

FTC Understanding Competition in Prescription Drug Markets: Entry and Supply Chain
Dynamics Workshop
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Segment 5: Discussion
Transcript

SUZANNE MUNCK: So thank you very much for being with us here today. We thought for our final program we would do something a little bit different. This is not going to be a moderated discussion. Instead, we have asked our next two speakers to sit through the day and think about policy outcomes that can come from what we've learned today. So really, you're now hearing from them in real time, their thoughts based on what they've heard since the fire drill this morning. And my joke on the fire drill is that this topic is so hot-- how hot is it?-- it's so hot that we set off the fire alarm. So thank you so much for being with us throughout the day.

But it's my pleasure to introduce Rena Conti. Rana Conti is an Associate Professor at the University of Chicago Departments of Pediatrics and Public Health Sciences. Her research applies economic methods to analyze the incentives driving prescription drug development.

After Rena speaks, we'll hear from David Mitchell. David is a patient with an incurable but treatable blood cancer called multiple myeloma. And so I think it will be interesting to hear the academic and the patient perspective on everything we've heard today.

After they speak, I will come up for a few short closing remarks. And take it away. Thank you.

RENA CONTI: Thank you. So thank you very much for the opportunity to comment on today's proceedings. And really, thank you to the FTC and also the FDA for hosting such a fantastic day of discussion. I have prepared remarks. They are publicly available. But actually, I'm going to go off script today and use this time to summarize and also to highlight some comments that I believe need amplification, and also, self-servingly, are complementary to some of the comments that I was going to make in my own remarks.

They're grouped into several buckets. I know bucket's not a formal, fancy word, but I'm going to use it anyway. First bucket is the following. High and growing prices of drugs are a problem, and they're a problem for patients, and they're a problem for payers. There are at least three sets of actors that bear some-- depending on who you act-- maybe more, or ask, maybe even the majority of blame-- for the situation that we are currently in.

They include big pharma pursuing monopoly pricing, intermediaries, which include PBMs, GPOs, physicians and hospitals, and even pharmacies that profit off of list prices and also profit off the spread between acquisition costs and reimbursement policies set by public and private payers. And then lastly, generic pharma, which, in my own work, we have shown is increasingly concentrated. Approximately 50% of all generic drugs made in the US and sold by volume are currently manufactured and sold by manufacturers that are either monopolists or they're duopolists at this stage. There's only two manufacturers making those drugs. This allows them to pursue monopoly pricing as well in a market that we continually consider to be virtuous and really exemplifying competitive pressure.

These actors are interrelated, and therefore my takeaway from this is that in a system that's this complex, there are no silver bullets to this problem. And actually, good intentioned solutions can have very unintended consequences. And that's something that both academics study, but also policymakers and others should be aware of when they are contemplating reform but also studying reforms that occur.

Bucket two is the following. We have two very well-functioning, well-helmed federal agencies, the FTC and the FDA, that are on the front lines of assessing competition, ensuring competition, ensuring entry, and making sure that drugs that are available in the US are safe and efficacious. But the pursuit of their policies and what's in their jurisdiction to examine is not done in a vacuum. There are other agencies, including, not the least, CMS, that is also looking for answers and solutions to the high pricing of drugs. And Congressmen and women are also looking at prices and what can we do about them.

So in other words, from a regulatory perspective, this is also a complex series of actors that can have interrelated and potentially conflicting goals in mind when they're promulgating policy.

Bucket three. What do we do? So I believe that directions forward really need to be attuned to the drug types and agency jurisdiction. First-- and this was touched upon in the last panel, I think, quite nicely-- on branded, patent protected drugs with no therapeutic competition. These are drugs that have seen escalating launch prices, including cancer drugs, but there are other therapeutic classes that look like this as well. And these have clearly impacted patients, but also payers.

The pricing of these drugs does not appear to be linked to their value, but rather appears to be linked, at least in some cases, to the chutzpah of the manufacturer. Now policymakers-- not the FDA and the FTC-- are thinking about experimenting to help tame these prices of really breakthrough products. And frankly, this is just hard because market price is ultimately linked to further investment and new innovation.

But there are some possible solutions which have potentially less negative consequences on innovation, at least in theory, notably under the guise of value-based contracting or outcomes-based contracting. These are relevant to the DOJ and the FTC as they percolates through the system because they may create opportunities and contractual arrangements between pharma, hospitals, physicians, and pharmacies, including specialty pharmacies, and PBMs that can run afoul of the anti-kickback statutes and other types of regulations that we worry about.

So really-- people have mentioned bundling and tying behavior here through the day-- but I'm going to kind of put on the table, again, think about bundling, tying, and anti-kickback when you're thinking through the potential of these arrangements moving forward.

Perhaps more importantly, or germane to this conversation, we've spent much more time focusing on existing drugs that have therapeutic competition, and whether they're branded or not, and ways to improve access and affordability for these drugs. So I'm going to focus my last comments on this.

Here we have two general themes of reform options, the first being increasing competition and the second being decreasing profit seeking or rent seeking off the list price, and revenue seeking off the difference between acquisition price and the list price.

So on competition, it's very sensible for the FTC to focus on increasing competition, and really to underscore that this is a game of whack-a-mole, as Michael Carrier and others have mentioned. Pay for delay is the first iteration of these type of evergreening policies, but product hop cases and other types of activities that the industry has evolved to pursue are really important as well. And the FTC should-- I think it's a really sensible idea for the FTC to really play a key role here in defining what is reasonable and not behavior, considering that, again, the courts may not always get this right or may have conflicting opinions in real time.

Also, less well-articulated today is the role the agency should play in continuing to scrutinize merger and acquisition activity between pharma and other actors in the system, specifically understanding that modern pharmaceutical companies are not binary. They're not generic standalone full stop and brand standalone full stop. But they're some combination of the two, and there's a whole, really, a continuum of companies out there.

Here, it's very important that the Scott Hart Rodino thresholds for triggering assessments within products between firms potentially be looked at again because here, mergers and acquisitions that affect even very small revenue markets could actually have very big implications for competition moving forward, both in terms of how many manufacturers stay in the market for small revenue products, but also the pricing of those products over time.

Secondly, for the FDA, Dr. Gottlieb and others have done a very nice job articulating that competition matters. But really, the economic principle here that's most important is not the actual number of manufacturers that are making the drug, but the potential number of manufacturers that could make the drug if needed and allowed to do so.

What I mean by this is that we should not pursue policies that would reduce the number of potential entrants or potential willing manufacturers to be in this market. And there can be some unintended consequences of fee structures, but other types of registration policies, for example, that try to really hold the manufacturer to actually making the drug in all times under all circumstances, that we actually want a flexible policy where manufacturers can enter, may choose for whatever reason to mothball or not make products for a time, but then preserve the ability to actually enter the market over time if needed or wanted.

In addition, and really where we've seen this be important, is GDUFA fees in GDUFA I that potentially have the unintended consequence of increasing manufacturers' willingness to use contract manufacturing organizations, which in some sense are good because they increase the redundancy of suppliers potentially in the market, particularly in the branded space, but may actually be perverse in the generic and biosimilar space, where manufacturers who have an ANDA for manufacturing one of these drugs are actually not making the drug.

Instead, many manufacturers holding an ANDA are actually pushing the manufacturing onto one or a handful of contract manufacturers, that when they run into quality manufacturing problems

or problems with getting ingredients for making these drugs, can actually threaten the adequacy of supply and may really ultimately impact patients' ability to get care, but also the prices that we pay for that care.

Lastly, on reforms targeted to disintermediating this system, the FTC and the DOJ have a very key role to play here in scrutinizing exactly whether and how reimbursement is built on rebates and discounts, not just for PBMs and GPOs, but also for pharmacists, for physicians, and for hospitals, which we know profit off list price as well.

This scrutiny is important because, again, this is a little bit of a moving target. Reforms are percolating through both CMS in terms of their rulemaking, but also in Congress, that is rethinking the way that we are reimbursing hospitals, physicians, and potentially pharmacies. And this alters the incentives to use more or less expensive drugs, and again, to profit off of rebates and discounts that exist in the system.

The recently released CMS ruling on 340B reimbursement for hospitals that are paid under OPPI is a case in point. Reducing payment for those institutions that have been making money off 340B discounts alters their incentive to be affiliated, to merge, and acquire between physicians and hospital practices, and may have ripple effects moving forward.

But also, the DOJ and FTC have a key role to play here in scrutinizing formal proposed merger and acquisition activity in vertical merger arrangements. And those are, again, really in disparate entities that profit off the system in disparate ways in pharmaceutical policy.

For example, we've heard much about the proposed CVS Aetna merger. This frankly hearkens back to an older time period in the 1990s when PBMs and pharmaceutical companies were vertically integrated. We broke up those arrangements because of anti-competitive practices. In addition to this blockbuster example, there appear to be many more arrangements that are vertical between hospitals and GPOs, hospitals and pharmacies and PBMs, insurers and PBMs, then likely require increased scrutiny both from an academic perspective in terms of what are the potential or intended and unintended consequences of this, but also from a regulatory standpoint moving forward. I'll stop there. Thank you.

[APPLAUSE]

DAVID MITCHELL: The clicker.

RENA CONTI: The clicker. The key.

DAVID MITCHELL: Thank you, Rena.

So good afternoon. It's really a pleasure to see so many of you still hanging in there. It's been a long day. And try and make this last 15 minutes reasonably interesting.

I am David Mitchell, and I am President and Founder of Patients for Affordable Drugs. We're the only national patient organization focused exclusively on policies to lower drug prices, and we

don't take funding from any organizations that profit from the development and distribution of prescription drugs. We're about patients, only about patients. And because of our funding sources, we can speak without fear or favor.

I'm also a cancer patient. I have an incurable blood cancer called multiple myeloma. I've had it for seven years almost to the day. It's incurable, but it's treatable with very expensive drugs. So a week ago I had five hours of infusion. They give me about six drugs, but the two main drugs, every time they're given to me, cost \$20,000. And they'll give them to me 22 times over the course of a year. So standing, sitting before you today, \$450,000 worth of drugs are literally keeping me alive. I'm relapsed, and if I stop taking these drugs, I'll die.

And eventually, my cancer is smart-- that's why it's incurable-- it'll find its way around drugs, so I need new ones. So I am a patient who cares deeply about innovation and R&D and new drug development. But there's a fundamental effect that has been taught me by my experience, and that is drugs don't work if people can't afford them, which is why we are here today.

So I'm going to give you a patient perspective. It's not just mine. It comes from having collected more than 8,500 patient stories in the last eight months since we launched, 18,000 e-mails from patients. We're building a community of patients that can be mobilized in support of policies that will lower drug prices. And I want to tell you that patients are hurting out there. They're skipping doses, they're cutting pills. They're literally going without food to pay for their drugs. They're not taking the recommended amounts that they should. They're trying to manage Type 1 diabetes with diet and exercise and foregoing their insulin until their blood sugar spikes, which is a very bad strategy to manage T1.

Our view-- and it sort of echoes Rena's title slide-- is that our priorities in this country regarding prescription drugs are radically out of balance. We believe that we should be developing drugs and allowing a market to work to maximize affordability and accessibility while ensuring R&D and profit. And right now we think that the whole thing is tilted to profit on the basis that all that profit is required to finance the R&D, which we don't think is true. In fact, it's not true. So I'm going to highlight some of the issues raised today, and do that, hopefully, from a patient perspective in terms of what seems to be important.

Acting Chair Ohlhausen reviewed the importance of Hatch Waxman, the balance it aims for, which is one of the points I want to leave with you most importantly, and the need to allow the Hatch Waxman framework to work. We give drug companies incredible incentives to do the research, make the investment, take the risk to bring new drugs to market. And then we give them five years or seven years or 12 years of exclusivity to recoup that.

But in most cases, for many of those drug companies, those periods of exclusivity are insufficient, and they seek to game the system to extend their monopolies on the backs of patients, consumers, and taxpayers. Along the way today someone said no one really pays the price, but the fact is, we all pay the price, every one of us. Either we're paying it through our taxes or we're paying it through our premiums or we're paying it out of our pocket when we have to buy the drug.

So I think it's also important to reference what Commissioner Gottlieb said. High prices being set by drug companies at the outset are a problem, and he's trying to do everything he can to stimulate more competition. And he said if innovators abuse the system, they need to understand that they're going to lose support. His message to brand companies was quote, "End the shenanigans, including abuse of REMS. That needs to stop. It's unfair and it's exploitive, and there's a bill in Congress that could fix that right now called the CREATES Act. And we should all be telling Congress to enact that bill because it would make it different for patients, including people like myself.

Aaron Kesselheim spent a lot of time detailing all of the anti-competitive brand behavior, and Rena just took us through some of it, whether it's product hopping or evergreening or pay for delay even though it's in decline, abuses of REMS and restricted distribution networks. They're all strategies by the drug companies to say, the exclusivity we're granted in a government-awarded monopoly are insufficient. We want more. And they'll take as much as they can get, and they're content to fight the legal battles in order to have that monopoly pricing power sustained.

Chip Davis highlighted something that's really important, I think, for patients. And that is the dangers of consolidation in the generic industry, because it leads to pricing power that we don't want to have happen. On the other hand, we need to look after the generic industry because it is the vehicle through which we express competition in the drug market in this country. And in the absence of generics-- they're our vehicle-- we do not have a way to project competition. I'm trying to make the point that it is not generics per se in and of themselves that lower prices. It's the introduction of competition.

Someone put up a chart today that showed you that if there's one generic competitor, the price falls to about 80% of the brand, and then down it goes with two, three, four, and five competitors till we get to 20% or 10%. So we need a robust generic industry in order to project competition.

Dr. Gal made the point that should not be lost on anybody here, and that is it's patients with no insurance who are paying cash who are getting the worst abuse. Michael Carrier talked about the fact that pay for delay may be declining, but there are many other ways that brand drug companies are trying to maintain their monopoly power. He called for-- and I want to echo this call this strongly as I possibly can while I'm here in this building-- called for much more aggressive FTC anti-trust investigative power to be expressed, and enforcement power. We really need that to happen, and not just looking at the tactics of brand drug companies, but also the tactics of PBMs.

Dr. Sood made a point that's really important, asked the question, are we getting good value from the PBMs? And we really need to be able to look inside to make a determination. As long as the PBMs are a black box and none of us know what the hell is going on, we can't decide if we're getting good value. That's why we need the kind of investigative work that the FTC could do to let us have a look inside and see what's happening there.

And I think we need to really pay attention to another issue that was raised, which is the perverse incentives that PBMs can cause in our system, where an insulin cartel that controls 80% of the market, three companies, can say, in order to be on the formulary of the biggest, say, Express

Scripts, we're going to bump the price in order to give you a bigger spread on the rebate so you can make more money. There is actually an incentive that is completely the opposite of competition, which is to raise the price in order that people can make more money downstream. We have to look at all of that inside the PBMs in order to protect patients.

Mark Merritt, on behalf of PBMs, told us that big payers wouldn't use PBMs if they didn't add value. But I think-- and I want to be corrected if I'm wrong-- that Medicare does not have a choice. It can't bargain directly with the drug companies. PBMs are, in fact, the expression of our public policy in Medicare, which I believe is the largest if not one of the largest purchasers of prescription drugs in this country. And we also know that increasingly, big insurers are trying to figure out a way to shed themselves of PBMs. So Mr. Merritt said twice, all these smart people use us because we save them money. I don't think that's true.

Ms. Bryant made the point about the importance of getting the benefits of competition to patients. But ironically, pharma opposes steps to enable competition. And I've talked about them, and Rena talked about them, and Aaron talked about them. I won't go into it. The chart that she put up showing cost growth for prescription drugs is completely misleading because it includes generics, which are, in fact, deflationary, as Chip Davis said. But it takes credit for generic drugs causing prices to decline when, in fact, pharma-- the big drug companies, the brand drug companies-- try to stop generics from coming to market.

And in fact, her drugs, the drugs produced by her members, are the fastest growing segment of health care costs in this country. She did make an important point. We gotta fix this right now. I'm on Medicare. The idea that patients pay their co-payments and deductibles based on the retail price and everybody else pays the rebate price is crazy, and it's wrong. And it just shows how this system is built to benefit everybody who's making money off of it. And the only people who pay are patients, consumers, and taxpayers. One way or the other, we pay for everything. They pay on the rebate price, we pay on the retail price. It's just wrong.

So I want to mention a couple of things that weren't stated. About two months ago we crossed onto new terrain. A drug that was developed using taxpayer money, developed with \$200 million worth of NIH investment, called Kymriah. It's a CAR-T drug-- was priced at almost \$500,000. NIH does incredibly important work that I want to have go on as fast as possible and with as much effect as possible.

But NIH takes the approach that we do the science, the free market sets the price of the drug. Well, there is no free market. We give government-granted monopolies. And if we are going to convey the IP that we all invest, then NIH has to start to take a position that says it was all right to wash our hands of that ugly pricing issue at \$150 drugs or \$15,000 drugs, but not at \$500,000 drugs. And it's time the policy of NIH changed, and it has the statutory authority to do that. I think that's incredibly important for patients because if we keep going the way we're going and say, well, the drug companies, they want credit for all the money that's going to be saved.

The sugar cube, by a cure, for example, if CAR-T is, in fact, a cure-- we're not sure-- but if we're going to use that model of value pricing without paying attention to how much the

commercializer makes off of the drug, the sugar cube they gave me when I was five years old that prevented polio would have cost \$1 million.

We can't do that. We're going to have a whole series of drugs coming out that are half a million, \$750,000, \$1 million. We can't do this anymore without bankrupting families and buckling our system.

So I hope that we will all do more to stop patent abuse-- I'm going to wrap up here-- stop patent abuse, allow generics to come to market, make the Hatch Waxman framework work the way it was intended, restore the balance that Chairman Ohlhausen referred to this morning. There's a bill in Congress, the CREATES Act. Everybody should call their Congresspeople and tell them to vote for that bill because it would stop REMS abuses. It would say that just because you have a dangerous drug-- and I took one of those drugs for five and 1/2 years-- doesn't mean that you shouldn't give samples so a bioequivalent can be developed. We need PBM transparency, and we really need the FTC to get involved here, look inside.

And then I want to say one more thing, quoting someone else today. Tony Beretta from Kaiser Permanente said manufacturers increasing price for no reason is not innovation. And filing additional patents when you are about to lose your patent protection on the core-- what's the word I want-- the active ingredient in a drug, is not innovation. In fact, it stifles innovation. The longer we let companies game the system to get more profits off of old drugs, the less we're going to have innovation.

And just last week, maybe two weeks ago, Celgene, a company that makes a drug called Revlimid that I took for five and 1/2 years, increased the price of that drug by 9%. It's a total increase on the year of over 20%. This is an old drug. It was invented in the 1950s. And they did it because a clinical trial they were doing on a Crohn's Disease drug failed to the tune of \$700 billion. So they took a 9% price increase on Revlimid that generates \$500 million to plug that hole and prop up their stock price. And you know who's going to pay for that? We are.

And we have to stop this. We have to stop these abuses of the system from happening. So as a patient, I urge all of you in this room who have power to affect the system to think about these various ways that were highlighted today to do that. Thanks.

[APPLAUSE]