



United States of America  
**Federal Trade Commission**

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**Diagnosing the Treatments:  
Issues in Post-Patent Pharmaceutical Markets**

*FTC Workshop Opening Remarks from the Federal Trade Commission's  
Understanding Competition in Prescription Drug Markets:  
Entry and Supply Chain Dynamics*

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Thank you all for coming out bright and early this morning 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 in putting together 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 lifesaving medicines needed by our citizens. This agency does a lot of important work, but protecting the interests of consumers in the markets for prescription pharmaceuticals is one of our most critical responsibilities.

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<sup>1</sup> The views expressed in these remarks are my own and do not necessarily reflect the views of the Federal Trade Commission or any other Commissioner.

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 am happy to report that we have made much progress on many of these fronts. We have 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 continue the fight, challenging attempts to game the regulatory system for anticompetitive purposes.

It's been a great honor for me to serve at the FTC and be part of these varied and successful efforts to protect competition in the 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 a somewhat different focus. When you consider our pharmaceutical enforcement history in 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<sup>2</sup> framework. Many 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.

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<sup>2</sup> Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271, 282 (1984)).

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 have spoken about many times before, the protection of intellectual property rights is critical to drive innovation, and the Hatch-Waxman framework recognizes and enshrines that essential truth in law.

That said, providing 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 20-30% discount to the price charged by the branded product.<sup>3</sup> Subsequent generic entry continues to lower prices, with discounts of 85% or more seen when a large number of generic firms are each competing for business.<sup>4</sup> This evidence suggests that there are 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

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<sup>3</sup> FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* ii-iii (2011), <https://www.ftc.gov/reports/authorized-generic-drugs-short-term-effects-long-term-impact-report-federal-trade-commission>.

<sup>4</sup> FTC, *Pay-For-Delay: How Drug Company Pay-offs Cost Consumers Billions* 8 (2010), <http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf>.

assumed that once patent protections expired, the natural operation of market forces would drive prices down to something approaching marginal cost and that policymakers wouldn't have to do much more than get out of the way to see those 85% reductions in price. 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 low-cost generic drugs, and that is a great thing. However, we can also see that this has not occurred in every market. Some pharmaceuticals lose patent protections, but then draw no generic entry, allowing the incumbent firm to maintain high prices. Other medicines may draw some limited generic competition after the patents expire, 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 bought up off-patent, single source drugs and raised prices dramatically, without drawing an immediate competitive response.

Whenever any of these situations occurs, we should seek to understand why. Although these issues are complex, I'd 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.

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 the Hatch-Waxman Act is failing to deliver the full measure of its expected benefits, what are the root causes and what should the appropriate policy response be?

I recognize that when a law enforcement agency like the FTC identifies an area of concern, some people assume that it is a prelude to a raft of new enforcement actions. That assumption might seem particularly appropriate here, given our substantial enforcement history in this space and the critical nature of these products. Before we go any further here, 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 that we would have already fixed them.

The complex, multi-faceted nature of these problems strongly suggests that antitrust enforcement is not a cure-all that can fix all the potential problems in this space. Just as there is no single drug to cure every ailment, the antitrust laws are not a panacea for every economic concern. As I have said before, antitrust 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 a sector regulator. We may ultimately determine there is a need for greater antitrust 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 antitrust 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:

- (1) 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 or market participants alter those incentives to better align with the public interest in robust competition? If so, how?
- (2) 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?
- (3) 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?
- (4) How should all stakeholders evaluate proposals to reduce drug prices and increase consumer access?

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.

Finally, I am happy to note that we at the FTC are 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 our previous discussions. Our two agencies may have different missions and 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 U.S. consumers get the safe, efficacious and affordable medicines they deserve.

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

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 organizations can work together.