

Prepared Remarks of
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“Injecting Competition into Pharmaceuticals:
Combatting Anticompetitive Tactics that Keep Drug Prices High for American Consumers”

Good morning, and many thanks to the University of Florida for hosting today’s Competition Policy Enforcement Conference. I’m delighted and honored to be a part of today’s event.¹

The public’s interest in antitrust and competition policy today is at an historic high. It’s perhaps matched only by the fervor of public attention paid to antitrust in the days of the original trustbuster, President Theodore Roosevelt. And we at the FTC take that mission as seriously as he did.

I was privileged to join the FTC just one year ago, so to me, it’s satisfying to look back on the last 12 months’ worth of FTC accomplishments in the competition space just since then. Some of the top hits from the past year:

- We created a new division dedicated to high-tech investigations and cases, the Technology Enforcement Division.
- We hosted the 21st Century Hearings, a massive intellectual and empirical undertaking that spanned 23 days and drew over 900 comments, all aimed at considering whether fundamental changes in the economy require us to rethink our policies and enforcement priorities.
- We challenged 21 mergers.² One to keep your eye on right now: This month, the federal district court for the District of Columbia is hearing our request for a preliminary injunction to challenge a \$625 million deal that would, in our view, drive up prices for a critical industrial input: hydrogen peroxide.³

¹ These remarks reflect my own views. They do not necessarily reflect the views of the Commission or any individual Commissioner.

² More specifically, the FTC challenged 21 mergers in FY 2019, which runs from October 1, 2018 to September 30, 2019.

³ *FTC v. RAG-Stiftung [Evonik/PeroxyChem]*, Civil Action No. 1:19-cv-2337 (D.D.C).

- In September, the Commission filed an administrative complaint to block a \$1.2 billion title insurance merger that would have reduced an industry dominated by “the Big 4” players to “the Big 3.”⁴
- In June, the Eighth Circuit agreed with our arguments in *FTC v. Sanford Health*,⁵ affirming an injunction blocking an anticompetitive physician group merger in North Dakota.

But I would like to focus today on one critical part of our active antitrust agenda: health care. I want to talk today about the FTC’s power to combat high drug prices when a monopolist harms competition. We of course have a strong program to investigate and stop anticompetitive mergers in the pharmaceutical space. But I’ll focus today on the substantial resources we have dedicated to fighting anticompetitive practices in pharmaceutical markets. In the last five years, we have won judgments or settlements approaching \$2 billion – with the goal of returning much of that money to consumers or other purchasers.

In particular, I will focus on a number of practices that can result in high drug prices that we’re investigating and challenging when they injure competition:

- reverse payments
- abuse of government processes, including citizen petitions, sham litigation, and REMS abuse, and
- product hopping.

REVERSE PAYMENTS

One anticompetitive practice that the FTC has targeted with great success has been so-called “reverse payments.” In fact, just this year, we favorably settled *FTC v. Actavis*, the landmark reverse-payment case that ensures we can rely on antitrust law to prevent anticompetitive agreements that drive up drug prices.⁶ We settled the case on the eve of trial on remand from the Supreme Court.

Actavis. The FTC had taken *Actavis* all the way to the Supreme Court to fight for the position that antitrust law could challenge anticompetitive conduct that kept efficacious, lower-cost drugs off the market. The lower court had disagreed, holding that patent law shielded the conduct from competition challenge.

To understand what the case was about, you have to know a bit about the statutes that Congress passed to encourage companies here to bring lower-cost, safe and efficacious drugs

⁴ See FTC, *In the Matter of Fidelity National Financial/Steward Information Services*, <https://www.ftc.gov/enforcement/cases-proceedings/181-0127/fidelity-national-financialsteward-information-services>. The parties have since abandoned the transaction.

⁵ *FTC v. Sanford Health*, 926 F.3d 959 (8th Cir. 2019), 2019 WL 2454218 (June 13, 2019). We are particularly glad to have been joined in our challenge by North Dakota’s state attorney general.

⁶ 570 U.S. 136 (2013).

to market for American consumers. In a nutshell, it's this: To bring a *new* drug to market, the drug manufacturer has to show the FDA that the drug is safe and effective, which often involves an expensive, time-consuming regulatory process, including intensive safety and efficacy studies.⁷ But to bring a *generic version* of that drug to market, the generic manufacturer can take advantage of a regulations that Congress enacted to speed the introduction of safe, effective, lower-cost drugs.⁸ Under those regulations, the generic drug company need only show that the generic has the same active ingredients and is biologically and pharmacologically equivalent to the original drug. It doesn't have to duplicate the expensive and time-consuming safety and efficacy studies; it can rely on the safety and efficacy data that the original drug manufacturer provided.⁹

If the generic drug company seeks to enter with its product before expiration of any patents covering the branded drug product, the generic company has to certify that its generic version of the drug doesn't infringe any valid patents.¹⁰ The branded drug manufacturer may disagree with that assertion; if it does, it can sue the generic company for infringement. If it does that within 45 days, the FDA has to withhold approval of the generic drug for 30 months or until the infringement suit is over in district court, whichever comes first.¹¹ The first generic applicant to seek such treatment gets to be the only generic version of that drug on the market for 180 days; no other generic company can enter during that time period.¹² That's a very valuable financial benefit to that first-filing generic company.¹³

In *Actavis*, the original drug maker sued the first and second filing generics for patent infringement – and settled the case under circumstances that drew the FTC's attention. Under the terms of their settlements, the generics agreed not to enter until a certain date, and the branded drug maker agreed to pay each of the generics millions of dollars. The companies said that these payments were for "other services that the generics promised to perform," but the FTC alleged that "the true point of the payments was to compensate the generics for agreeing not to compete against [the branded drug maker] until 2015."¹⁴ This, we believed, was a "reverse payment," a payment made by the patent holder to the alleged infringer to forestall competition – and keep drug prices high.

⁷ More specifically, to market a new brand-name drug in the United States, a company must obtain FDA approval of a new drug application ("NDA") showing that the drug is safe and effective. 21 U.S.C. 335(a), (b)(1).

⁸ The statute at issue here the Drug Price Competition and Patent Term Expiration Act, more commonly known as the Hatch-Waxman Act. Under it, the generic company may file an abbreviated new drug application ("ANDA") demonstrating bioequivalence to the original drug. 28 U.S.C. 335(j).

⁹ Once the FDA approves the generic drug, the generic drug company can ask the FDA to rate its drug as "therapeutically equivalent" to the original drug. That designation makes a difference. Under state laws, pharmacists can dispense the generic's therapeutically equivalent – and less expensive – drug instead of the original – and more expensive – drug.

¹⁰ This certification is called a "paragraph IV" notice. 21 USC 355(j)(2)(A)(vii).

¹¹ 21 USC 355(j)(5)(B)(iii).

¹² The branded drug manufacturer can, however, launch a generic of its own – called an "authorized generic" – during that 180-day time period.

¹³ *Actavis*, 570 U.S. at 144.

¹⁴ *Id.* at 145.

The Eleventh Circuit, reviewing our case in 2012, said that such reverse payments are “immune from antitrust attack” absent sham litigation or fraud on the Patent & Trademark Office “so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.” It recognized that, as a matter of antitrust law, it is typically unlawful to pay your competitor not to enter the market. But, it said, reverse payment cases were different “because one of the parties owns a patent,” and a patent “conveys the right to cripple competition.”¹⁵

On appeal, the Supreme Court agreed with us that that was wrong. The Court rejected the Eleventh Circuit’s test and determined that reverse payments are not immune from antitrust challenge, but are subject to rule of reason review. The Court acknowledged that settlements are desirable and that patents can spur innovation, but neither of those things immunize conduct from antitrust challenge. As the Court noted, a “large and unjustified” reverse payment “can bring with it the risk of significant anticompetitive effects.”¹⁶ That can drive up drug prices for consumers, and antitrust law is right to police such conduct.

Impax. Building on the Supreme Court’s ruling, the FTC has remained active in the reverse-payments area. Just this spring, the Commission struck down another type of agreement in another reverse-payment case: *Impax*.

That case, in brief: Endo feared that Impax was about to enter the market with a generic – that is, less expensive – rival to Endo’s profitable and expensive drug, Opana ER. Once Endo and Impax were locked in Paragraph IV patent litigation, Endo and Impax reached an agreement. Under this agreement, Impax would refrain from entering the market with its less expensive generic drug, and Endo, for its part, would do four things: (1) it would provide Impax with a license to Endo’s current and future patents covering Opana ER, as well as a promise by Endo not to sue Impax for infringing those patents; (2) it wouldn’t launch an authorized generic that would spoil Impax’s 180 days of first-filer exclusivity; (3) it would protect Impax in the event the Opana market declined while Impax was waiting to enter, which ultimately resulted in Endo paying Impax more than \$100 million; and (4) it would pay Impax \$10-40 million for a “development and co-promotion deal” that the Commission thought “may have been a means of masking value transferred in exchange for eliminating the risk of competition.”¹⁷

The FTC’s administrative law judge ruled that Impax’s conduct did not violate antitrust standards. But in late March of this year, the Commission reversed, finding that the agreement was unreasonable and not justified by a procompetitive business justification. The case is now on appeal to Fifth Circuit.

¹⁵ *Id.* at 146 (quoting *FTC v. Watson Pharmaceuticals, Inc.*, 677 F.3d 1298, 1307, 1310 (2012)).

¹⁶ *Id.* at 158.

¹⁷ *In re Impax Laboratories, Inc.*, Dkt. 9373, Commission decision p. 7, n. 8 (Apr. 3, 2019) https://www.ftc.gov/system/files/documents/cases/d09373_impax_laboratories_opinion_of_the_commission_-_public_redacted_version_redacted_0.pdf.

One particularly interesting aspect of the *Impax* case is how the Commission handled Impax's defense that it wasn't likely to introduce its generic Opana drug before the date fixed by the reverse-payment agreement. That meant, in Impax's view, the agreement didn't pay for any delay.

The Commission ruled that it only needed to find that the reverse payment reduced the *risk* of competition. In other words, Complaint Counsel has to show only that the generic drug "might plausibly have entered" sooner than the reverse payment agreement allowed for.

Why? Because of what the Supreme Court said in *Actavis*. The *Actavis* court fingered the real harm in reverse payment cases: the prevention of "the risk of competition."¹⁸ Before it settles, a brand drug company faces the risk of generic competition. That risk is inherently probabilistic: there's uncertainty about when the generic will enter, what its market impact will be, and how the court would rule on the patent case. But, as the Supreme Court made clear, the relevant antitrust harm is using monopoly profits to replace the *possibility* of competition with the *certainty* of none for some period of time. Given that, the Commission said, it "asks too much" to demand that a fact-finder pinpoint the exact date of competition. Rather, it's enough to show that the settling parties agreed to eliminate the *risk* of competition.

* * *

We are proud of our successes in our reverse-payment docket, but we certainly don't win them all. For instance, we believe that although a district court allowed us to go to trial on our sham litigation claim (discussed below), it incorrectly interpreted *Actavis* and dismissed the FTC's reverse-payment count in *FTC v. AbbVie*.¹⁹ The FTC has appealed that loss to the Third Circuit, where it is pending now.

But the legacy of the FTC's reverse payment challenges is bigger than any individual case. It's encouraging that since the Supreme Court's decision in *Actavis*, there's been a significant decrease in the number of settlements that contain provisions that raise reverse-payment flags, like side deals and no-authorized-generic commitments.²⁰ ("No-authorized-generic commitments" are agreements by the branded drug maker not to launch an authorized generic during the first filer's 180 days of exclusivity.) But we are on the lookout for new techniques that could work the same harm.²¹

ABUSE OF GOVERNMENT PROCESSES: SHAM LITIGATION, CITIZEN PETITIONS, REMS ABUSE

In addition to policing for anticompetitive reverse payments, we are also on the watch for abuses of government processes that keep efficacious, less expensive drugs from consumers.

¹⁸ *Actavis*, 570 U.S. at 157.

¹⁹ *FTC v. AbbVie, Inc.*, 107 F.Supp. 3d 428, 438 (E.D. Pa 2015).

²⁰ The Medicare Modernization Act of 2003 requires parties to file with the FTC (and the Department of Justice) their Paragraph IV settlement agreements, which allows us to spot trends like this.

²¹ For example, we are watching now for patent settlement agreements that include promises not to use a third party to sell an authorized generic in competition with the first filer. This could have the same effect as a no-authorized-generic commitment.

I'll walk through three examples of that today: sham litigation, citizen's petitions, and REMS abuse.

Sham litigation. In a case challenging companies for abusing the litigation process, the FTC last year won the largest monetary award ever in a litigated FTC antitrust case.²² The case was *FTC v. AbbVie*.²³ According to the district court, the defendant pharmaceutical companies sold a highly profitable drug, at high prices. They knew that when their generic rivals entered the market, price would plummet, and so would their profits. So they filed meritless patent lawsuits against those competitors in order to keep them off the market. That did the trick. The meritless suits blocked at least one competitor from entering, and that propped up the price.

To understand how the strategy worked, you have to recall the regulatory scheme I talked about a moment ago. As I've mentioned, if the brand drug maker has flagged that it has patents protecting its drug, a generic drug manufacturer that wants to use the congressionally created path to speed entry needs to certify that its generic product isn't infringing any of the brand drug maker's valid patents. If the brand drug maker thinks that's wrong – that it does have valid patents that are being infringed – then it can halt (at least temporarily) the generic's entry by suing it for patent infringement.

The problem arises when the original drug maker brings an entry-barring patent suit that's nothing more than a sham. In *AbbVie*, the district court found that the branded drug maker's attorneys' "only reason for filing the infringement suits was to impose expense and delay on [the generic companies] so as to block their entry into [this drug] market with lower price generics and to delay defendants' impending loss of hundreds of millions of dollars in [drug] sales and profits."²⁴ The case is now on appeal to the Third Circuit.

Citizen Petitions. The FTC has likewise kept a watchful eye on another kind of government-process abuse that can keep drug prices high: the abuse of citizen petitions.

Anyone – including drug companies – can petition the FDA through a device called a "citizen petition" to ask the FDA to take (or refrain from taking) an action. But problems can arise when drug companies abuse the citizen petition process by using meritless arguments to keep competing drugs off the market – and keep less expensive, helpful drugs from patients.

The FTC has brought a case challenging such conduct: we sued Shire ViroPharma, alleging – among other things – anticompetitive abuse of the citizen-petition process. Shire had a lucrative drug that treated a life-threatening gastrointestinal infection. But it knew, we alleged,

²² Statement of FTC Chairman Joe Simons Regarding Federal Court Ruling in *FTC v. AbbVie* (June 29, 2018) <https://www.ftc.gov/news-events/press-releases/2018/06/statement-ftc-chairman-joe-simons-regarding-federal-court-ruling>. The judgment was for \$448 million.

²³ *FTC v. AbbVie, Inc.*, 329 F.Supp.3d 98 (E.D. Pa 2018).

²⁴ *AbbVie*, 329 F.Supp.3d at 126.

that competitors were going to try to enter its market with lower-cost, equally-good drugs, if they could get the FDA to approve their entry.

Once Shire learned that other companies were considering making generic equivalents of its drug, it swamped the FDA with allegedly meritless citizen petitions, in order to prevent those generics from coming on the market any time soon. According to our complaint, from March 2006 to April 2012, Shire submitted a total of 43 filings to the FDA and instituted three federal court proceedings — all allegedly to delay the approval of generic Vancocin capsules by convincing the FDA to require ANDA applicants to conduct in vivo clinical endpoint studies.²⁵

It took a while, but the FDA eventually rejected those citizen petitions, concluding that Shire’s scientific challenges to the bioequivalence recommendation “‘lack[ed] merit’ and ‘were unsupported.’”²⁶ The competitors could finally bring their less expensive, safe products to market. “On that same day, the FDA approved three ANDAs for generic Vancocin capsules. Shire lost almost 70% of its unit sales for Vancocin capsules within three months.”²⁷ But consumers had continued to pay higher prices all the while. By delaying generic entry for years, Shire ViroPharma had reaped hundreds of millions of dollars in profits, the FTC alleged. Unfortunately, the FTC’s loss on a statutory construction issue relating to the timing of the FTC’s case has kept the Third Circuit from ruling on the merits of these allegations.²⁸

Meanwhile, Congress has acted to try to stem the abuse of citizen petitions. In 2007, Congress enacted a provision that gives the FDA a deadline for responding to citizen petitions. It also lets the FDA summarily deny petitions that were filed primarily to delay FDA approval of another drug or biologic and that raise no facially valid scientific or regulatory issue. As laudable as this improvement is, it’s no panacea: The FDA “continues to be concerned” that current law still “allows the submission of petitions that are intended primarily to delay the approval of competing drug products and do not raise valid scientific issues,” and that culling them out takes resources the FDA would rather use to address important public health issues.²⁹ There is plenty of work here left to do.

REMS abuse. Another abuse-of-process practice that can harm competition and drive up drug prices for patients is REMS abuse. Some pharmaceuticals have real safety risks, and the FDA

²⁵ *FTC v. Shire ViroPharma*, No. 1:17-cv-00131 (D. Del.) (Feb. 7, 2017).

²⁶ *Id.*, FTC Complaint ¶ 104,

https://www.ftc.gov/system/files/documents/cases/170216viropharma_unredacted_sealed_complaint_.pdf.

²⁷ *Id.* at ¶ 149.

²⁸ The Third Circuit held that 15 USC 53(b), Section 13 (b) of the FTC Act, “does not permit the FTC to bring a claim based on long-past conduct without some evidence that the defendant ‘is’ committing or ‘is about to’ commit another violation.” *FTC v. Shire ViroPharma, Inc.*, 917 F.3d 147, 156 (3d Cir. 2019).

²⁹ FDA Report to Congress, *Ninth Annual Report on Delays in Approvals of Applications Related to Citizen Petitions and Petitions for Stay of Agency Action for Fiscal Year 2016* (submitted Jan. 2018) at 7 (adding that the law “requires FDA to prioritize these petitions above other matters, such as safety petitions, that do raise important public health concerns. The Agency remains concerned about the resources required to respond to 505(q) petitions within the 150-day deadline at the expense of completing the other work of the Agency, when these petitions are not based on public health concerns.”).

requires the makers of those drugs to have a strategy – called a Risk Evaluation and Mitigation Strategy, or REMS – to mitigate that danger by, among other things, restricting the drug’s distribution. When used as intended, a REMS can be a critical tool to protect patient safety. For example, pharmacies selling the drug may have to be enrolled in the drug’s REMS, and the dispensing pharmacist may have to confirm that the prescriber and patient are enrolled in it, too.

Problems arise when drug makers use REMS not to protect patients but to keep prices from falling by forestalling competitors’ entry.³⁰ The maker of a big, profitable drug knows price will fall – and so will its profits – when a rival enters with a generic or biosimilar version of its drug. But it also knows that the generic or biosimilar rivals need samples of its drug to enter. Without samples of the branded drug, competitors can’t conduct the bioequivalence testing they need to do to get the FDA’s approval to launch.³¹ If those competitors can’t enter, price never falls, the branded drug maker profits, and consumers suffer.

Ordinarily, generic or biosimilar competitors get the testing samples they need from wholesale distributors. REMS abuse may make that impossible – and generic companies aren’t likely to get a welcome reception when they ask the brand to make samples available. In short, a REMS abuse strategy could be a way for a monopolist to stave off on-the-horizon competition, maintaining high prices by using its REMS as an excuse not to let generic or biosimilar rivals get what they would need to compete.

The FTC has alerted Congress and federal agencies to this problem³² and has flagged the issue for the courts in amicus briefs.³³ Helpfully, the FDA has issued letters clarifying that a given generic firm’s protocols are safe – and that a branded drug manufacturer can safely share samples with such a firm, without risking violating the terms of their REMS.³⁴ But the FDA recognizes that “‘gaming’ tactics” can still “delay generic competition ... when potential generic applicants are prevented from obtaining samples of certain brand products necessary to support approval of a generic drug. The inability of generic companies to purchase the samples they need slows down, or entirely impedes, the generic drug development process – leading to delays in bringing affordable generic alternatives to patients in need.”³⁵ I commend to you all

³⁰ Problems can also arise in connection with voluntary restricted distribution systems that are not required by the FDA. They can have the same anticompetitive effects as abuse of a REMS process.

³¹ As noted above, firms that can show the FDA that their products are equivalent to a branded pharmaceutical or biologic product can take advantage of speedier paths to market.

³² See, e.g., Statement of the Federal Trade Commission to the Department of Health and Human Services Regarding the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (July 16, 2018); Prepared Statement of Markus H. Meier, Acting Director, Bureau of Competition, Federal Trade Commission before the U.S. House of Representatives, Judiciary Committee, Subcommittee on Regulatory Reform, Commercial and Antitrust Laws, on “Antitrust Concerns and the FDA Approval Process” (July 27, 2017).

³³ The FTC filed amicus briefs on this issue in *Mylan v. Celgene*, Case No. 2:14-cv-2094 (D. N.J. June 17, 2014) and *Actelion v. Apotex*, Case No. 1:12-cv-05743 (D. N.J. March 11, 2013)). *Actelion* settled in 2014. The parties in *Mylan* stipulated to dismissal with prejudice in August 2019.

³⁴ <https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/reference-listed-drug-rld-access-inquiries>

³⁵ *Id.*

the FDA’s online posting of all the drugs – over fifty of them, now – that generic firms have told the FDA they are having trouble getting samples of.³⁶

PRODUCT HOPPING

Another category of anticompetitive conduct that can sustain high drug prices is “product hopping.” Broadly speaking, there’s nothing wrong with introducing new or reformulated products. It can be really good for consumers when companies improve product efficacy or safety by introducing new or reformulated drugs.

But product hopping can also be anticompetitive. Product hopping involves tactics to defeat the substitution of lower-priced generics at the pharmacy counter. Product hopping raises antitrust concerns when a brand introduces a reformulated product and then takes steps to impede competition on the merits between the original and the reformulated drug, thereby eliminating the prescription base for the original product before generics even have a chance to be substituted at the pharmacy.

This summer, we brought a product-hopping case against Reckitt Benckiser Group plc.³⁷ Under the terms of the settlement, Reckitt had to contribute \$50 million to a fund to be distributed back to those who were overcharged.

The basic facts of this case: Reckitt, through its former subsidiary Reckitt Benckiser Pharmaceuticals (now known as Indivior), sold Suboxone – a drug that treats opioid addiction – as a tablet. With generic competition for that tablet on the horizon, Reckitt and Indivior developed and introduced a film version of the product.

Reckitt and Indivior appreciated that under state law, the film version would not be substitutable with generic tablets. So it pushed the market toward the film and away from the tablet, the FTC alleged, in a number of ways: It said that the film was safer than the tablets, without any data to back that up; it significantly raised the tablet’s price, an especially odd move given that the film was costlier to make and (according to Reckitt) better; and ultimately, it stopped making the tablet.

The net effect of these moves was that 85% of Suboxone prescriptions were for the film – not the tablet – by the time generic tablets were approved. In effect, that meant that Reckitt never really had to compete against lower-cost generics on the merits.

Our consent order in this case reflects the “egregiousness” of Reckitt’s alleged conduct.³⁸ In addition to the \$50 million payment, our order bans Reckitt from destroying the market for a current product when it introduces a reformulated one.

³⁶ The RLD Access Inquiries list is available here: <https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/reference-listed-drug-rlid-access-inquiries>. It is updated semi-annually.

³⁷ *FTC v. Reckitt Benckiser Group, PLC*, Civil Action No. 1:19CV00028 (W.D. Va.).

CONCLUSION

The bottom line here is that as all these cases and advocacy show, the FTC takes very seriously its responsibility to combat anticompetitive pricing in the health care space. We are using all the tools at our disposal— including investigations, cases, and advocacy before Congress and other agencies — to ensure that the competitive process can drive affordable prices for critical drugs and spur medical innovation that benefits us all.

Thank you.

³⁸FTC News Release, “Reckitt Benckiser Group plc to Pay \$50 Million to Consumers, Settling FTC Charges that the Company Illegally Maintained a Monopoly over the Opioid Addiction Treatment Suboxone,” (July 2019) <https://www.ftc.gov/news-events/press-releases/2019/07/reckitt-benckiser-group-plc-pay-50-million-consumers-settling-ftc>.