Statement of Commissioner Christine S. Wilson
In the Matter of Bristol-Myers Squibb Company / Celgene Corporation
File No. 191-0061
November 15, 2019

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)[1] 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.[2] 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.[3]

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[1] *See* Dissenting Statement of Commissioner Rebecca Kelly Slaughter, In the Matter of Bristol-Myers Squibb and Celgene; Dissenting Statement of Commissioner Rohit Chopra on Bristol-Myers Squibb/Celgene.

[2] While Commissioner Chopra agrees that there is no evidence of harm to innovation, he concludes that the lack of evidence implies there is a problem with the investigative process. I disagree with Commissioner Chopra's hypothesis.

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.

[3] *See, e.g.*, SUZANNE M. KIRCHHOFF ET AL., CONGRESSIONAL RESEARCH SERVICE, FREQUENTLY ASKED QUESTIONS ABOUT PRESCRIPTION DRUG PRICING AND POLICY, at 8-9 (Apr. 24, 2018), *available at* https://fas.org/sgp/crs/misc/R44832.pdf (plotting CPI-U data from the U.S. Bureau of Labor Statistics); STEPHEN W. SCHONDELMEYER & LEIGH PURVIS, AARP PUBLIC POLICY INSTITUTE, RX PRICE WATCH REPORT: TRENDS IN RETAIL PRICES OF BRAND NAME PRESCRIPTION DRUGS WIDELY USED BY OLDER AMERICANS: 2017 YEAR-END UPDATE, at 6-8 (Sept. 2018), *available at* https://www.aarp.org/content/dam/aarp/ppi/2018/09/trends-in-retail-prices-of-brand-name-prescription-drugs-year-end-update.pdf (using data from Truven MarketScan to estimate that "brand name drug prices went up more than 8.5 times the rate of general inflation during [the] 12-year period [from December 31, 2005 to December 31, 2017]"); Robert Pearl, *How Big Pharma Might Be Cut Down to Size*, FORBES.COM, May 11, 2017, *available at* https://www.forbes.com/sites/robertpearl/2017/05/11/how-big-pharma-might-be-cut-down-to-size/ ("[A]ccording to the U.S. Bureau of Labor Statistics, prices for U.S.-made pharmaceuticals have climbed over

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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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); *Amneal 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).

challenged wrongful listings in the FDA Orange Book[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.[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.[11] In remarks before a Subcommittee of the Senate Committee on Commerce, Science, and Transportation, I encouraged Congress to take action on this front.[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.[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.[14]

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[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).

[10] *See* Complaint, *Bristol-Myers Squibb Co.*, Dkt. No. C-4076 (F.T.C. filed Apr. 14, 2003).

[11] *See, e.g.*, Statement of the Federal Trade Commission to the Department of Health and Human Services Regarding the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (July 16, 2018); Prepared Statement of Markus H. Meier, Acting Director, Bureau of Competition, Federal Trade Commission before the U.S. House of Representatives, Judiciary Committee, Subcommittee on Regulatory Reform, Commercial and Antitrust Laws, on "Antitrust Concerns and the FDA Approval Process" (July 27, 2017).

[12] *See* Commissioner Christine S. Wilson, Oral Statement before Senate Committee on Commerce, Science & Transportation, Subcommittee on Consumer Protection, Product Safety, Insurance, & Data Protection (Nov. 27, 2018).

[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).

[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,[15] REMS and restricted distribution systems,[16] and product hopping.[17]

This list of actions by the FTC is by no means exhaustive.[18] 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.[19] Similarly, former FDA Administrator Scott Gottlieb has identified several flaws in the market for biosimilars – generic biologic medicines – that he believes require Congressional action.[20] And Professors David Hyman (also a former FTC Special Counsel) and Charles Silver have identified a host of other

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[15] *See, e.g.*, Br. of *amicus curiae* Federal Trade Commission in Support of Plaintiffs-Appellants, *In re* Lamictal Direct Purchaser Antitrust Litigation, No. 2:12-cv-995, (3d Cir. filed Apr. 28, 2014) (explaining that a commitment not to introduce an authorized generic product is the type of settlement subject to antitrust scrutiny); Supp. Br. of *amicus curiae* Federal Trade Commission in Support of Plaintiffs-Appellants, *In re* Effexor XR Antitrust Litig., No. 3:11-cv-05479 (3d Cir. filed Mar. 17, 2016) (explaining that litigation settlements among private parties are private commercial agreements and are not exempt from antitrust scrutiny under the *Noerr* doctrine).

[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 minor, non-therapeutic changes to a branded pharmaceutical product that harm generic competition can constitute exclusionary conduct that violates U.S. antitrust laws).

[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.

[19] U.S. DEP'T OF HEALTH AND HUMAN SERVS., AMERICAN PATIENTS FIRST: A TRUMP ADMINISTRATION BLUEPRINT TO LOWER DRUG PRICES AND REDUCE OUT-OF-POCKET COSTS (May 2018), *available at* https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf; U.S. DEP'T OF HEALTH AND HUMAN SERVS., U.S. DEP'T OF THE TREASURY, & U.S. DEP'T OF LABOR, REFORMING AMERICA'S HEALTHCARE SYSTEM THROUGH CHOICE AND COMPETITION 63-67 (2018), *available at* https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf (discussing, *e.g.*, the use of "any-willing-provider" laws in the context of drug prescription plans and Medicare Part D). FTC staff consulted with HHS on the latter report. *See id.* at 3 ("Executive Order 13813, … requires the Secretary of Health and Human Services (HHS), in consultation with the secretaries of the Treasury and Labor and the Federal Trade Commission, to provide a report to the President.").

[20] Scott Gottlieb, Op-Ed, *Don't Give Up on Biosimilars—Congress Can Give Them a Boost*, WALL ST. J., Aug. 25, 2019, https://www.wsj.com/articles/dont-give-up-on-biosimilarscongress-can-give-them-a-boost-11566755042

legal and regulatory factors that increase drug prices,[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.[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.

[21] *See, e.g.*, Charles Silver & David A. Hyman, *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, *supra* note 1, at 2 n.10 (citing Silver & Hyman approvingly).
[22] *See* SILVER & HYMAN, *supra* note 3, at 53-60.