Unfortunately, many of the causes of higher drug prices, including systemic distortions created by massive regulatory regimes and a pervasive principal/agent problem, fall outside the jurisdiction and legal authority of the Federal Trade Commission. But within its limited authority as a competition agency, the Commission can – and does – pursue a comprehensive agenda to address anticompetitive mergers and unfair conduct in the pharmaceutical industry. Specifically, the Commission:

- Carefully Screens Pharmaceutical Mergers: Similar to the current enforcement action, the Commission routinely has challenged anticompetitive mergers and acquisitions. During the past five years, the Commission has issued complaints challenging 13 mergers and required the divestiture of 130 branded and generic products to address competitive overlaps for the sale or development of particular drugs.[4]

- Combats Anticompetitive Patent Litigation Settlements: In 2013, the FTC won a landmark victory at the Supreme Court in the *Actavis* case,[5] and has prevailed in subsequent challenges of similar agreements. For instance, earlier this year, the Commission issued a unanimous opinion condemning a patent litigation settlement after finding that the brand manufacturer possessed market power in the market for branded and generic oxymorphone ER, the potential generic entrant received a large and unjustified payment, and the respondent failed to show a cognizable justification for the restraint.[6] The Commission's successful challenges of prior settlements have substantially reduced the number of anticompetitive patent litigation settlements into which companies are entering today.

- Challenges Abuse of FDA Regulatory Processes: The Commission has brought several cases alleging that pharmaceutical companies misuse FDA regulatory processes to impede competition. For example, in 2014 the FTC challenged a pharmaceutical company for abusing the litigation process by filing meritless patent lawsuits against competitors to keep them off the market. The Commission won a judgment for $448 million.[7] The FTC also sued Shire ViroPharma in 2017, alleging anticompetitive abuse of the FDA citizen-petition process to keep the FDA from approving the competitive products, thereby keeping the lower-cost drugs off the market. (Unfortunately, the Commission lost the case on a statutory construction issue that kept the Court of Appeals from ruling on the merits of the allegations.[8]) And under Chairman Tim Muris, the FTC

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the past decade six times as fast as the cost of goods and services overall."); CHARLES SILVER & DAVID A. HYMAN, OVERCHARGED: WHY AMERICANS PAY TOO MUCH FOR HEALTH CARE 25-27 (2018) (discussing analyses from Schondelmeyer & Purvis, Pearl, and others).

[4] See Baxter Int'l Inc., Dkt. No. C-4620 (F.T.C. July 20, 2017); Almeal Holdings, LLC, Dkt. No. C-4650 (F.T.C. Apr. 27, 2018); 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).

[5] FTC v. Actavis, Inc., 570 U.S. 136 (2013).

[6] See, e.g., Impax Laboratories, Inc., Dkt. No. 9373 (F.T.C. April 3, 2019) (Commission Decision).

[7] FTC v. AbbVie, Inc. 329 F. Supp. 3d 98 (E.D. Pa. 2018).

[8] FTC v. Shire ViroPharma, Inc., 917 F.3d 147, 156 (3d Cir. 2019).

- Informs Courts of Relevant Competition Principles and Policies: The Commission has filed briefs as amicus curiae in cases involving pay-for-delay settlements,[16] REMS and restricted distribution systems,[17] and product hopping.[18]

This list of actions by the FTC is by no means exhaustive.[19] But the message is clear — the FTC uses the full force and weight of its authority to protect consumers from unlawful conduct that increases prices and reduces innovation in this important sector of our economy.

Notwithstanding the Commission's vigorous efforts, there are many factors that contribute to increasing drug prices but that are not cognizable under the antitrust laws, and therefore that the FTC does not have the legal authority to fix. Even if the FTC and other government enforcers did their job flawlessly (and our "retrospective" reviews of our past work suggests we do quite well), pharmaceutical prices would still rise for many (often good) reasons. For example, last year, [illegible] (Notwithstanding