The Commission has accepted, subject to final approval after receiving public comments, an Agreement Containing Consent Order from Bristol-Myers Squibb Company and Celgene Corporation that remedies the anticompetitive effect that otherwise would arise from BMS’s proposed acquisition of Celgene. All members of the Commission (including Commissioners Chopra and Slaughter) agree that the only evidence of harm to competition that staff found was in the market for oral products that treat moderate-to-severe psoriasis. All members of the Commission also agree that the remedy in that market – a complete divestiture of all of Celgene’s products and associated assets in that area – will preserve competition in that market. Moreover, this $13 billion divestiture is the largest in the history of U.S. merger enforcement.

I agree with Commissioner Slaughter that pharmaceutical price levels in the United States today are cause for concern. And there is ample evidence that prices of branded pharmaceuticals have increased much faster – perhaps six to eight times as fast – as prices in the rest of the economy.

Staff conducted the investigation of this proposed transaction in the same careful manner that all pharmaceutical transactions are investigated. The investigation examined the likely competition between and among all of BMS and Celgene’s current products and those now in development. The investigation identified a likely harm to innovation involving oral products to treat moderate-to-severe psoriasis; the identified overlap includes a product that is still in development by BMS. In addition, staff investigated whether the proposed transaction would decrease innovation competition; instead, the investigation found that reduced innovation competition was unlikely. Moreover, there is no reason to believe there will be reduced innovation in the pharmaceutical industry as a result of this transaction. No fewer than 711 companies are conducting late-stage research and development in oncology, the therapeutic category in which BMS and Celgene conduct research. See IQVIA Institute Global Oncology Trends 2019, at 19, May 2019, available at https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/global-oncology-trends-2019.pdf.

To support his hypothesis that there must be additional unidentified harm to innovation, Commissioner Chopra seeks to introduce factors outside the analytical framework demanded by the statutes enforced by the Commission, including Section 7 of the Clayton Act, without offering any evidence to show that these non-competition factors may reduce innovation.

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 unlawful 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 those 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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\(^8\) FTC v. Shire ViroPharma, Inc., 917 F.3d 147, 156 (3d Cir. 2019).
challenged wrongful listings in the FDA Orange Book\textsuperscript{9} by BMS, one of the very parties before us today, that allegedly were used obtain unwarranted automatic 30-month stays of FDA approval of generic pharmaceuticals that would have competed with BMS branded products.\textsuperscript{10}

- **Advocates for the Reform of Misused Regulations:** The FTC advised the FDA and Congress of possible abuses of the Risk Evaluation and Mitigation Strategy (REMS) framework to forestall competitors’ entry by denying access to branded drugs required to conduct bioequivalence testing, a gating factor for FDA approval to launch.\textsuperscript{11} In remarks before a Subcommittee of the Senate Committee on Commerce, Science, and Transportation, I encouraged Congress to take action on this front.\textsuperscript{12} And under the bipartisan leadership of first Chairman Bob Pitofsky and then Chairman Tim Muris, the FTC conducted a 6(b) study of generic drugs and issued a report recommending refinements to the Hatch Waxman Act and changes to the FDA regulatory framework, many of which were implemented, so as to fulfill the original balance of innovation and competition struck by the Hatch Waxman Act.

- **Challenges Novel Anticompetitive Strategies As They Arise:** Earlier this year the Commission challenged and settled a case against Reckitt Benckiser Group plc alleging that Reckitt introduced a film version of Suboxone, which treats opioid addiction, and pushed the market to use the film version rather than the existing tablet version that was about to face generic competition.\textsuperscript{13} The complaint alleged that Reckitt pushed the market toward the film and away from the tablets by claiming the film was safer than tablets while having no data to back up the claim and significantly raising the price of the tablet when the film was costlier to make. Under the terms of the settlement, Reckitt was required to contribute $50 million to a fund to be distributed to those who were overcharged.\textsuperscript{14}

\textsuperscript{9} Pursuant to the FDC Act, a brand-name drug manufacturer seeking to market a new drug product must first obtain FDA approval by filing a New Drug Application (“NDA”). At the time the NDA is filed, the NDA filer must also provide the FDA with certain categories of information regarding patents that cover the drug that is the subject of its NDA. 21 U.S.C. § 355(b)(1). Upon receipt of the patent information, the FDA is required to list it in an agency publication entitled “Approved Drug Products with Therapeutic Equivalence,” commonly known as the “Orange Book.” Id. § 355(j)(7)(A).


\textsuperscript{13} 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).

\textsuperscript{14} I was recused from this enforcement action because, before joining the Commission, I represented a generic drug company before the FTC and FDA challenging this anticompetitive conduct.
Informs Courts of Relevant Competition Principles and Policies: The Commission has filed briefs as amicus curiae in cases involving patent litigation settlements, REMS and restricted distribution systems, and product hopping.

This list of actions by the FTC is by no means exhaustive. 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 valiant 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 other reasons. For example, last year the Trump Administration released two reports identifying various market imperfections in health care markets, including prescription drug markets, and various regulatory and legislative reforms that would increase consumer choice and provider competition. Similarly, former FDA Administrator Scott Gottlieb has identified several flaws in the market for biosimilars — generic biologic medicines — that he believes require Congressional action. And Professors David Hyman (also a former FTC Special Counsel) and Charles Silver have identified a host of other

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16 See, e.g., Br. of amicus curiae Federal Trade Commission, Mylan Pharmaceuticals, Inc. v. Celgene, No. 2:14-cv-2094 (D.N.J. filed June 17, 2014) (explaining that a monopolist’s refusal to sell to potential competitors may, under certain limited circumstances, violate Section 2 of the Sherman Act and that a brand name drug manufacturer’s patents do not reach activities undertaken in connection with bioequivalence testing).

17 See Br. of amicus curiae Federal Trade Commission, Mylan Pharmaceuticals, Inc. v. Warner Chilcott Public Ltd. Co., No. 12-cv-3824 (E.D. Pa. filed Nov. 21, 2012) (explaining that litigation settlements among private parties are private commercial agreements and are not exempt from antitrust scrutiny under the Noerr doctrine).

18 For a complete review of the Commission’s ongoing and extensive efforts to combat anticompetitive mergers and unlawful conduct in the pharmaceutical industry, see Markus H. Meier, Bradley S. Albert, & Kara Monahan, Overview of FTC Actions in Pharmaceutical Products and Distribution (Sept. 2019), available at https://www.ftc.gov/system/files/attachments/competition-policy-guidance/20190930_overview_pharma_final.pdf.


legal and regulatory factors that increase drug prices,\textsuperscript{21} including FDA delays in processing
generic applications and a Medicare system pursuant to which the government purchases one-
third of all retail drugs but is barred from negotiating the prices that it pays.\textsuperscript{22}

There is broad concern about prescription drug price levels, and I share those concerns. But
here, Commission staff conducted a thorough investigation and found evidence that the
acquisition of Celgene by BMS would, if not addressed, diminish competition in one relevant
market. Commission staff then negotiated a record-breaking consent agreement that replaces the
competition otherwise lost because of the merger by divesting all of Celgene’s relevant products
and assets to a new and robust competitor. Rather than asserting that staff should have found
something – anything – more to justify asking a court to block the transaction, we should
recognize the limited authority we have been granted by Congress and encourage other
responsible governmental actors to fix the many problems in this sector that lie beyond our
jurisdiction.

\textsuperscript{21} See, e.g., Charles Silver & David A. Hyman, \textit{Here’s a Plan to Fight High Drug Prices that Could Unite
Libertarians and Socialists}, VOX.COM, June 21, 2018, https://www.vox.com/the-big-
idea/2018/6/21/17486128/prescription-drug-prices-monopolies-epipen-shkreli-sanders-patents-prizes; see also
Statement of Commissioner Rebecca Kelly Slaughter, \textit{supra} note 1, at 2 n.10 (citing Silver & Hyman approvingly).
\textsuperscript{22} See S\textsuperscript{ILVER} & H\textsuperscript{YMAN}, \textit{supra} note 3, at 53-60.