Oral Remarks – Open Commission Meeting
June 16, 2022

Policy Statement of the Federal Trade Commission on Rebates and Fees in Exchange for Excluding Lower Cost Drug Products

Report to Congress on Combatting Online Harms through Innovation

I. Policy Statement of the Federal Trade Commission on Rebates and Fees in Exchange for Excluding Lower Cost Drug Products

Health care spending accounted for 19.7 percent of the nation's GDP in 2020.[1] Recognizing that health care issues have a daily and frequently significant impact on consumers, the FTC has long pursued a comprehensive agenda to address unlawful conduct in the health care space generally,[2] and in the pharmaceutical space specifically.[3] According to one analysis, over 45% of non-merger antitrust complaints filed by the FTC since 2009 were in health care industries, and over half of those complaints were in the pharma space.[4] In addition, the agency carefully screens pharmaceutical mergers,[5] combats anticompetitive

---

[1] Historical National Health Expenditure Data, CENTERS FOR MEDICARE & MEDICAID SERVICES, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical#:~:text=The%20data%20are%20presented%20by,spending%20accounted%20for%2019.7%20percent (last visited June 14, 2022).

[2] For an overview of FTC actions in the health care space generally, *see* FED. TRADE COMM'N, OVERVIEW OF FTC ACTIONS IN HEALTH CARE SERVICES AND PRODUCTS (Apr. 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/2022.04.08%20Overview%20Healthcare%20%28final%29.pdf.

[3] FED. TRADE COMM'N, OVERVIEW OF FTC ACTIONS IN PHARMACEUTICAL PRODUCTS AND DISTRIBUTION (Apr. 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/2022.04.08%20Overview%20Pharma%20%28final%29.pdf.

[4] *Nearly half of FTC antitrust complaints in healthcare industries – Analytics*, PARR (June 14, 2022), https://app.parr-global.com/intelligence/view/intelcms-mszmc7?utm_source=Notifications&utm_medium=Email&utm_campaign=Alert&utm_term=5bd82c78ea4893001df3da2f&ssouid=B9B89930-CE7C-4730-9604-7F1B0EAD2165.

[5] *See, e.g.*, ANI Pharmaceuticals, Inc./Novitium Pharma LLC, C-4754, FTC File No. 211-0101, (final order approved January 12, 2022); Bristol-Myers Squibb Company/Celgene Corporation, C-4690, FTC File No. 191-0061, (complaint filed November 15, 2019; final order issued January 13, 2020; modification of settlement approved November 12, 2021); Pfizer Inc./Mylan N.V., C-4727, FTC File No. 1910182 (proposed consent order issued October 30, 2020; final order issued January 28, 2021); AbbVie Inc. /Allergan plc, FTC File No. 1910169 (proposed final order accepted for public comment on May 5, 2020); Amneal Pharmaceuticals LLC/Impax Laboratories Inc., C-4650, FTC File No. 1810017 (final order approved on July 10, 2018); Baxter Int'l Inc., Dkt. No. C-4620 (F.T.C. July 20, 2017); FTC v. Mallinckrodt ARD Inc., No. 1:17-cv-00120 (D.D.C. Jan. 18, 2017); Mylan, N.V., Dkt. No. C-4590 (F.T.C. July 26, 2016); Teva Pharmaceutical Indus. Ltd., Dkt. No. C-4589 (F.T.C. July 26, 2016); Hikma Pharmaceuticals PLC, Dkt. No. C-4572 (F.T.C. Mar. 28, 2016); Hikma Pharmaceuticals PLC, Dkt. No. C-4568 (F.T.C. Feb. 26, 2016); Lupin Ltd., Dkt. No. C-4566 (F.T.C. Feb. 18, 2016); Endo Int'l PLC, Dkt. No. C-4539 (F.T.C. Sept. 24, 2015); Pfizer Inc., Dkt. No. C-4537 (F.T.C. Aug. 21, 2015); Impax Labs, Inc., Dkt. No. C-4511 (F.T.C. Mar. 5, 2015); Novartis AG, Dkt. No. C-4510 (F.T.C. Feb. 20, 2015); Sun Pharmaceutical Indus. Ltd, Dkt. No. C-4506 (F.T.C. Jan. 30, 2015).

patent litigation settlements,[6] seeks to halt the abuse of FDA regulatory processes,[7] works closely with the FDA to promote competition in pharma,[8] and challenges novel anticompetitive strategies as they arise.[9]

The FTC also continuously seeks to improve its understanding of the competitive dynamics in these markets through studies, workshops, hearings, and roundtables. For example, the FTC studied generic drug competition in 2002,[10] many aspects of the health care industry in the Antitrust & Health Care Hearings in 2003,[11] the PBM industry in 2005,[12] follow-on biologic drug competition in 2009[13] and again in 2014,[14] authorized generics in

---

[6] *See, e.g.*, Impax Laboratories, Inc., D-9373, FTC File No. 1410004 (complaint filed January 19, 2017; initial decision May 18, 2018; Commission opinion and final order issued March 28, 2019; affirmed by U.S. Court of Appeals for the Fifth Circuit April 13, 2021); FTC v. Actavis, Inc., 570 U.S. 136 (2013).

[7] *See, e.g.*, FTC v. AbbVie Inc., et al., 329 F. Supp. 3d 98 (E.D. Pa. 2018), aff'd in part, rev'd in part and remanded, 976 F.3d 327 (3d Cir. 2020), cert. denied sub nom., AbbVie Inc. v. FTC, No. 20-1293, 2021 WL 2519407, at *1 (U.S. June 21, 2021); (global settlement entered with Teva February 19, 2019; reverse payment claim against AbbVie withdrawn July 30, 2021).

[8] Joint Statement of the Food & Drug Administration and the Federal Trade Commission Regarding a Collaboration to Advance Competition in the Biologic Marketplace, FED. TRADE COMM'N & FOOD & DRUG ADMIN. (Feb. 3, 2020), https://www.fda.gov/media/134864/download; *Emerging Health Care Competition and Consumer Issues: Competition Issues Involving Follow-on Biologic Drugs*, FED. TRADE COMM'N. (Nov. 21, 2008), https://www.ftc.gov/news-events/events/2008/11/emerging-health-care-competition-consumer-issues-competition-issues-involving-follow-biologic-drugs.

[9] *See, e.g.*, FTC, et al. v. Vyera Pharmaceuticals, LLC, et al., No. 20-cv-00706, FTC File No. 161-0001 (complaint issued January 27, 2020; amended complaint filed on April 14, 2020; stipulated order for permanent injunction issued December 7, 2021; 2022 WL 135026 (S.D.N.Y. Jan. 14, 2022)); *See* Joint Motion for Entry of Stipulated Order for Permanent Injunction and Equitable Monetary Relief, FTC v. Reckitt Benckiser Group, PLC, No. 1:19-cv-00028 (W.D. Va. filed July 11, 2019).

[10] FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY (July 2002), https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf.

[11] *Health Care and Competition Law and Policy Hearings*, FED. TRADE COMM'N & DEP'T OF JUST. (Feb. 26, 2003), https://www.ftc.gov/news-events/events/2003/02/health-care-competition-law-policy-hearings.

[12] FED. TRADE COMM'N, PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL-ORDER PHARMACIES (Aug. 2005), https://www.ftc.gov/sites/default/files/documents/reports/pharmacy-benefit-managers-ownership-mail-order-pharmacies-federal-trade-commission-report/050906pharmbenefitrpt_0.pdf.

[13] FED. TRADE COMM'N, EMERGING HEALTH CARE ISSUES: FOLLOW-ON BIOLOGIC DRUG COMPETITION (June 2009), https://www.ftc.gov/sites/default/files/documents/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report/p083901biologicsreport.pdf.

[14] *Follow-On Biologics Workshop: Impact of Recent Legislative and Regulatory Naming Proposals on Competition*, FED. TRADE COMM'N (Feb. 4, 2014), https://www.ftc.gov/news-events/events/2014/02/follow-biologics-workshop-impact-recent-legislative-regulatory-naming-proposals-competition.

2011,[15] and entry and supply chain dynamics in prescription drug markets in 2017.[16] More recently, in 2018, the FTC joined HHS, the Department of the Treasury, and the Department of Labor in issuing a report on "Reforming America's Healthcare System Through Choice and Competition"[17] and launched studies on physician group and health care facility mergers[18] and certificates of public advantage.[19]

On June 7, 2022, the Commission launched a 6(b) study of the PBM industry.[20] That study will examine insulin and other prescription drugs, including the costs and fees associated with these drugs and how the use of formularies, rebates, and other mechanisms impacts consumers who depend on these prescriptions.[21] I look forward to the results of that study.

I want to thank FTC staff for their unsung work in the health care space generally, and in the pharma industry specifically. Resources are scarce, and the requests from the Commission, Congress, and other stakeholders can seem limitless. But the FTC is blessed with seasoned and dedicated professionals who choose to devote their time to protecting consumers and competition, and I have no doubt staff will continue to rise to the challenges ahead.

I also want to thank Chair Khan for facilitating a collaborative drafting process for this policy statement. The document underwent multiple rounds of edits and was the subject of many internal discussions. I believe that process matters, and that the work of the FTC is stronger when all views and thoughts are considered.

---

[15] FED. TRADE COMM'N, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT (Aug. 2011), https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf.

[16] *Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics*, FED. TRADE COMM'N (Nov. 8 2017), https://www.ftc.gov/news-events/events/2017/11/understanding-competition-prescription-drug-markets-entry-supply-chain-dynamics.

[17] U.S. DEP'T OF HEALTH & HUMAN SERVICES, REFORMING AMERICA'S HEALTHCARE SYSTEM THROUGH CHOICE AND COMPETITION (Dec. 3, 2018), https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf ("We are pleased to provide you with this report, prepared by the Department of Health and Human Services (HHS) in collaboration with the Departments of the Treasury and Labor, the Federal Trade Commission, and several offices within the White House").

[18] Press Release, Fed. Trade Comm'n, FTC to Study the Impact of Physician Group and Healthcare Facility Mergers (April 14, 2021), https://www.ftc.gov/news-events/news/press-releases/2021/01/ftc-study-impact-physician-group-healthcare-facility-mergers.

[19] Press Release, Fed. Trade Comm'n, FTC to Study the Impact of COPAs (Oct. 21, 2019), https://www.ftc.gov/news-events/news/press-releases/2019/10/ftc-study-impact-copas.

[20] Press Release, Fed. Trade Comm'n, FTC Launches Inquiry Into Prescription Drug Middlemen Industry (June 7, 2022), https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry.

[21] Order to File A Special Report, FTC File No. P221200 (June 6, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/P221200PBMModelOrder.pdf.

The rebate and fee issues in pharma, and especially for insulin, are clearly an area worthy of investigation. Today's policy statement reiterates the role and ability of the antitrust laws to bring enforcement actions when appropriate in this space. I have previously expressed concerns that policy statements can give the illusion of taking action, and can provide cover for skipping the hard work that is required of us.[22] Issuing a policy statement cannot replace the work of conducting an investigation and bringing an enforcement action when necessary. I hope that sufficient resources are dedicated to ensuring that enforcement actions in this area can be brought if the Commission has reason to believe there are unlawful practices in this space.

Some observers may be surprised to see Section 2(c) of the Robinson-Patman Act included in this policy. The role of the FTC is to protect competition and consumers. The Robinson-Patman Act has been used in ways that elevate protection of rivals over benefits to consumers.[23] I oppose using Robinson-Patman in ways other than protecting consumers and competition; I support enforcing the Robinson Patman Act where doing so would protect competition and consumers.

II. Report to Congress on Combatting Online Harms through Innovation

Thank you, Chair Khan. And thank you also to Michael Atleson for that informative presentation. In addition, I would like to thank the many staff who worked with Mike on this Report:

- Division of Advertising Practices (BCP) – Tawana Davis, Serena Viswanathan
- Division of Consumer and Business Education (BCP) – Daniele Apanaviciute
- Division of Privacy and Identity Protection (BCP) – Robin Wetherill
- BCP Director's Office – Elisa Jillson
- Office of Policy and Planning – Amba Kak, Olivier Sylvain, Sarah Myers West
- Office of International Affairs – Ellen Connelly

In the 2021 Appropriations Act,[24] Congress directed the Federal Trade Commission to study and report on whether and how artificial intelligence (AI) "may be used to identify, remove, or

---

[22] Christine S. Wilson, Oral Remarks – Open Commission Meeting May 19, 2022 at 4-5, https://www.ftc.gov/system/files/ftc_gov/pdf/P155401WilsonRemarks_0.pdf.

[23] Robert T. Pitofsky, *Antitrust at the Turn of the Twenty-First Century: A View from the Middle*, 76 ST. JOHN'S L. REV. 583, 586 & 588 (2002), https://scholarship.law.stjohns.edu/cgi/viewcontent.cgi?article=1357&context=lawreview ("There will always be outliers – for example, people on the enforcement margin who believe that virtually all mergers among large firms should be blocked and people on the free market margin who believe that cartels are unstable, self-containing, and need not be challenged by the government. But a broad range of informed people now finds common ground between those extremes. … Price discrimination is almost never an anti-consumer strategy and, therefore, challenges to price discrimination under the Sherman Act, and particularly according to the quasi-per se rules of the Robinson-Patman Act, should be approached with great caution.").

[24] Consolidated Appropriations Act, 2021, Pub. L. No. 116-260, Title XV, § 1501(j), https://www.govinfo.gov/app/details/BILLS-116hr133enr/summary.

take any other appropriate action necessary to address" a wide variety of specified "online harms." Congress also sought recommendations from the FTC regarding legislation to "advance the adoption and use of AI for these purposes."[25] Specifically, Congress asked the FTC to recommend laws that would "advance the adoption and use of artificial intelligence to address" the enumerated online harms.[26]

In response to this specific Congressional request, today's Report makes the following recommendation: "Congress should generally steer clear of laws that require, assume the use of, or pressure companies to deploy AI tools to detect harmful content."[27] I would like to underscore my agreement with this recommendation. In addition, the Report contains much useful information about how AI is being used. The field of AI is complex, still nascent in many ways, and evolving. Like most technologies AI holds the potential to generate benefits and impose harms. It is an area that the FTC should continue to study and analyze.

That said, I am concerned about the extensive discussion of "misinformation," "inoculation," and "prebunking" in the Report. There are certain pieces of information that are verifiably true (my office is located in Washington, DC) and certain pieces of information that are verifiably false (I am 29 years old). And some verifiably false information can be highly problematic. In July 2020, when I met with the Hispanic Technology & Telecommunications Partnership, the organization shared examples of "get out the vote" ads on social media targeted at Spanish-language speakers that touted the wrong date for the 2020 presidential election (*i.e.*, Nov. 5, 2020 instead of the actual date, Nov. 3, 2020). But the vast bulk of information online falls somewhere between those two extremes.

Cultures and worldviews differ, and science, philosophy, and other fields are continually evolving. An assertion that one finds implausible today later may be proven correct. I am reminded of Galileo Galilei, the brilliant scientist who was hauled before the Inquisition for advancing the Copernican theory of a heliocentric solar system. Galileo was found "vehemently suspect of heresy," condemned to house arrest, and forbidden to publish his writings.[28] But science has since proven that the Earth does indeed revolve around the Sun. And Albert Einstein subsequently christened Galileo the father of modern science.

I worry that the swift labeling of ideas as "misinformation," or worse yet, the "prebunking" of ideas, will stymie the development of new theories, research, and ideas. The answer to speech that we view as incorrect or misguided is not suppression, but more speech that explains our opinion of the errors and presents an alternative perspective. As Justice Brandeis observed, the remedy for bad speech is more speech, not enforced silence.[29]

---

[25] Combatting Online Harms Through Innovation, FTC, Report to Congress at 1 (June 16, 2022).
[26] *Id.* at 74.
[27] *Id.* at 75.
[28] *See* Numbers, Ronald, Galileo Goes to Jail and Other Myths about Science and Religion (2010).
[29] *See* Whitney v. California, 24 U.S. 357 (1927). In this opinion, Justice Brandeis wrote: "If there be time to expose through discussion the falsehood and fallacies, to avert the evil by the processes of education, the remedy to be applied is more speech, not enforced silence." *Id.* Similarly, Justice Kennedy has written "the remedy for speech that is false is speech that is true." United States v. Alvarez, 567 U.S. 709 (2012); *see also* Hudson, David "More Speech, Not Enforced Silence" Freedom Forum Institute (Feb. 7, 2020), available at: https://www.freedomforuminstitute.org/2020/02/07/more-speech-not-enforced-silence/.

With respect to this Report, I again commend the staff for their extensive analysis and their work in combing through a vast array of source material for inclusion in the Report. While I disagree with certain aspects of the Report, I support the narrow recommendation described above and the provision of this Report to Congress.