

FTC Understanding Competition in Prescription Drug Markets: Entry and Supply Chain
Dynamics Workshop
November 8, 2017
Segment 1: Intro and Keynote Remarks
Transcript

SVETLANA GANS: All right, folks. Can we get seated please? Good morning, everyone. My name is Svetlana Gans, and I'm the FTC's Chief of Staff. I'm pleased to welcome you to today's workshop, Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics. Drug development and competition are key to meeting some of society's most pressing unmet needs. From curing cancer to combating the unprecedented opioid crisis, which has devastated American communities.

Concerns about rising drug prices have caused policymakers to question whether there are obstacles to competition in pharmaceutical and intermediary markets that are affecting prices for and access to these lifesaving products. The FTC, under the direction of Acting Chairman Ohlhausen convened today's workshop to bring together top experts in these areas to better understand the dynamics at play.

I'm proud of the workshop team, which consists of Suzanne Munck, Dave Schmidt, Markus Meier, Randy Weinsten, Elizabeth Jex, Katie Ambrogi, Kelly Signs, Kari Wallace, Meredith Andrus, and Gabrielle Koenig, as well as various other professionals from throughout the agency. On behalf of the entire workshop team, we are delighted that you are joining us today-- in person and via our live webstream.

We are particularly grateful for our sister agency's FDA participation in this event, and you'll hear more from Dr. Gottlieb and his staff later today. We also wanted to extend a special thank you to our speakers and special guests in the audience.

Before we begin our substantive program, I was asked to give you emergency evacuation instructions. However, a few of us experienced that firsthand this morning, so you could just ask those people where to meet at the emergency designated spot. I call that our FTC networking hour, so hopefully you met some folks who you see here in this room today.

If you have received an FTC visitor's badge, we do reuse those, so please turn that into the staff when you leave the building. And if you notice any suspicious activity, please alert building security.

As indicated in the program, lunch is on your own today. We do have a cafeteria on the left side of the building. It is closed from 11:00 to 11:30 and after 3:00 PM, but it will be open during our lunch break, so you're welcome to go to the cafeteria for lunch.

Also, you have maybe seen that there's no food or drink allowed in this auditorium, so please enjoy those items outside of this room. Please also be advised that this event may be photographed, webcast, or recorded, and by participating in this event, you are agreeing that your

image and anything you say or submit, or do or say, or even whisper may be posted indefinitely at FTC.gov or on one of the Commission's publicly available social media sites.

As I mentioned, the workshop will be livecast. The webcast will be recorded, and a transcript will be generated. These materials will be available on the FTC website within the next few weeks. Also, as you know, we are accepting public comments. The public comment period will run through December 8th, so if you have not had an opportunity to submit a public comment, please do so.

So with those housekeeping matters out of the way, it's my great pleasure to turn to the substance and introduce our first speaker FTC Acting Chairman Marureen Ohlhausen. She was sworn in as an FTC Commissioner in April of 2012, and was designated to serve as Acting FTC Chairman by President Trump in January of 2017. The Chairman has been a vigorous advocate for consumer welfare in the health care space.

Under her leadership, the FTC formed an economic liberty task force charged with identifying and advocating for the reduction of unnecessary and overbroad occupational licensing restrictions. Such laws often restrict beneficial health care options like telehealth services for rural patients, and access to nurse practitioner skilled in treating addictions.

Under her leadership, the FTC has also strived to ensure there is vigorous competition in the health care marketplace, bringing a host of merger challenges in the hospital space, as well as investigations and litigation in the pharmaceutical space.

She is particularly concerned about abuses of government process to delay the entry of low-cost generics. We are very grateful for her leadership in convening this workshop, and like to welcome to the stage our acting chairman, Maureen Ohlhausen.

MAUREEN OHLHAUSEN: Well, good morning, everyone. We started off the day with quite a lot of excitement with that fire drill, so I hope we can live up to that level of energy through the rest of the day. But thank you all for coming to the FTC's workshop on competition issues in prescription pharmaceuticals.

I know from my prior life as the Head of the FTC's Policy Shop just how much work goes into putting together a day like this. So I want to thank both our distinguished group of panelists and the tireless staff of the FTC for putting this together, and for what promises to be an extremely valuable program.

We come together today to discuss a topic that has long been a central focus of the agency's competition mission, protecting the markets that develop and produce the life-saving medicines needed by our citizens. This agency does a lot of important work, but protecting the interests of consumers in the markets for prescriptions pharmaceuticals is one of our most critical responsibilities.

The FTC has done countless merger investigations involving prescription pharmaceuticals, and also taken aim at some of the biggest and most difficult problems in this space. Problems like

pay-for-delay agreements and the abuse of government drug approval process through behavior such as sham petitioning.

I'm happy to report that we've made much progress on many of these fronts. We've required divestitures that preserve competition and protect consumers in dozens of pharmaceutical merger cases. We fought the issue of pay-for-delay agreements in courts across the country, battling through a series of adverse lower court rulings to eventually obtain a critical victory in the Supreme Court. And we continued to fight, challenging alleged attempts to game the regulatory system for anti-competitive purposes.

It's been a great honor for me to serve as the FTC chair and to be part of these varied and successful efforts to protect competition in pharmaceutical markets. That said, I realize we have likely not seen the last of pay-for-delay deals, sham petitioning, or problematic proposed mergers in this space.

I fully expect that competition issues involving patented pharmaceuticals will remain a significant focus of the agency's enforcement efforts in the years ahead. However, today's event has somewhat of a different focus. When you consider our pharmaceutical enforcement history in the aggregate, it becomes strikingly clear that most of our work in this space has clustered around just one part of the broader Hatch-Waxman Act framework.

Now many of the people in this room are intimately familiar with the details of the Hatch-Waxman Act, but most of us spend very little time thinking about the overarching structure of the act, or the broader policy goals it embodies. So let's take a minute to do just that.

This groundbreaking piece of legislation imagined a structure that would protect the important intellectual property rights associated with new medicines so that firms would retain appropriate economic incentives to develop vital new drugs, and to undertake the costly work necessary to demonstrate their safety and efficacy.

As I've spoken about many times before, the protection of intellectual property rights is critical to drive innovation, and the Hatch-Waxman framework recognizes and enshrines this essential truth in law. That said, providing enough innovation incentives was only the first step in the broader framework envisioned by Hatch-Waxman.

Fostering healthy competitive markets for post-patent pharmaceuticals was another critical policy objective of this legislation. Eventually, patent protections expire, and the legislative framework includes incentives to induce generic entry once patents have run their course.

Rapid generic entry is an important driver of lower pharmaceutical prices. The first generic competitor's product is typically offered at a 20% to 30% discount to the price charged by the branded product. Subsequent generic entry continues to lower prices, with discounts of up to 85% or more seen when a large number of generic firms are each competing for business.

This evidence suggests that there are a few things more effective in lowering the cost of prescription drugs than fostering substantial generic entry upon patent expiration, and letting

competitive markets drive prices ever lower. Despite its critical importance in lowering overall spending on pharmaceuticals, this second vital part of the Hatch-Waxman framework has received far less attention.

It was largely assumed that once patent protections expired, the natural operation of market forces would drive prices down to something approaching marginal cost, and the policy makers wouldn't have to do much more than get out of the way to see those 85% reductions in price. Now, fortunately for many drugs-- particularly those with large demand-- that assumption seems correct.

But what we know today is that these assumptions do not necessarily hold in every case. In reality, the markets for pharmaceuticals that have lost patent protection are considerably more diverse and complex than many policymakers originally realized.

These markets can involve simple, easily manufactured products that have been sold for decades, or highly complex injectable drugs with daunting manufacturing requirements. They can be the big, prototypical markets for blockbuster drugs, or small markets for products that treat comparatively rare diseases.

To be clear, the Hatch-Waxman framework has undeniably and dramatically improved access to lower-cost generic drugs, and that is a great thing. However, we can see that this has not occurred in every market. Some pharmaceuticals lose patent protection, but then draw no generic entry, allowing the incumbent firm to maintain high prices.

Other medicines may draw some limited generic competition after the patent expires, but not enough generic firms enter to drive prices down to the modest levels that we might otherwise reasonably expect to see. We have also seen some shortages of inexpensive, but critical medicines.

In some isolated cases that have generated a lot of media attention, speculators have brought up off-patent, single-source drugs and raised prices dramatically without drawing an immediate competitive response. Whenever any of these situations occur, we should seek to understand why.

Although these issues are complex, I would suggest there are a few guiding principles we should apply here. Most important among them is the fact that market forces and competition are remarkably effective mechanisms at driving down prices and improving consumer welfare.

Further, the basic laws of supply and demand still apply in this industry. If we are not seeing results that are consistent with well-established, basic economic theory, we need to figure out why. And fundamentally, that is what today's program is all about.

What are the impediments to vigorous competition once pharmaceuticals are no longer protected by intellectual property rights? In other words, where we see that the framework laid out by Hatch-Waxman is failing to deliver the full measure of its expected benefits, what are the root causes? And what should the appropriate policy response be?

Now, I recognize that when a law enforcement agency like the FTC identifies an area of concern, many people assume that this is a prelude to a raft of new enforcement actions. And that assumption might seem particularly appropriate here, given our substantial enforcement history in this space and the critical nature of these products. But before we go any further, I would like to caution you about drawing quick conclusions about our future enforcement plans.

We already know that there are many highly complex issues in these markets, and there likely will be no simple, easy solutions to the problems we currently observe. If these problems were straightforward and easy to solve, I would hope we would already have fixed them. The complex, multifaceted nature of these problems strongly suggest that anti-trust enforcement is not a cure-all that can fix all potential problems in this space.

Just as there is no single drug to cure every ailment, the anti-trust laws are not a panacea for every economic concern. And as I've said before, anti-trust works best when it focuses its attention on harms to the competitive process and the protection of consumer welfare.

We are neither a price regulator nor sector regulator. We may ultimately determine that there is a need for greater anti-trust enforcement in pharmaceutical markets, but that decision will be made on the basis of specific facts and actual market effects, using the familiar methods and processes of anti-trust law.

For now, I think we need to learn more about how these markets are working today, with an eye towards not just what antitrust enforcers can do to help, but what changes in the regulatory system as a whole may be appropriate in response to some of the concerns we've identified in these markets. Here are some of the specific questions we are most interested in understanding.

First, what are the incentives and disincentives that generic manufacturers consider when making the decision to enter or refrain from entering the market for a particular pharmaceutical no longer protected by patents? Should policymakers and market participants alter those incentives to better align with the public interest in robust competition? And if so, how?

Second, what strategies, if any, are being undertaken with the intent to reduce generic drug competition today? Are these strategies working, and what impact are they currently having on these markets?

Third, what is the current role of intermediaries like group purchasing organizations and pharmacy benefit managers in these markets? What benefits do these intermediaries provide, and what costs are they imposing today?

And fourth how should all stakeholders evaluate proposals to reduce drug prices and increase consumer access? Now, these questions aren't going to capture every nuance of these large and complex markets, but they are certainly a good place to start. And the FTC staff has assembled a great set of panels today to begin digging into these important issues in much greater detail.

And finally, I'm happy to note that the FTC is not the only federal agency paying close attention to these issues. Dr. Scott Gottlieb, the Commissioner of the Food and Drug Administration, and I

share a desire to identify and address the hurdles to better generic drug competition, whatever the source.

Indeed today's workshop-- bringing together outside experts from academia, industry, and both of our agencies-- is a direct result of previous discussions that I had with Dr. Gottlieb. Our two agencies may have different missions in different spheres of responsibility, but we plan to work together closely to ensure that the markets for generic drugs work the way they should, and that US consumers get the safe, efficacious, and affordable medicines they deserve.

And it's now my pleasure to introduce Dr. Scott Gottlieb. Dr. Gottlieb was sworn in as the 23rd Commissioner of Food and Drugs on May 11th, 2017. Dr. Gottlieb is a physician, medical policy expert, and public health advocate who previously served as the FDA Deputy Commissioner for Medical and Scientific Affairs, and before that, as a Senior Adviser to the FDA Commissioner.

Under his tenure as the head of the agency, the FDA has already taken a number of actions to improve consumer access to generic drugs. These efforts include streamlining the ANDA review process and undertaking various initiatives to significantly improve the transparency of agency actions. And we look forward to having him here today to talk about the vital contribution that access to generic drugs can make to public health, and the ways in which our two agencies can work together. So please join me in welcoming Dr. Gottlieb.

SCOTT GOTTLIEB: Thanks a lot. Thanks for the nice introduction and for inviting me to join you here today.

Although FDA and the FTC have very different responsibilities relating to health care, among our shared goals is a critical one of ensuring that all Americans are able to benefit from competition when it comes to the medical products that they use.

This is especially true when it comes to drugs and the availability of safe and effective generic medicines. Generic drugs provide a vital benefit to the public. They can cost, as you know, a fraction of the price of brand name versions of the same medication.

And so it should come as no surprise that 9 out of 10 prescriptions today are filled using generic drugs. Yet even as generic medicines comprise a growing share of the overall drugs that people use, many patients still find themselves priced out of getting the medicines they need. And this reflects a number of trends.

Many of today's medicines are transformative drugs that are highly effective, where patients quite literally can't live without one of these new medicines. This includes many new and innovative treatments for serious and sometimes fatal diseases, such as cancer or rare diseases.

The good news is that many critical medical problems can now be addressed through safe and effective medicines, but a patient can't benefit from a medicine if they can't afford to pay for it. The costs are high for many reasons because, in many cases, these drugs face little to no competition when they're first launched.

That's precisely because they're so novel, and the investment in developing one of these innovative treatments and cures is very high. On average, as many of you know, the price to develop a single novel drug can top \$2 billion once all the costs are added up. And even the direct, out-of-pocket costs can be a billion dollars or more. These costs do factor into the price.

Moreover, these medicines often treat increasingly targeted, and thus, very small populations of patients. And so, to make the economic model work in cases where high costs of drug developments are being applied to drugs that are increasingly specialized and spread over a small number of patients, the result is that the drugs are often priced very high.

And then, there's also an issue with the inefficiency of the pharmaceutical supply chain. Discounts and rebates may be provided, but these typically don't flow directly to the consumers who use those drugs. The system, as it exists today, does not incentivize savings for consumers who are paying the high costs for medicine they need.

The question is, what can be done about this? Well, some elements of this issue are not in FDA's purview. I think there's a lot we can do at the agency, and even more by working together with our partners at the FTC and elsewhere to address some of these challenges and help address the needs of patients.

I want to talk about some of the places where I think there could be more common ground between FDA and FTC to address these issues, and where I hope to steer our collaboration. A lot of this boils down to the steps we can take to address the root cause of high drug prices, and that's often a lack of competition.

Sometimes, competition is lacking because a pioneering drug has a monopoly on some highly novel and highly effective new technology. In these cases, we want the market to be efficient and to reward the innovation. If a biotech company discovers a novel cure for a rare cancer, that's precisely the kind of innovation we want to encourage because patients deserve to have such treatments.

But we still want to see competition enter all categories-- and especially, these transformative categories-- as quickly as possible. Patients benefit when they have more than one choice of a drug, both clinically and economically. There are often small differences between even similar medicines that can have important clinical implications.

But just as important, we've seen that when a second drug enters a new drug category, it creates competition that can lower prices and improve access, even in rare diseases. And that's an important public health goal. FDA is taking steps to make the drug development process more efficient, so competition can enter novel drug categories more quickly. And will have much more to say about this effort in the coming weeks.

But I'm also committed to making sure that we allow for brisk competition when the exclusivity periods have lapsed on these branded medicines and they're eligible to be subject to generic competition. The Chairman of the FTC has outlined some of the history and critical responsibilities of the FTC within the regulatory judicial framework surrounding generic drugs,

and her agency's key role in helping to address some of the challenges that impact the costs of generic medicines.

I'd like to spend a few minutes filling you in on the details of FDA's role in the development and approval of generic drugs, and how we're helping to strengthen competition to benefit the American consumer. First, we've taken a number of actions that will help encourage the development of generic versions of drugs that lack competition so that safe and effective generics can come to the market as quickly as possible.

For instance, we've expanded our prioritization policy to expedite the review of the first three generics of drug applications where competition is limited. New entry predicts lower generic prices, and earlier work suggests that there are large price declines with competition among as few as three generic products in a category. And soon, we'll be updating this analysis.

In addition, earlier this year, we posted a list of off-patent, off-exclusivity products with no approved generic to proactively signal which products are available for immediate generic competition. We also held a public meeting to discuss additional ways we can work to address unfair practices that can stall generic entry.

At that meeting, Markus Meier from the FTC's Bureau of Competition joined us in a similar way that FDA colleagues are joining the FTC here today. Now, I'll pause to note that our docket related to that meaning still remains open a little while longer. We'd welcome your comments there as well.

One of the practices that concerns me the most is when branded firms game the system, taking advantage of certain rules or exploiting loopholes in our system to delay generic approval and, thereby, extend a drug's monopoly beyond what Congress intended. I see this clearly, for example, in steps branded companies sometimes take to make it hard, or altogether impossible, for generic firms to get access to the doses of the branded drugs that are needed in order to complete bioequivalence studies that FDA requires for generic approval.

Consider this. The FDA requires generic firms to complete certain bioequivalence and bioavailability studies as a condition of approval of a generic drug. To do these studies, the generic firms need to purchase doses of the branded drug that they seek to copy to prove that their generic copy performs the same way as the original medicine. The generic companies are willing to go into the market and buy these branded drugs at full market price.

They're not asking for a discount. They're just asking for the right to be able to buy these drugs at its retail price, just like a pharmacy or a hospital can make these legal purchases, but we know that branded companies sometimes adopt tactics to make it nearly impossible for generic firms to accumulate the doses they need to run their studies.

That's a real concern of mine. We have a system that relies on and requires the ability of generic firms to conduct certain studies for approval. When drug manufacturers game that system in ways such as this, they abandon the generic drug framework created by Hatch-Waxman.

The effects of this gaming do not end within FDA or drug manufacturers. Medicare relies on this process working to help make sure its beneficiaries get access to the benefits of low-cost generics, and patients depend on this system. So does innovation.

So I'll say this plainly. Our economic model, which rewards highly innovative drugs with the opportunity to hold monopolies for a limited period of time through patents and exclusivity, and to freely price their products to measure the value that a transformative drug offers, also depends on the generic approval process working as intended. It depends on the ability to have rigorous and vigorous competition once those patents and exclusivities have lapsed.

Our system would not have functioned so well for so long without this carefully crafted balance between access and innovation. And so, if innovators want the current structure to continue to work, but they actively prevent certain parts of that system from functioning as Congress intended, then at some point, I think they'll find more advocacy for moving away from this incentive-based model.

I don't want to see that day come because I'm convinced that this model-- one that was a result of careful compromise-- properly balances rewards for innovation with eventual competition and increased access. It's worked for decades, and as a result, Americans have the most productive and innovative life science sector in the world.

But it has to continue to work, and that means that it must work at both ends of the marketplace. The end where highly innovative drugs are developed and rewarded, and also at the other end, where those medicines face brisk competition once their patents and exclusivities have lapsed.

So my message is this: end the shenanigans. Branded companies use of REMS, for example, which FDA adopts as a way to ensure the safe use of certain drugs, is also sometimes being used as a way to frustrate the ability of generic firms to purchase the doses of a branded drug that they need to run their studies. This needs to stop.

I believe drug makers also sometimes use restrictive agreements with the pharmaceutical supply chain intermediaries, like specialty pharmacies, to frustrate or block the sale of branded drugs to a generic firm. I consider these tactics unfair and exploitive practices, and they're in direct conflict of our broader public health goals.

These practices frustrate the generic drug regulatory system that Congress created, and that Americans depend on for FDA to execute. So in the coming weeks, I plan to take other steps to address this anti-competitive behavior. Among other things, I'm going to contact pharmaceutical supply chain intermediaries to inform them of FDA's interest in making sure that generic firms can gain access to the doses they need to run bioequivalence studies.

When intermediaries sign onto these restricted games, I want them to know that they're challenging a broader public health goal. I'm also going to make sure that our own regulatory processes are harder to abuse in ways that can disadvantage consumers. That means changing how we implement our REMS programs.

For example, we're announcing today steps we're taking to make it easier for branded companies and generic firms to develop one common master file for the implementation of a REMS. I view this as a first step towards also making it easier to implement a single, shared REMS. Our goal is to see sponsors share REMS systems to reduce burdens on providers.

But when branded drug makers drag out these negotiations-- sometimes, as a way to forestall generic entry-- we're going to be in a strong position now to say enough is enough. Now that we've taken steps to make it easier to share REMS as part of one program, when a drug maker won't share their systems, we'll have a stronger basis to issue a waiver that will allow generic drug makers to go their own way if they have to, and develop their own REMS.

These aren't the only things we're doing to help increase generic competition. We've also now several new policies concerning complex generics. The category of medicines that represent some of the most expensive and widely used drugs, for which there is no robust generic competition.

We believe that our new policies will make it more feasible to expand generic competition for these complex drugs in cases where they don't currently face competition. We're also streamlining our process for reviewing generic drug files to reduce review times. We're especially focused on continuing to reduce the number of review cycles that an application undergoes.

We promise to reduce review times to just eight months for priority drugs, down from a previous average of as much as 42 months, owing to the very hard work of our Generic Drug group at FDA. Efficiencies in the drug development approval process, along with regulatory certainty, helped drive down costs of drug development and create incentives for new market entrants.

We know there's no easy, single solution to the challenges posed by high drug development costs and the high prices that result from these and other factors. But we also know that by strengthening and effectively applying policies and regulations, and our scientific and clinical standards to this problem, we can make significant headway.

And so, I look forward to building on enhancing our partnership with the FTC in order to achieve our shared goal of increasing competition, expanding access to quality generic drugs, and protecting consumers. Thanks a lot.