

Multilateral Pharmaceutical Merger Task Force Seeks Public Input

The Federal Trade Commission and its counterpart competition enforcement agencies, the Canadian Competition Bureau, the European Commission Directorate General for Competition, the U.K.'s Competition and Markets Authority, the U.S. Department of Justice Antitrust Division, and Offices of State Attorneys General (the **Task Force agencies**) [have launched](#) a working group to update their approaches to analyzing the effects of pharmaceutical mergers. These agencies seek input from the public to inform their review. The Task Force will receive and make available all submissions online through the FTC's portal on www.regulations.gov.

This joint project taps expertise from competition authorities with whom the FTC cooperates frequently, as well as others with relevant experience. The goal of this initiative is to identify concrete and actionable steps to review and update the analysis of pharmaceutical mergers. This project will ensure that investigations by the Task Force agencies include fresh approaches that fully analyze and address the varied competitive concerns that these mergers and acquisitions raise, including in light of rapidly changing drug development and manufacturing approaches.

The Multilateral Pharmaceutical Merger Task Force is exploring new or refreshed theories of harm to address all anticompetitive effects from pharmaceutical mergers, acquisitions, joint ventures, and consolidation. The Task Force will explore what evidence may be relevant to determine whether a merger gives rise to competition concerns and, where applicable, sustain a challenge should the agencies seek to block these mergers in the future. And the Task Force likewise will consider potential remedies to resolve competition concerns, such as the feasibility and effectiveness of divestitures under new or refreshed theories of harm.

The Multilateral Pharmaceutical Merger Task Force seeks to enhance its members' understanding of the impact of mergers on prices, quality, access, drug supply chain resilience, capital market investment, and innovation for pharmaceutical products, including biologics and pipeline products. We encourage empirical and pharmaceutical research by academics and healthcare industry stakeholders regarding these topics, as well as suggestions regarding potential case studies and data sources. In addition, we invite public comments regarding the effects of pharmaceutical mergers. We anticipate hosting a public workshop to facilitate discussion among researchers, policymakers, regulators, law enforcers, industry stakeholders, and consumers regarding their experiences with pharmaceutical mergers.

Request for Public Comment:

This Notice is intended to facilitate a rigorous discussion of the ways to study the impact of pharmaceutical mergers. The Task Force's goal is to encourage the public, including health policy experts, economists, attorneys, scientists, health care practitioners, academics, and consumers, to share ideas that will lead to the development of future enforcement and policy efforts.

Accordingly, the Task Force poses these general questions, and encourages the public to submit comments on other issues concerning the effect of pharmaceutical mergers:

1. What theories of harm should enforcement agencies consider when evaluating pharmaceutical mergers, including theories of harm beyond those currently considered?

2. What is the full range of a pharmaceutical merger's effects on innovation? What challenges arise when mergers involve proprietary drug discovery and manufacturing platforms?
3. In pharmaceutical merger review, how should we consider the risks or effects of conduct such as price setting practices, reverse payments, and other ways in which pharmaceutical companies respond to or rely on regulatory processes?
4. How should we approach market definition in pharmaceutical mergers, and how is that implicated by new or evolving theories of harm?
5. What evidence may be relevant or necessary to assess, and if applicable, challenge a pharmaceutical merger based on any new or expanded theories of harm?
6. What types of remedies would work in the cases to which those theories are applied?
7. What factors, such as the scope of assets and characteristics of divestiture buyers, influence the likelihood and success of pharmaceutical divestitures to resolve competitive concerns?

If your response relates to a particular agency or agencies within the Task Force, please indicate that differentiation in your submission.

Instructions for Filing Public Comments:

Interested parties are invited to submit written comments on the topics described above to the FTC, on behalf of the Task Force, electronically or in paper form. For the Task Force to consider your comment, we should receive it on or before June 25, 2021. Staff at the Task Force agencies will consider these comments when developing potential research projects or a public workshop agenda, and may use these comments in subsequent reports or policy papers, if any. Comments should refer to "Pharmaceutical Task Force, Project No. P212900."

Comments filed in electronic form should be submitted using the following web link: <https://www.regulations.gov/docket/FTC-2021-0025> and following the instructions on the web-based form.

A comment filed in paper form should include the "Pharmaceutical Task Force, Project No. P212900" reference both in the text and on the envelope, and should be mailed or delivered to the following address: Federal Trade Commission, Office of the Secretary, Room H-113 (Annex X), 600 Pennsylvania Avenue, NW, Washington, DC 20580. Because paper mail addressed to the FTC is subject to delay due to heightened security screening and COVID-19, please consider submitting your comments in electronic form, if possible.

Please note that your comment – including your name and state – will become part of the public record of this project. In addition, comments may eventually be included on a publicly accessible FTC or other Task Force agency website in connection with a public workshop. Because comments will be made public, they should not include any sensitive personal information, such as an individual's Social Security Number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number;

or credit or debit card number. Comments also should not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, comments should not include “trade secret or any commercial or financial information which is obtained from any person and which is privileged or confidential,” as provided in Section 6(f) of the Federal Trade Commission Act (FTC Act), 15 U.S.C. § 46(f), and FTC Rule 4.10(a)(2), 16 C.F.R. § 4.10(a)(2). Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled “Confidential,” and must comply with FTC Rule 4.9(c).¹ For any copyrighted material, please provide authorization (signed by the publisher or author if they retain the copyright) so that the material may be republished on the Agencies’ websites.

The U.K.’s Competition and Markets Authority will treat information submitted in the context of this consultation in accordance with Part 3 of the Enterprise Act 2002, UK General Data Protection Regulation and any other applicable legislation.

The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives, whether filed in paper or electronic form. As a matter of discretion, the FTC makes every effort to remove home contact information for individuals from the public comments it receives before placing those comments on the FTC website. More information, including routine uses permitted by the Privacy Act, may be found in the FTC’s privacy policy, available at <http://www.ftc.gov/ftc/privacy.htm>.

For Further Information Contact:

Heather M. Johnson, Acting Deputy Director, Bureau of Competition, Federal Trade Commission, 600 Pennsylvania Avenue, NW, Washington, DC 20580, hjohnson@ftc.gov.

¹ The comment must be accompanied by an explicit request for confidential treatment, including the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. The request will be granted or denied by the Commission’s General Counsel, consistent with applicable law and the public interest. See FTC Rule 4.9(c), 16 C.F.R. § 4.9(c).