What if plaintiffs' common evidence or their economic model is based on an underlying factual or causal predicate that is just disputed or even demonstrably false?

There are lots of these factual predicates underlying a pay-for-delay case. It could be the underlying validity of the patent; it could be FDA approval issues; it could be at-risk entry by a generic that has occurred even apart from any agreement that is being challenged in the case; and it

could deal with other issues related to a but-for entry date — all sorts of underlying factual predicates that are assumptions that are built into the economic models that we talked about earlier in the day.

So what if some of those predicates are just not true or disputed? Is a court required to grapple with those at class certification? There are some conflicting cases in this area, and we've talked about some of them already, but I am going to talk about them in a little bit different way than just what the economic model might predict.

Lamictal is one of the cases that has come up repeatedly today. There, of course, it's a direct purchaser. The part that I'm going to talk about is the drug purchaser case challenging GSK's agreement with Teva not to launch an authorized generic.

The district court certified the class. The Third Circuit reversed with some really strong language about how the judge should have resolved

factual disputes. If you are a defense attorney primarily, you are going to see a lot in here that you will like — we will talk in a bit about the language in other cases that if you are on the plaintiff's side you might like — but there is a lot of strong language, including the language on this slide, about how the judge really should have grappled with some of those factual disputes, and language that is stronger than you see in a lot of class certification opinions. The question is: "Why?"

Here I think it is important to understand the predicate for the Third Circuit's finding that the model masked averages and masked uninjured consumers. One of those predicates is that the Third Circuit noted that the defendants argue that GSK competed with Teva, even though it did not have an authorized generic, through this unique contracting strategy of offering targeted discounts to pharmacies on the branded product, the branded Lamictal; and that that strategy, in turn, led Teva to reduce the price of its

generic even though there was no authorized generic (AG) on the market. In some ways, this is a frontal assault to the legal theory in the case, that the No-AG provision actually reduced competition. Here you had a contrary theory being offered by the defendants that there was robust price competition even with the alleged reverse-payment agreement.

You could imagine some court saying, "Well, that's a merits issue. Let's kick the can down the road. We'll deal with that at summary judgment. The plaintiffs are entitled to assume for purposes of their economic model that there was causality, there was impact, despite this contracting strategy. That is something for a jury or a fact finder to resolve later on in the case."

But the Third Circuit said, "No." The defendant tried to argue, successfully here, that this contracting strategy led to lower prices for certain purchasers than they would have paid even if GSK had launched an authorized generic. The court said that

the district court should have grappled with that underlying factual dispute about whether Teva lowered its price in response to this contracting strategy, and whether absent the settlement agreement GSK would have pursued the strategy.

In other words, the Third Circuit was saying, "You need to resolve this battle of the experts. You need to resolve this underlying factual predicate about causality at the class certification stage; it's not something you can punt on and just make an assumption about later on in the case."

Again, there are the other issues that are premised on that about averages and lack of injury to a certain proportion of consumers, but there is this underlying causal question that the Third Circuit said the district court should have resolved.

And there are cases going the other way. Again, these are cases that we've talked about before too.

In re Solodyn Antitrust Litigation (2017 WL

4621777, C.D. Mass. 2017) was a direct purchaser case challenging reverse payment from Medicis to Impax. Here the issue was at-risk generic entry: you had various generics that were entering at risk, and the defendants argued that the plaintiffs could not satisfy the prominence inquiry under Rule 23 because, in part, generic Solodyn was available through at-risk entry during the class period; so even though you had exclusion of a potential generic competitor, you've had generic competition present in the market; and, if there was, then how could you have an actual impact to class members?

This sounds in some ways similar to the *Lamictal* story: If you have this underlying factual or causal predicate that is missing for the alleged harm, or some reason why the harm would not be suffered by the class members, then shouldn't the court consider that at the class certification stage?

Here in *Solodyn* the court reached the exact opposite conclusion with some language that is helpful

to plaintiffs in these cases, finding essentially that the question of whether the agreement reduced competition in light of at-risk injury was a question for the jury; it is not a question for the court that applies certification — let's push that back and decide it later — but the plaintiffs are entitled to rely on this assumption of causality and that the at-risk entry would not have impacted the class members and prevented the injury that they suffered.

In re Glumetza Antitrust Litigation (2020 WL 4732333 (N.D. Cal. 2020) was a similar story, a direct purchaser case challenging a no-authorized-generic agreement. The defendants argued that Lupin would not have entered because it expected to lose the patent suit. Again, this is a core factual predicate: if there would have been no entry, there would have been no harm to any of the class members.

The court there, sort of like with *Solodyn* said, said that the plaintiff's expert was of course permitted to assume the "causal link" for purposes of

the model of impact and assume that Lupin would have entered and that the alleged price hikes would not have occurred. Again, the court said, in language that will be helpful to plaintiffs, that these questions would be decided at summary judgment or at trial and can be answered with common evidence.

I think the common thread that I see in these cases — because I think there is a common thread, even though on their face they seem to be anomalous with one another — I think the court in *Glumetza* put its finger on one of the important distinctions here, and that is whether or not those causal questions, those questions related to impact, are capable of yielding common answers to the class. If those causal questions could result in individualized inquiry and break down into mini-trials for each of the individual consumers, then those are causal questions that I think under *Lamictal* courts are obligated to address at the class certification stage. You can't just punt on those questions if the

answers to those causal questions do not reveal common answers.

But I think in *Glumetza* the court was saying that when you have this underlying factual predicate that is common to the class, or potentially common to the class, and yields common answers, that is not one that the court should be wading into.

There are some specific quotes in *Glumetza* that go to this issue. "Defendants raised the patent merits to change the but-for scenario and jump ahead to the impact analysis," and the court said that wasn't appropriate.

The court also said: "The class doesn't just break down if the defendants are right. Instead, the entire class loses."

Another way the court put it is: The harms don't become individualized; instead "the harms will simply fall away entirely."

In other words, if the defendants are right that there would not have been injury, then nobody was

injured, and that is susceptible to common proof and something that the court can address later on after the class is certified.

I think that's where I would leave things in terms of the overall conclusion here. The plaintiffs and defendants both tried to inject merits-related issues or questions that they perceived to favor them in the class certification inquiry for the court to resolve, and where we see those getting traction, if at all, is where those underlying causal questions or impact or injury questions are not susceptible to common proof.

Maybe another way to frame it — although this is sort of a semantic distinction — is in my mind the causation question is about whether the alleged conduct caused the anticompetitive harm — for example, whether the reverse payment settlement caused delayed generic entry.

The impact question is a slightly different question: Whether a particular class member was

injured by the anticompetitive harm. Courts might grapple with those underlying causation or merits question, that it's necessary in order to determine whether common proof can show impact to each of the individual consumers.

If the answer is yes, that that question related to causation or impact could lead to individualized inquiry, then that is something that courts should, and sometimes do, as in *Lamictal,* to resolve at the class certification stage.

I'm intentionally trying to be brief in order to have a little bit of time for questions at the end, so back to you, George.

DR. KORENKO: Thank you, Justin. Very interesting. I appreciate the discussion.

One question I have for you is: when you are talking about the causation issues, I am wondering — obviously, this is a slightly different tack — when we look at the *Comcast* case, where the damages analysis had to line up with the theory of the case, how does

that dovetail with the causation issues you are discussing?

MR. BERNICK: I think it dovetails pretty well actually. *Comcast* has taken on sort of a mythical life of its own in the class certification arena where people try to make *Comcast* arguments in every case and they will spin *Comcast* in different ways.

At its core what I think *Comcast* is about is that the plaintiff's expert's model must be rejected as common evidence of impact if it cannot distinguish the impact of the unlawful conduct from other factors. In that case, as folks probably know, there were four theories of impact and injury. Only one of those actually survived by the time the case got to the Supreme Court.

The Supreme Court said that because the model just calculated aggregate damages from all four theories but could not isolate the effect or impact of the one theory that survived, then the model had to

fail; the model was no longer causally linked to the theory that had survived in the case. Another way of putting it might be that the expert model did not fit the legal theory that was still on the table and could not isolate those particular damages.

In my personal experience, *Comcast* is often invoked but somewhat rarely successful in isolation in defeating class certification. I think that is probably true largely because plaintiffs and experts are careful to try to ensure at least some alignment between the legal theory or the causal theory that is being alleged and the economic model particularly in light of *Comcast.*

The actual situation at issue in *Comcast*, where you have a damages model that contemplates harm from theories that are no longer being alleged or things that are not unlawful, is somewhat rare, but again it is invoked pretty often.

There are some exceptions where *Comcast* does get some traction. *Skelaxin* would be a good example,

where the district court denied certification for end-payors for a variety of reasons, including ascertainability. But the court also there noted problems under *Comcast*, that the plaintiffs' model included transactions with entities that the plaintiffs later argued should be excluded from the class. So there was a disconnect between what the model was actually modeling and what the plaintiffs were alleging in terms of harm, and that is the type of situation where *Comcast* can get some traction.

In contrast, you have cases like *Modafinil* where the Third Circuit reversed the denial of certification. It was over objections by the defendants that the plaintiffs' model inappropriately masked individual issues, like *Comcast* did, and just calculated aggregate damages from five separate reverse-payment agreements rather than looking at them individually. The court said: No, that *Comcast* issue is not really sufficient to deny certification here, and distinguished *Comcast* on the grounds that the

plaintiffs' theory was premised on the aggregated injury from those five different agreements.

So there are cases that go in different directions, but in a vacuum, George, I do not see *Comcast* as often the sole reason why certification is denied in these cases. It is often invoked but, again, because everyone is sort of hyper-focused on this issue of alignment between the legal theory and causal theory and the model of impact. I have not seen it be successful in a vacuum by itself with a lot of regularity.

DR. KORENKO: Thank you, Justin.

With that, I'm happy to turn to questions. While we wait for some questions to come in, I am curious if any of our panelists have questions for each other in terms of these presentations. There has been an overlap clearly in terms of these discussions, but there are a lot of issues that are nuanced, as you all distinguished the *Lamictal* case from some others because of the unique contracting strategies

and new fact patterns.

I think fundamentally that gets down to some of the merits-based issues that Jeff and Justin talked to, and then, ultimately, those issues affect the *de minimis* issue because once you have that fact pattern and you have identified these uninjured class members, how many are there; and, to Tram's point, how do you figure out who they are even if you know how many?

MS. FOLEY: I can ask a question for Tram just as an economist. What do you think are the most difficult issues to answer as an economist? What are the most interesting ones to look at from your perspective in the class certification arena?

For me, each of the questions under Rule 23 really do have an economic aspect to them. I would be curious from an economic perspective which ones you think are the most interesting or the most difficult to answer.

DR. NGUYEN: I think the most interesting issue to look at usually from my experience is how do

we determine the but-for scenario for each individual consumer, whether they are a TPP or an end-payor, because the data in these types of cases does not really include everything and we have to tease information from the documents, from the line structure, and the data and transactional data together. We do not observe net prices, for example, that a TTP paid or an end-consumer paid, so in order to figure out that whole story and piece them together I think is one of the most exciting and interesting exercises that we have done.

I think it is also a valuable lesson for both plaintiffs' and defendants' experts to think about rather than just immediately jump to looking only at the average price because that doesn't really tell even a small part of the whole story.

MR. BERNICK: I have one comment/question that anyone can chime in on. One thing lurking in the background here is if you are on the defense side and you identify that there is a bunch of uninjured

consumers, very often you find yourself in the box of saying, "Well, now that I've identified them, the court can draw a circle around them and exclude them from the class."

There is a tension between digging into the model and identifying who is not injured and walking into a situation where they can be easily carved out and excluded and have a more cohesive class. So there is this tightrope of "Well, there are uninjured consumers, but we have no idea who they are. We can tell the court that it is 10 percent of the class, but we really do not know who that 10 percent is."

I am curious about others' experiences and how they navigate that issue. I know that's always a tightrope that you run into.

MS. FOLEY: I'll be happy to take that one because that is one of the issues you often face in these cases. Conceptually, you can say, "Look, there are uninjured" — I think, as the court in the *Modafinil* case said it — "but I cannot tell you

exactly who they are because every single one of these consumers has the possibility of being the brand loyalist, the flat co-payer, and you have to look at the coupon usage. I can tell you from looking at the group of data I have that there is at least 10 percent or so that are uninjured, but I cannot tell you 'It's Joe, it's Sally, it's Mary' — I cannot tell you who they are."

Trying to get the court to understand that issue is definitely a struggle because you do not want to fall into that trap of "Oh, I have identified the people right here; just carve them out; it is easy," because it is really just not that hard to do. I think that is a real problem.

MR. BANK: I think it also highlights the difference between direct purchasers and end-payors. With the direct purchaser classes, especially in pharma antitrust, they are usually limited to a few dozen at most, and identifying uninjured direct purchasers or power purchasers may be a lot easier at

that level. But once you start getting down to the end-payors, consumers, insurers, or even indirect reseller plaintiffs, the ability to identify the particular uninjured customers gets harder and harder.

I expect that to play out over the next few years in the cases where, again, it is another hurdle to certification for the end-payors that maybe the direct purchasers figure out. Maybe their experts are better equipped to come up with the analysis that excludes the uninjured plaintiffs in the first instance whereas the end-payors have a bit harder of a time to do so.

DR. NGUYEN: I agree on the issue with the end-payor cases. I think even in the situation where we know, let's say, 90 or 95 percent of the consumers would switch from the brand to the generic, it is impossible to know who they are.

Or, in particular, if we have a case where the generic was not even in the market during the class period, then even if we know this is the

literature or the approximate market share of the generic, we cannot know in that situation who would have switched because there is actually no data to show that.

DR. KORENKO: We do have a question from one of our attendees: "It seems like the impact could be common even when there are individual differences in pricing. Are there case precedents for finding common impact based on an analysis of average even though class members pay a variety of different prices that are not susceptible to common analysis? If so, what kinds of models or fact patterns did you see in those cases?"

MR. BANK: I'll start this off. I think it is certainly possible that if the plaintiffs can show impact through common proof, that they can certify the class even where there are individualized differences in pricing.

We see that with direct purchaser classes all the time in pharmaceutical antitrust cases. You

have the three big wholesalers and their pricing is certainly different than the medium-sized or small wholesalers out there, and yet direct purchaser classes are certified regularly. So I do think that the experts can come up with models to show common impact and deal with differences in individualized pricing.

Now, when there might be certain nuances as to a particular product or a market that causes wide variation in those differences in pricing, then defendants may have an argument to raise as to why the class in that particular circumstance should not be certified.

MR. BERNICK: I agree with that.

Taking one step back — and no particular case comes to mind that illustrates this principle because it runs throughout the cases — I think it is really important to keep in mind the distinction between the fact of injury and the amount of injury. Typically, in the class certification stage the courts

are concerned with the fact of injury — can you demonstrate that all or substantially all class members have been harmed or not, and is there a proportion of the class members who have not been harmed? That is what we have been talking about today.

Typically, the fact that there is variation in the amount of injury, the fact that people paid different prices and might have been harmed by individual amounts, that alone often is not sufficient to the class certification, those individualized damages issues.

At the class certification stage, it is really about: "Can you demonstrate impact on all or substantially all class members and is there some model for calculating aggregate damages? If there are individualized damages issues, we will kick those down the road to deal with at a later day."

I don't know if that addresses the question, but that is how we typically see the cases now.

MR. BANK: That's exactly what the court in *Lamictal* said. It said: "While every plaintiff must be able to show antitrust injury through evidence that is common to the class, damages need not be susceptible of measurement across the entire class for purposes at least of Rule 23(b)(3); so you can deal with some of those individualized inquiries as to damages later on."

MS. FOLEY: On same point, what you see in the cases too is the plaintiffs have their model and then you have the defense side come in and test it with the individual class members' data. It is really on the margins. Can you show that using, for example, the named direct purchasers' data that a number of them are not actually paying that average wholesale price; some of them are actually paying much lower? Then you are going to get some traction.

But it is hard because there are not that many named class members often in these cases and you can see the opportunity for the plaintiffs to test

their data in advance before they bring a case. It is often a number of the same firms bringing the cases over and over again.

DR. KORENKO: Danielle, your point actually dovetails very well into a second question that we received. When Tram was discussing the uninjured customers in the *Lamictal* case — I think you know that twenty-three of the direct purchasers were found by the defendant's expert to have potentially paid less, or at least no more, than the but-for price. How do you efficiently deal with those individual inquiries? In other words, how do you identify those folks either before you go into litigation and test your own models as a plaintiff's expert or as a defense expert to actually dig in and figure out who those folks are?

MS. FOLEY: As a defense lawyer, I am excited to see those examples. I don't think that is any surprise.

Obviously, we rely on the economists to help us figure that out. A lot of it really depends on the

model that the plaintiff's experts try to put up and giving us a target to shoot at.

Obviously, the devil is in the details — as I think Jeff was saying — the market, the product, the purchasers, and what uniquely was going on in each individual case. But, obviously, we have a problem like you see in *Lamictal* — you are going to have a problem getting your class certified.

DR. NGUYEN: In the case of *Lamictal,* I think it is also important as a defendant's expert to look at the situation regarding negotiations between the manufacturers and the pharmacies in the case because there are multiple individual negotiations going on. Immediately we should be careful about relying on just one average price, but instead look at in the but-for world absent the price competition what would happen to individuals' but-for prices across these pharmacies. I think those are the question that will have to be dealt with on both sides.

MR. BERNICK: Lurking in the background of

the efficiency question is the concept, particularly for direct purchaser cases, of whether or not a class certification mechanism is even the efficient mechanism for resolving a dispute at all.

I admit being biased somewhat because I represent defendants in these cases, but you cross a point where the class is so small and the individualized issues are so great that, to the point of the questioner, it is just not efficient.

Then you have other case where the number of class members is higher and the amount of individualized variation is smaller and the class mechanism can be perhaps a more efficient way of resolving the dispute.

But I think it is a much closer question when you are dealing with a direct purchaser case with a small set of plaintiffs, each of whom has a pretty large volume of commerce and could bring a claim on their own. So at what point does it cross the hurdle of being an efficient case management tool to proceed

as a class? I think that is one thing the courts are grappling with in those cases.

DR. KORENKO: I was going to say from an economist's perspective that is where the discovery is really important. Relying on defendant's data, digging in where they sell to whom for what price — and, as Tram mentioned, there are negotiations — and you see there is a lot of variation in the prices and they are different across different purchasers and they are different across different purchasers over time. These are things that you have to dig into both as a plaintiff's expert and as a defense expert to figure out what is the appropriate way to capture what is really going on in this marketplace.

I don't have any more questions.

I have one question actually that occurred to me while we were talking. It's funny that Jeff talked about looking at other cases that come in and we have to talk about averages and how they work in the pharmaceutical space, looking outside of pharma.

To what extent do you think the pharma cases that we are looking at will bleed into other areas, other industries and issues that we deal with in other cases, or is the supply chain so unique in pharmaceuticals that it does not really translate?

MR. BANK: I think that the courts in cases that are focused on other industries will have to look at the pharmaceutical antitrust cases because these issues are coming up so often in the pharmaceutical antitrust context that the courts are really digging in and trying to understand what it means to conduct a rigorous analysis and look at certain merits issues that overlap with class certification issues.

The *Tyson Foods* case was not an antitrust case, but it certainly has impacted the antitrust world, and I think the vice-versa is true.

Now, there are certain other industries with more simplified distribution chains where some of the specific nuanced arguments about pharma will not be relevant, but overall the concepts may be

transportable to those cases as well.

MS. FOLEY: I agree. Without a doubt, given the number of the pharmaceutical cases that have percolated through the appellate courts, they are setting the standard for what you have to do.

Whether it is the basic question of numerosity from the *Modafinil* case that we were talking about — you know, how many class members do you need to have a class — to the questions of using averages and individualized inquiries about impactives — the issues will spread and impact the entire range of antitrust class actions.

DR. KORENKO: Those are all the questions that we have.

I want to thank our panelists. This has been a fantastic discussion that brought up a lot of interesting issues. I hope it has been informative to all of the participants and that you have learned a little bit about where we do stand in the world of pharmaceutical class certification and that there is a

little less confusion about where we are going to head with that.

I also want to thank the folks at Fordham, specifically James and Karen for organizing this. I want to thank Bill for the technical things working as well as they did. I understand there are a few kinks to work out, but by and large this was pretty smooth.

I want to thank everybody again. Have a good day. Everybody stay safe and healthy and enjoy the rest of the conference.