Additional Questions for the Record

Subcommittee on Consumer Protection and Commerce
Hearing on
"Profits Over Consumers: Exposing How Pharmaceutical Companies Game the System"
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The Honorable Cathy McMorris Rodgers (R-WA)

1. When a brand company discontinues its branded drug, and takes it off the market for reasons unrelated to safety or efficacy, can a generic drug company file a generic drug application for such a discontinued drug and go to market?

Answer: Yes, a generic drug can come to market as long as the patent for the branded drug has expired.

2. When a brand company introduces a reformulated drug and discontinues the original drug, does that prevent a generic company from going to market with a generic copy of the original drug?

Answer: No, a generic drug can still come to market once the patent for the branded drug has expired.

   a. And would consumers (or their physician) then have a choice between the generic old product and the branded new product?

Answer: Yes, both the branded new product and the generic version of the older product would be on the market, so consumer and their physicians would have a choice.

3. Under existing legislative proposals, the only permissible justification for a hard switch is that the change to the product was made for reasons related to safety. However, this ignores the fact that important improvements may be made related to the efficacy of a drug. Do you believe that a manufacturer should be held liable for an antitrust violation if they develop a new product that is significantly more effective than the previous version of the drug and remove the less effective drug from the market? For example, if a manufacturer develops a new version of a drug that increases the cure rate for an otherwise fatal disease from 40% to 80% and then removes the less effective version from the market, do you not consider that a legitimate justification for switching the market to the new product?

Answer: I consider this a legitimate justification because it will ensure that more patients are directed to more effective drugs.

4. If we seek to preclude drug makers from "unfairly disadvantaging" existing products, do you think this will result in fewer choices for consumers? 1f so, why?

Answer: Yes, the phrase “unfairly disadvantaging” is extremely vague and potentially very broad. Legislation that is too broad in that it covers too many standard business practices, or too vague in that drug companies can’t predict what behavior will lead to significant litigation or penalties, will end up reducing innovation. This reduced innovation will mean that fewer products come to market, resulting in fewer choices for consumers.

5. In your testimony, you highlight that certain incentives established by patent law, motivate brand drug makers to innovate rather than hand their sales over to generic competition - which the FTC has actually recognized as benefitting consumers. Can you please explain?

Answer: As their patent period expires, brand companies face the likely loss of 80-90 percent of their sales to generic versions of the drug under state substitution laws. These laws allow or even require pharmacists to automatically substitute a generic equivalent drug when a patient presents a prescription for a brand drug. To avoid losing most of their sales to generic companies, brand companies have the incentive to shift their marketing efforts to a new patent-protected drug which can serve as a substitute for the drug about to go off patent. To acquire a patent and FDA approval, the new drug must be different and innovative. Thus, incentives under patent law—incentives to innovate in order to obtain the exclusionary patent period—motivate brand companies to create new drugs instead of handing over the majority of their sales to the generic companies. As the FTC has explained, these new drugs can, in turn, benefit consumers: “The threat posed to existing brand drugs by generic competition can incentivize the brand company facing a dramatic loss of sales to develop new and innovative drugs that benefit consumers.” [1]

6. Your testimony indicates that there is a window of time during which a hard switch can be presumed anticompetitive. Can you please explain when you believe that window should begin and end?

Answer: There is a window during which a hard switch can be presumed to be anticompetitive. For conventional, small-molecule drugs this window starts around the time a generic company files an acceptable ANDA containing a Paragraph IV challenge to the drug as this indicates that there is a generic competitor that could potentially enter the market. The window should end when the generic drug has penetrated the market. According to existing research, generics are able to capture

[1] Brief for Federal Trade Commission as Amicus Curiae, Mylan Pharmaceuticals, Inc. v. Warner Chilcott Public Limited Company, No. 12-3824, 2012 WL 7649225, (E.D. Pa. Dec. 3, 2012).

over 70 percent of the brand drug's market share within only 3 months of their market entry. Thus, the relevant window should end sometime around 3 months after generic entry.

a. If a manufacturer withdraws an older product from the market outside of the window, would this eliminate consumer choice?

Answer: No, outside of that window, it is extremely unlikely that the product replacement eliminates consumer choice. If a brand company replaces a drug with plenty of patent life remaining and no generics anywhere on the horizon, consumer choice is not eliminated because it does not reduce the drugs that consumers could choose from; they had one drug to choose before the switch and one drug to choose after the switch. Replacing a drug after generics have already penetrated the market also does not eliminate consumer choice because patients would already be accustomed to taking the generic versions of the older drug, so replacement would not coerce them into switching from the generic they had been taking.

i. If not, should the action be presumed anticompetitive?

Answer: No.

7. As discussed in the hearing, patients have long benefited from improvements to existing drugs made by the original manufacturer. However, broad and vague legislation that would impose antitrust liability on original manufacturers is likely to chill incentives for such companies to invest in improvements to existing drugs. Accordingly, broad or vague legislation leaves only one option for manufacturers: to start drug development anew, which will slow development of life-saving medicines and increase the costs to produce medicines.

a. Can you provide your view on the impact of decision-making within a pharmaceutical manufacturer in light of the economic burden and uncertainty this legislation may result in? In your view, is this legislation likely to drive up costs to consumers by eliminating the option for pharmaceutical manufacturers to improve on their innovation over time?

Answer: Vague legislation will create significant uncertainty for brand innovators. If brand companies cannot reliably predict whether the introduction of new products will be considered anticompetitive, they will have less incentive to engage in costly R&D. The companies will not spend the billions of dollars it typically costs to bring a new drug to market when they cannot be certain if, years down the road, the introduction of that new drug will lead to significant litigation, market-stopping injunctions or penalties.

This reduction in innovation is likely to drive up healthcare costs over time for two reasons. First, less innovation means that fewer products will come to market, and fewer products mean there is less competition to keep prices low. Second, newer and more effective drugs reduce medical spending on doctor visits, hospitalizations, and other medical procedures; data show that for every incremental $1 spent on new drugs,

total medical spending decreases by more than $7. Thus, less drug innovation will likely result in increases in other healthcare spending.

8. Professor Carrier has recommended that Congress include an "'economic sense" test as part of drug pricing legislation. Do you agree with an "economic sense" test approach or would you recommend Congress consider a more pinpointed standard? Please explain your reasoning.

Answer: I would not recommend the "no-economic-sense" test for several reasons. First, it asks the wrong conceptual question in situations where brand companies have introduced a new product to market—activity that it typically considered procompetitive. If this new product provides some therapeutic value for consumers, society should not care what impact the value-creating product has on the company's profits. Second, the "no-economic-sense" test would be very difficult to operationalize. For a brand company producing several products, many of the costs are jointly shared across multiple products, and it would be difficult or even impossible to allocate a share to an individual product. Finally, and most importantly, the "no-economic-sense" test would create terrible incentives. Because brand companies would face the risk of severe penalties if the investment they make in developing a new product outweighs the profit they earn, the companies would have the perverse incentive to either economize on their investments, which may curtail important research and development activities, or not invest in bringing new products to market at all. This could have signifcant impacts on drug innovation.

9. In your testimony, you note that a minor change to a follow-on product is often, in and of itself innovative? Can you elaborate on this point?

Answer: Most innovation in the pharmaceutical industry involves development of next generation improvements, such as creating new products that expand therapeutic classes, increase available dosing options, remedy physiological interactions of known medicines, or improve other properties of existing medicines. According to FDA data, two-thirds of new drug approvals are for these incremental innovations. And according to the World Health Organization, over 60 percent of drugs deemed necessary for combating prevalent diseases are the result of incremental innovations.

10. In the hearing, you noted that patients have benefited from adjusted or improved dosages in medicines that have occurred as a result of advancements and better understandings of the science over time. Yet if the-soft switch language is too broad or vague, do you believe such legislation would chill investment in improved products? If so, what impact might the legislation have on specific patient populations that did not respond to the original product? How would you narrow the soft switch language to address this concern?

Answer: Soft-switch language that is too broad in that it covers too many standard business practices, or too vague in that drug companies can't predict what behavior will lead to

significant litigation or penalties, will reduce investment in the development of next generation improvements. Reduced investment means that fewer improved products will come to market. This will harm patients that benefit from these improvements because they cannot tolerate the route of administration or dosage form of the original product or suffer side effects from the original product.

Legislation should clearly indicate that a soft switch will only be presumptively anticompetitive if it so significantly interferes with consumer choice that consumers have no practical alternative but to switch to the new product, with no offsetting consumer benefit. Legislation should also indicate that this degree of interference will typically require some other wrongful conduct, such as fabricating safety concerns or falsely disparaging a product

11. Absent specific actions by a manufacturer to prevent generic entry into the market, you suggest that innovation resulting in a follow-on product should not qualify as product hopping. Can you elaborate on the potential negative unintended consequences that would stifle innovations in medicine?

Answer: The introduction of a new or improved product that does not prevent generic entry is generally procompetitive. Consumers have access to more products, and the new product is likely to be safer or more effective in some way. We should encourage drug companies both to invest in improving their products and to bring those drugs to market when they are available. Overly broad legislation that defines too many standard business practices as anticompetitive will deter drug companies from investing in and introducing superior products. This decrease in innovation will result in reduced choice for consumers, which will negative impact consumer health and increase health care spending.

12. Do you believe "consumer coercion" or "lack of choice" should be added as a factor in the soft switch provision of the product hopping legislation? If so, can you provide specific examples that would trigger "consumer coercion" or "lack of choice" in a soft switch?

Answer: Yes, I believe that legislation should make clear that a soft switch is only presumptively anticompetitive if it involves wrongful conduct that so significantly interferes with consumer choice that it effectively eliminates it, with no offsetting consumer benefit.

A soft switch significantly interferes with consumer choice to the point of effectively eliminating it when customers have no practical alternative but to switch to the new product. For example, if a brand drug company keeps an older drug on the market but communicates unambiguously fabricated safety concerns to doctors while championing the newer alternative, then patients effectively have no choice but to switch to the new drug. Similarly, if a brand company destroys inventory of the older drug to create a shortage so that prescribers stop prescribing it, then consumers effectively have no choice.

13. In the hearing, you stated that it should not be considered a "soft switch" to merely introduce a follow-on product and leave the original product on the market - that there must be other wrongful conduct. Can you explain what you meant by this statement? What "other wrongful conduct" should be required to trigger a soft switch?

Answer: Generally, the market introduction of a new or improved product while leaving an older product on the market is procompetitive: consumers have access to more products, and the new product is likely to be safer or more effective. However, if a soft switch includes wrongful conduct that gives consumers no practical alternative but to switch to the new product, then it has effectively eliminated consumer choice. For example, if a brand drug company keeps an older drug on the market but communicates unambiguously fabricated safety concerns to doctors while championing the newer alternative, then patients effectively have no choice but to switch to the new drug. Similarly, if a brand company destroys inventory of the older drug to create a shortage so that prescribers stop prescribing it, then consumers effectively have no choice.

14. As currently contemplated, product hopping legislation may also include a transparency component that would require manufacturers to disclose marketing plans and other strategic communications to both the FDA and the FTC. What trade secret concerns might occur with such disclosure requirements? Should Congress create an exception from such disclosure for confidential business information?

Answer: Congress should create an exception for the disclosure of confidential business information. Otherwise, the disclosure could result in confidential business information becoming available to competitors, which will likely weaken competition in the drug industry and increase drug prices. Federal antitrust agencies have long recognized that the disclosure of sensitive business information can lead to tacit collusion and higher prices: "the sharing of information related to a market in which the collaboration operates or in which the participants are actual or potential competitors may increase the likelihood of collusion on matters such as price."[2] Similarly, the FTC notes that the disclosure of price and cost information is particularly harmful to competition: "the sharing of information relating to price, output, costs, or strategic planning is more likely to raise competitive concerns than the sharing of information relating to less competitively sensitive variables."[3]

15. New products can increase competition through brand-to-brand competition. Can you describe how this can happen, and how certain proposals on "product hopping" may serve to disincentivize these innovations, and therefore decrease brand-to-brand competition?

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[2] THE FEDERAL TRADE COMMISSION AND THE DEPARTMENT OF JUSTICE, ANTITRUST GUIDELINES FOR COLLABORATIONS AMONG COMPETITORS §3.31(b) (2000), *available at* http://www.ftc.gov/os/2000/04/ftcdojguidelines.pdf.
[3] *Id.*

Answer: Overly broad or overly vague legislation that reduces incentives to improve drug products and bring those drugs to market, will result in less brand innovation. The companies will not spend the billions of dollars it typically costs to bring a new drug to market when they cannot be certain if, years down the road, the introduction of that new drug will lead to significant litigation, market-stopping injunctions or penalties. Less innovation by brand companies means there will be fewer brand products brought to market to compete with other brand products.

16. Many of the witnesses have testified that "product hopping" undermines a generic or interchangeable biologic ability to be automatically substituted for the reference product. If this is the primary concern, is there a reason to include non-interchangeable biosimilars within scope of any purported “product hopping” bill? Wouldn't including biosimilars have a negative impact in innovation in the biologics space?

Answer: There is no reason to consider non-interchangeable biosimilars in product-hopping legislation. These non-interchangeable biosimilars cannot take advantage of automatic substitution laws, so whether an original drug is replaced by an improved version is irrelevant: the non-interchangeable biosimilar could not be substituted for either the original or the new drug.

17. Legislation pending in the Senate would give rise to a presumption of anticompetitive "product hopping" if a manufacturer introduced a "follow-on product" and took any action that "unfairly disadvantaged" the older product. You testified that any approach to "product hopping" must be precisely drafted to avoid negatively impacting innovation. Would this standard of "unfairly disadvantag[ing]" provide manufacturers with sufficient guidance on the types of activities that would be presumptively anti-competitive?

Answer: The phrase “unfairly disadvantaging” is extremely vague and gives no practical guidance on the types of activities that would be presumptively anticompetitive. Legislation that is unclear about when the introduction of new products will be deemed anticompetitive will create significant uncertainty for brand innovators. This uncertainty will lead to less innovation because brand companies will not engage in costly R&D if they cannot be certain whether, years down the road, the introduction of that new drug will lead to significant litigation, market-stopping injunctions or penalties.

18. The FTC already has significant authority to prohibit anticompetitive activity. What risks does industry-specific "product hopping" legislation have on reducing innovation in the biopharmaceutical space?

Answer: Legislation targeting the pharmaceutical industry that is overly broad or overly vague could harm consumers by reducing drug innovation. This reduced innovation will likely reduce consumer choice, negatively impact health outcomes, and increase overall health care spending.

The Honorable Michael C. Burgess, M.D. (R-TX)

1. When a pharmaceutical company engages in a "soft-switch" - what is the impact on patients? Can you give an example of harm to a patient as a result of a "soft--switch"?

Answer: In general, the market introduction of a new or improved product while leaving an older product on the market is procompetitive: consumers have access to more products, and the new product is likely to be safer or more effective in some way. However, if a soft switch includes wrongful conduct that so significantly interferes with consumer choice that customers have no practical alternative but to switch to the new product, then the soft switch effectively eliminates consumer choice. In this situation, the patient may not have the ability to choose a product that would be better or safer for them.

2. As you mentioned in your testimony the determination whether product hopping is anticompetitive is dependent on the situation. It is the FTC's job to identify and challenge anticompetitive behavior and patent-gaming. What is the FTC currently doing to prevent anticompetitive patent practices?

Answer: Although the FTC is in the best position to explain what they are doing in this area, I know that they have been challenging anti-competitive product-hopping behavior. For example, in July, 2019, FTC announced a $50 million settlement with Reckitt Benckiser Group over charges that the company violated antitrust laws through a deceptive scheme to thwart lower-priced generic competition to its branded drug Suboxone.[4]

3. ln light of your antitrust and competition-focused studies, arc the courts the best place to deal with anticompetitive determinations?

Answer: Courts have the advantage of analyzing each product replacement situation individually so that they can precisely determine when a replacement is anticompetitive. However, there is currently some inconsistency among court decisions and, as a result, a lack of clarity about when product replacements will be considered anticompetitive product hopping. As a result, legislation that is clear and not overly broad could provide important guidance on when the introduction of new products will be deemed anticompetitive.

4. What is the United States Patent and Trademark Office doing to monitor patents and prevent patent gaming?

[4] Federal Trade Commission, 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 11, 2019), https://www.ftc.gov/news-events/press-releases/2019/07/reckitt-benckiser-group-plc-pay-50-million-consumers-settling-ftc.

Answer: The USPTO is in the best position to explain what it is doing to ensure the quality of existing patents. However, USPTO Director Andrei Iancu has spoken publicly of his office's efforts to bring vigorous but balanced review of challenges to existing patents through the inter partes review process enacted as part of the America Invents Act.[5]

5. Your testimony notes that Congress "should be careful to ensure that any legislative solution be narrowly tailored" and that "improvements to existing products that provide real value and benefits to patients should be encouraged." Does he have concerns that existing legislative proposals may be overly broad and deter these important improvements?

Answer: Current proposals include the phrase "unfairly disadvantages" that is extremely vague and potentially very broad. Legislation that is too broad in that it covers too many standard business practices, or too vague in that drug companies can't predict what behavior will lead to significant litigation or penalties, will end up reducing innovation. This reduced innovation will mean that fewer products come to market, resulting in fewer choices for consumers.

6. ls "unfairly disadvantaged" an established principle in antitrust law? Is it dear what it means to you?

Answer: The phrase "unfairly disadvantaging" is extremely vague and gives no practical guidance on the types of activities that would be presumptively anticompetitive. Although the FTC and various courts have sometimes observed after-the-fact that anticompetitive behavior "unfairly disadvantages" competitors, the phrase is generally not used to proactively proscribe certain behaviors that will be deemed anticompetitive.

7. If we seek to preclude drug makers from "unfairly disadvantaging" existing products, do you think this will result in fewer choices for consumers?

Answer: Yes, because "unfairly disadvantage" is so vague a term, legislation that does not offer more clarity on when the introduction of new products will be deemed anticompetitive will create significant uncertainty for brand innovators. If brand companies cannot reliably predict whether the introduction of new products will be considered anticompetitive, they will have less incentive to engage in costly R&D. Less investment in R&D will result in less innovation, fewer new drugs brought to market, and reduced choice for consumers.

[5] United States Patent and Trademark Office, Remarks by Director Iancu at the American Intellectual Property Law Association Annual Meeting (Oct. 25, 2018), https://www.uspto.gov/about-us/news-updates/remarks-director-iancu-american-intellectual-property-law-association-annual.