the Assistant Attorney General, developed the HSR Rules and the corresponding Notification and Report Form.

On September 11, 2019, the Commission sought comment on the reporting requirements associated with the HSR Rules and corresponding Notification and Report Form. 84 FR 47951. No relevant comments were received. Pursuant to the OMB regulations, 5 CFR part 1320, that implement the PRA, 44 U.S.C. 3501 *et seq.,* the FTC is providing this second opportunity for public comment while seeking OMB approval to renew the pre-existing clearance for those information collection requirements.

The following discussion presents the FTC's PRA burden analysis regarding completion of the Notification and Report Form. For more details about the requirements of the HSR Rules, the background behind these information collection provisions, and the basis for the calculations summarized below, see 84 FR 47951.

Likely Respondents: Merging Parties.

Estimated Annual Hours Burden: 181,091 hours [derived from 4,894 non-index filings × 37 hours/each) + (five index filings × two hours/each) + (one withdrawn transaction later restarted × three hours)].

Estimated Annual Cost Burden: $83,301,860, which is derived from $460/hour × 181,091 hours.

Request for Comment

Your comment—including your name and your state—will be placed on the public record of this proceeding at the *https://www.regulations.gov* website. Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, such as anyone'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. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''trade secret or any commercial or financial information which . . . is privileged or confidential''—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Heather Hippsley,

Deputy General Counsel.

[FR Doc. 2019–26075 Filed 12–2–19; 8:45 am]

BILLING CODE 6750–01–P

FEDERAL TRADE COMMISSION

[File No. 191 0061]

Bristol-Myers Squibb Company and Celgene Corporation; Analysis of Agreement Containing Consent Orders To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement; request for comment.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair methods of competition. The attached Analysis of Agreement Containing Consent Orders to Aid Public Comment describes both the allegations in the complaint and the terms of the consent orders—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before January 2, 2020.

ADDRESSES: Interested parties may file comments online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write: ''Bristol-Myers Squibb Company and Celgene Corporation; File No. 191 0061'' on your comment, and file your comment online at *https://www.regulations.gov* by following the instructions on the web-based form. If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Kari Wallace (202–326–3085), Bureau of Competition, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for November 15, 2019), on the World Wide Web, at *https://www.ftc.gov/news-events/commission-actions.*

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before January 2, 2020. Write ''Bristol-Myers Squibb Company and Celgene Corporation; File No. 191 0061'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the *https://www.regulations.gov* website.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online through the *https://www.regulations.gov* website.

If you prefer to file your comment on paper, write ''Bristol-Myers Squibb Company and Celgene Corporation; File No. 191 0061'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex D), Washington, DC 20580; or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Because your comment will be placed on the publicly accessible website at *https://www.regulations.gov,* you are solely responsible for making sure that your comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information, such as your or anyone else'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. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually

identifiable health information. In addition, your comment should not include any ''trade secret or any commercial or financial information which . . . is privileged or confidential''—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

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). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on the public FTC website—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from the FTC website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC website at *http://www.ftc.gov* to read this Notice and the news release describing it. 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 on or before January 2, 2020. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *https://www.ftc.gov/site-information/privacy-policy.*

Analysis of Agreement Containing Consent Orders To Aid Public Comment

I. Introduction

The Federal Trade Commission (''Commission'') has accepted, subject to final approval, an Agreement Containing Consent Orders (''Consent Agreement'') from Bristol-Myers Squibb Company (''BMS'') and Celgene Corporation (''Celgene'') designed to remedy the anticompetitive effects resulting from BMS's proposed acquisition of Celgene. The proposed Decision and Order (''Order'') contained in the Consent Agreement requires Celgene to divest all rights and assets related to its Otezla business to Amgen, Inc. (''Amgen'').

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will review the comments received and decide whether it should withdraw, modify, or make the Consent Agreement final.

Pursuant to an Agreement and Plan of Merger dated as of January 2, 2019, BMS plans to acquire all of the voting securities of Celgene in a cash and stock transaction with an equity value of approximately $74 billion (the ''Acquisition''). The Commission's Complaint alleges that the proposed Acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, by substantially lessening competition in the U.S. market for oral products to treat moderate-to-severe psoriasis. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be lost in this market as a result of the proposed Acquisition.

II. The Parties

Headquartered in New York City, BMS researches, develops, manufactures, and sells prescription pharmaceutical products and biologic products in several therapeutic areas, including oncology, cardiology, virology, and inflammatory diseases. Among other products, BMS is developing an oral product to treat moderate-to-severe psoriasis. Like BMS, Celgene researches, develops, manufactures and sells prescription pharmaceutical products in the United States. Celgene markets eight products, including an oral treatment for moderate-to-severe psoriasis.

III. The Relevant Product and Structure of the Market

Psoriasis is a chronic skin disease caused by an overactive immune system. The disease causes skin cells to multiply faster than normal and leads to a build-up of cells on the skin surface, forming bumpy red patches that are covered with white scales, known as plaques. The plaques can appear anywhere on the body, although they are most commonly found on the scalp, elbows, knees, and lower back. The severity of psoriasis (mild, moderate, or severe) is determined based upon the percentage of body surface area affected and the parts of the body that are affected. Typically, mild psoriasis covers less than 3 percent of the body, moderate psoriasis covers 3 to 10 percent of the body and severe psoriasis covers more than 10 percent of the body.

When deciding how to treat psoriasis, dermatologists typically evaluate the severity of the disease, any risk factors or contraindications for the patient, and the patient's preferences. Dermatologists consider efficacy data, safety data, and side effect profile of each product, as well as mode of administration to select the appropriate treatment course for their patients. While many injectable and infused products are approved to treat moderate-to-severe psoriasis, a number of patients object to such injections or find them inconvenient. For those patients, dermatologists often select an oral product.

Celgene's apremilast, marketed under the brand name Otezla, is a phosphodiesterase 4 inhibitor. Otezla is the most popular oral product approved to treat moderate-to-severe psoriasis in the United States. Several older oral generic products, including methotrexate and acitretin, are approved by the U.S. Food and Drug Administration (''FDA'') to treat psoriasis that does not respond to light, topical agents, and other forms of therapy. These drugs are still occasionally used in the treatment of psoriasis, but most doctors have moved to prescribing newer agents with better efficacy, better safety, or a more favorable side effect profile for patients with moderate-to-severe psoriasis who desire an oral treatment. BMS is developing BMS 986165, an oral, selective tyrosine kinase 2 inhibitor that is the most advanced oral treatment in development for moderate-to-severe psoriasis.

IV. The Relevant Geographic Market

The United States is the relevant geographic market in which to assess the competitive effects of the proposed Acquisition. Oral products to treat moderate-to-severe psoriasis are prescription pharmaceutical products and regulated by FDA. As such, products sold outside the United States, but not approved for sale in the United States, do not provide viable competitive alternatives for U.S. consumers.

V. Competitive Effects of the Acquisition

The proposed Acquisition would likely result in substantial competitive harm to consumers in the market for

oral products to treat moderate-to-severe psoriasis. Celgene is currently the market leader and BMS would likely be the next entrant into the market. Upon entry, BMS 986165 likely will compete directly with, and take sales from, Otezla.

VI. Entry Conditions

Entry in the relevant market would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the proposed Acquisition. New entry would require significant investment of time and money for product research and development, regulatory approval by the FDA, developing clinical history supporting the long-term efficacy of the product, and establishing a U.S. sales and service infrastructure. Such development efforts are difficult, time-consuming, and expensive, and often fail to result in a competitive product reaching the market.

VII. The Consent Agreement

The Consent Agreement eliminates the competitive concerns raised by the proposed Acquisition by requiring BMS and Celgene to divest Celgene's worldwide Otezla business, including its regulatory approvals, intellectual property, contracts, and inventory to Amgen. BMS and Celgene also must transfer all confidential business information, research and development information, regulatory, formulation, and manufacturing reports related to the divested products, as well as provide access to employees who possess or are able to identify such information. Additionally, to ensure that the divestiture is successful and to maintain continuity of supply, the proposed Order requires BMS and Celgene to supply Amgen with Otezla for a limited time while Amgen establishes its own manufacturing capability. The provisions of the Consent Agreement ensure that Amgen becomes an independent, viable, and effective competitor in the U.S. market.

Founded in 1980 and headquartered in Thousand Oaks, California, Amgen discovers, develops, manufactures and sells innovative human pharmaceutical and biologic products. Amgen's existing business includes products that are highly complementary to the divestiture assets. Amgen has the expertise, U.S. sales infrastructure, and resources to restore the competition that otherwise would have been lost due to the proposed Acquisition.

BMS and Celgene must accomplish the divestitures no later than ten days after consummating the proposed Acquisition. If the Commission determines that Amgen is not an acceptable acquirer, or that the manner of the divestitures is not acceptable, the proposed Order requires BMS and Celgene to unwind the sale of rights and assets to Amgen and then divest the affected product to a Commission-approved acquirer within six months of the date the Order becomes final. To ensure compliance with the Order, the Commission has agreed to appoint a Monitor to ensure that BMS and Celgene comply with all of their obligations pursuant to the Consent Agreement and to keep the Commission informed about the status of the transfer of the Otezla rights and assets to Amgen. The proposed Order further allows the Commission to appoint a trustee in the event that BMS and Celgene fail to divest the products as required.

The purpose of this analysis is to facilitate public comment on the Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

By direction of the Commission.

April J. Tabor,

Acting Secretary.

Statement of Commissioner Noah Joshua Phillips

I write to address the dissenting statements issued by my colleagues, Commissioners Chopra and Slaughter.

From these statements, a reader unfamiliar with the U.S. antitrust laws could be forgiven for gleaning several inaccurate conclusions. First, companies in the U.S. may not merge unless the antitrust enforcement agencies permit them to do so. Second, to stop a merger, the government need not provide any theory as to why a merger violates the law, nor any evidence to support that theory. Third, antitrust enforcement agencies can and should condemn mergers they cannot prove violate the law because the agencies deem the business justifications for the merger insufficient.

The unfamiliar reader would be wrong on each count. That is not the law. (Nor, for that matter, is it sound policy.)

The structural remedy agreed to by the merging parties in this case addresses every competition concern uncovered after an extensive investigation. Every one. But Commissioners Chopra and Slaughter still dissent. Why?

Commissioner Chopra cites a study purporting to show that mergers ''can choke off innovation''. Okay. But how does this merger do that? Without an answer to that question, the logic is rather like saying an individual defendant is guilty of a crime because there is too much of that crime in society. Thank goodness that is not how our criminal justice system works.

He next writes that we must approach our investigations of pharmaceutical mergers with careful scrutiny and with great humility. I agree completely. What I fail to see is how careful scrutiny and great humility lead to the conclusion, without any clearly articulated theory of liability or facts to support it, that this merger violates the law—or, again without any facts in support, that the remedy is inadequate.

The next basis Commissioner Chopra offers for his dissent is his view that the merger is animated by financial and tax considerations, which he deems insufficient to justify the merger. Leaving aside the question of why he thinks the job of antitrust enforcers is to value-judge a merger beyond its impact upon competition, that gets the law precisely backwards. The parties get to merge unless we can show a harm to competition, not the other way round.

His dissent also alludes to ''distorted'' incentives of the buyer due to the overlapping ownership of the parties. I must admit that the precise meaning of that escapes me. Perhaps it is a reference to the theory of ''common ownership'', which has stoked great academic debate and about which I have spoken repeatedly.[1] Whatever the meaning, Commissioner Chopra fails to articulate how the merger will distort the buyer's incentives, much less in a way that violates the law. To sue, or to seek an additional remedy, we need more.

The dissenting commissioners both criticize the Commission's investigations of pharmaceutical mergers generally, expressing concern that they fail to capture all the harms to competition posed by such mergers.[2] But, again, the most they offer is speculation about vaguely articulated harms, without reference to any

[1] Noah Joshua Phillips, Commissioner, U.S. Fed. Trade Comm'n, Taking Stock: Assessing Common Ownership, Address at the Global Antitrust Economics Conference (June 1, 2018), *https://www.ftc.gov/system/files/documents/public_statements/1382461/phillips_-_taking_stock_6-1-18_0.pdf;* Noah Joshua Phillips, Commissioner, U.S. Fed. Trade Comm'n, Competing for Companies: How M&A Drives Competition and Consumer Welfare, Address at the Global Antitrust Economics Conference (May 31, 2019), *https://www.ftc.gov/system/files/documents/public_statements/1524321/phillips_-_competing_for_companies_5-31-19_0.pdf.*

[2] Like Commissioner Wilson, I believe staff conducted a careful investigation of this merger. *See* Statement of Commissioner Christine S. Wilson, In the Matter of Bristol-Myers Squibb Company/Celgene Corporation.

evidence that *this* merger is likely to exacerbate them. Nor do the dissenters cite a previous case that resulted in anticompetitive effects that they insinuate the Commission missed. The dissenting statements mention various violations of the antitrust laws committed by firms in the pharmaceutical industry, but neither explains how this merger makes such conduct more likely. For decades, the Federal Trade Commission has pursued enforcement against many different kinds of anticompetitive conduct in the pharmaceutical industry. That work, critical to controlling healthcare costs for Americans, will continue.

Neither dissenting commissioner argues that the consent order and associated divestiture are bad for competition or consumers, or identifies any additional remedy they believe is warranted. And neither proposes any basis to sue to stop the merger.[3] So, again, why dissent? At the end of the day, we are left only with the sense that Commissioners Chopra and Slaughter feel the merger will threaten competition and wish to dissociate themselves with it. To me, that is not enough. (Even if it were, a vote to join Commissioners Chopra and Slaughter would result, at the end of the day, in the merger without the remedy. Are they calling on their colleagues to vote with them?)

Returning to our unfamiliar reader, here is how the law actually works. First, to block a merger outright, U.S. antitrust enforcement agencies must convince a judge that it violates the law. In this country, where people and companies are free to do what they wish with their property subject to the constraints imposed by the law, our judges are somewhat hostile to the notion that we should block a merger when the parties have agreed to address *every* problem that we can identify. Second, we need to articulate a viable theory of harm to competition posed by the merger and produce evidence to support that theory. Third, our job is to enforce the antitrust laws, which guard against particular (competitive) harms that mergers may present. Other parts of the government guard against other harms posed by mergers, for example the Committee on Foreign Investment in the United States, which looks at certain investments for their potential impact on national security,[4] or the Securities and Exchange Commission, which reviews transactions to protect investors.[5] Our job is not to opine on whether a merger is ''good'' or ''bad'' for society as a whole, or to use our authority to make sure firms merge for reasons that someone might like (innovation) as opposed to reasons that they may not (tax).[6]

In reviewing the dissenting statements, readers—unfamiliar and otherwise—would do well to keep all of that in mind.

Statement of Commissioner Christine S. Wilson

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]

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]

[3] In fairness, Commissioner Chopra does state his view that the agency should litigate to block more pharmaceutical mergers outright. But he fails to answer whether the Commission should litigate *this case,* and—more importantly—on what legal and factual basis. That is the question we face today.

[4] *See* 50 U.S.C. 4565.

[5] *See, e.g.,* 15 U.S.C. 78m(d), 78n(d).

[6] This is not to say that we should view financial or tax considerations as improper motivations for a merger.

[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 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

• *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 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]

• *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

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).

[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.

[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.*

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 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.

Dissenting Statement of Commissioner Rebecca Kelly Slaughter

The Federal Trade Commission has a long history of reviewing mergers between pharmaceutical manufacturers using an analytical framework that identifies specific product overlaps between the merging parties, including of drugs in development, and requiring divestitures of one of those products. This approach addresses significant competitive concerns in these mergers,[1] but I am concerned that it does not fully capture all of the competitive consequences of these transactions.[2]

The consent decree in this case follows the Commission's standard approach. It remedies a serious concern about a drug-level overlap between BMS's development-stage BMS 986165 (or ''TYK2'') and Celgene's on-market Otezla for the treatment of moderate-to-severe psoriasis. This is important, and I support the Commission's effort to remedy this drug-level overlap. However, I remain concerned that this analytical approach is too narrow. In particular, I believe the Commission should more broadly consider whether any pharmaceutical merger is likely to exacerbate anticompetitive conduct by the merged firm or to hinder innovation.

Several recent developments enhance my concerns. Branded drug prices have increased substantially in recent years,[3] and pharmaceutical merger activity persists at a high pace.[4] The high rate of drug company consolidation has coincided with a sea change in the structure of pharmaceutical research and development; recent studies suggest mergers may inhibit research, development, or approval in this changing environment.[5] In addition, the pharmaceutical industry has long been the focus of anticompetitive conduct enforcement by both the Commission and private litigants, including for practices such as pay-for-delay settlements,[6] sham litigation,[7] and anticompetitive product hopping.[8] We must carefully consider the facts in each specific merger to understand whether or how it may facilitate anticompetitive conduct, and therefore be more likely to result in a substantial lessening of competition.

Going forward, I hope the Commission will take a more expansive approach to analyzing the full range of competitive consequences of

[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.*

[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.

[1] Within the standard analytical framework for pharmaceutical mergers, the Commission has done a good job of studying the effects of previous divestitures, and has taken seriously the lesson that divestitures of on-market, rather than pipeline products, are often more likely to succeed in preserving competition among the overlapping products. *See* Bruce Hoffman, *It Only Takes Two to Tango: Reflections on Six Months at the FTC,* at 6 (Feb. 2, 2018).

[2] The Commission has been very successful in negotiating settlements with merging parties to address drug overlaps. The Commission has not recently litigated pharmaceutical merger cases, and, although merger litigation in other industries and merger guidelines provide useful guidance, we simply do not have a contemporary body of pharmaceutical merger caselaw to clarify the boundaries for our analytical approach.

[3] *See* IQVIA Institute for Human Data Science, *The Global Use of Medicine in 2019 and Outlook to 2023,* at 11 (Jan. 29, 2019); IQVIA Institute for Human Data Science, *Medicine Use and Spending in the U.S.,* at 8 (Apr. 19, 2018); Laura Entis, *Why Does Medicine Cost So Much? Here's How Drug Prices Are Set,* Time (Apr. 9, 2019), *https://time.com/5564547/drug-prices-medicine/; see also* Joanna Shepherd, *The Prescription for Rising Drug Prices: Competition or Price Controls?,* 27 Health Matrix 315, 315–16 (2017); Aimee Picchi, *Drug Prices in 2019 are Surging, With Hikes at 5 Times Inflation,* CBS News (July 1, 2019), *https://www.cbsnews.com/news/drug-prices-in-2019-are-surging-with-hikes-at-5-times-inflation/.*

[4] *See* Barak Richman, et al., *Pharmaceutical M&A Activity: Effects on Prices, Innovation, and Competition,* 48 Loy. U. Chi. L. J. 787, 790–91 (2017); Meagan Parrish, *What's Behind all the M&A Deals in Pharma,* Pharma Manufacturing (July 31, 2019).

[5] *See* Justus Haucap & Joel Stiebale, *Research: Innovation Suffers When Drug Companies Merge,* Harvard Business Review (Aug. 3, 2016); Justus Haucap & Joel Stiebale, *How Mergers Affect Innovation: Theory and Evidence From the Pharmaceutical Industry* (2016) (finding a negative effect on research and development activity of the merged firm and rival firms); *but see* Richman, et al., *supra* note 4 at 799–801, 817–18 (finding a positive correlation between increased pharmaceutical merger and drug development activity, but noting competitive concerns about a ''bottleneck'' in FDA approval).

[6] *See* Press Release, Fed. Trade Comm'n, *Last Remaining Defendant Settles FTC Suit that Led to Landmark Supreme Court Ruling on Drug Company ''Reverse Payments''* (Feb. 28, 2019), *https://www.ftc.gov/news-events/press-releases/2019/02/last-remaining-defendant-settles-ftc-suit-led-landmark-supreme.*

[7] *See* Press Release, Fed. Trade Comm'n, *Statement of FTC Chairman Joe Simons Regarding Federal Court Ruling in FTC* v. *AbbVie* (June 29, 2018), *https://www.ftc.gov/news-events/press-releases/2018/06/statement-ftc-chairman-joe-simons-regarding-federal-court-ruling.*

[8] *See* Press Release, Fed. Trade Comm'n, *Reckitt Benckiser Group plc to Pay $50 Million to Consumers, Settling FTC Charges that the Company Illegally Maintained a Monopoly over the Opioid Addiction Treatment Suboxone* (July 11, 2019), *https://www.ftc.gov/news-events/press-releases/2019/07/reckitt-benckiser-group-plc-pay-50-million-consumers-settling-ftc.*

pharmaceutical mergers. I urge not only the Commission, but also researchers and industry experts to think carefully and creatively about these cases, and in particular to study the effects of recent consummated mergers on drug research, development, and approval. Outside of merger enforcement, we should also continue to police aggressively business practices that suppress competition. Indeed, as Commissioner Chopra and I have explained elsewhere, we should unleash the full scope of our authority under Section 5 to combat high drug prices.[9]

The problem of high drug prices is too important to leave any potential solutions unexhausted. As a society, we should also consider all other policy interventions that would help combat high drug prices.[10]

Dissenting Statement of Commissioner Rohit Chopra

Summary

- Today's troubles in the pharmaceutical industry are well known. Drug pricing is out-of-control and innovation is too slow. Given the consequences for human life, the FTC must ensure fierce competition in this market through close scrutiny of mergers and conduct.
- The agency has scored big victories in court to combat anticompetitive conduct in the industry. But, when it comes to mergers, Commissioners have typically voted to steer clear of the courtroom, instead focusing on settlements that address product overlaps.
- Given the size and potential impact of this massive merger, I am skeptical that the status quo approach will uncover the range of potential harms to American patients.

When it comes to life-saving pharmaceuticals, the Federal Trade Commission should never ignore serious warning signs that most Americans see clearly. Many of us depend on prescription drugs to survive, but too many cannot afford the high costs. The argument that sky-high prices are necessary for innovation has been falling apart, as more evidence reveals that many new drugs seem to be designed to extend exclusivity, rather than providing meaningful therapeutic benefits.[1]

Predicting the anticompetitive effects of massive mergers in any industry is difficult. This is especially true in pharmaceuticals, where research and discovery are core to competition. Some evidence shows that these mergers have choked off innovation,[2] creating harms that are immeasurable for those waiting for a cure.

Routine vs. Rigor

Over the years, the agency has worked to combat abuse of intellectual property and other anticompetitive conduct by pharmaceutical companies, achieving major victories in courts across the country. Our approach to pharmaceutical mergers, however, has focused primarily on reaching settlements, rather than litigation or in-depth merger studies. The agency has focused on seeking divestitures of individual products, usually to another major pharmaceutical player.

There have been longstanding, bipartisan concerns about whether this strategy is truly working. For example, in 2005, as he reflected on his six years of service as Commissioner, Thomas Leary lamented that the agency's approach to these investigations mostly stayed the same, despite overarching concerns about other anticompetitive harms.[3]

During my time as a Commissioner, I have pushed for the agency to be more rigorous across all of our work by opening our eyes to new types of analysis and sources of evidence,[4] while avoiding assumptions that may be outdated. Given some of the clear warning signs in the industry, we must approach our investigations of pharmaceutical mergers with careful scrutiny and great humility about our longstanding practices.

This massive $74 billion merger between Bristol-Myers Squibb (NYSE: BMY) and Celgene (NASDAQ: CELG) may have significant implications for patients and inventors, so we must be especially vigilant. In my view, this transaction appears to be heavily motivated by financial engineering[5] and tax considerations[6] (as opposed to a genuine drive for greater discovery of life-saving medications), without clear benefits to patients or the public. The buyer's incentives might also be distorted, given overlaps in ownership.[7]

[9] *See* Statement of Commissioners Rohit Chopra and Rebecca Kelly Slaughter Regarding the Federal Trade Commission Report on the Use of Section 5 to Address Off-Patent Pharmaceutical Price Spikes, (June 27, 2019).

[10] The problem of high drug prices has prompted a number of proposed policy solutions in addition to antitrust enforcement, including (1) reference pricing, (2) reforming import restrictions, (3) innovation prizes, and (4) Medicare Part D price negotiation. *See* So-Yeon Kang, et al., *Using External Reference Pricing in Medicare Part D to Reduce Drug Price Differentials With Other Countries,* 5 Health Aff. 38 (2019); Tim Wu, *How to Stop Drug Price Gouging,* N.Y. Times (Apr. 20, 2017), *https://www.nytimes.com/2017/04/20/opinion/how-to-stop-drug-price-gouging.html;* Charles Silver & David A. Hyman, *Here's a Plan to Fight High Drug Prices That Could Unite Libertarians and Socialists,* Vox (Jun. 21, 2018), *https://www.vox.com/the-big-idea/2018/6/21/17486128/prescription-drug-prices-monopolies-epipen-shkreli-sanders-patents-prizes;* Juliette Cubanski & Tricia Neuman, *Searching for Savings in Medicare Drug Price Negotiations,* Henry J. Kaiser Family Foundation (Apr. 26, 2018).

[1] Donald W. Light & Joel R. Lexchin, *Pharmaceutical R&D: What do we get for all that money?,* 345 British Med. J. 22, 24 (2012), *https://www.bmj.com/bmj/section-pdf/187604?path=/bmj/345/7869/Analysis.full.pdf.*

[2] *See generally,* Justus Haucap & Joel Stiebale, *How Mergers Affect Innovation: Theory and Evidence from the Pharmaceutical Industry* (Düsseldorf Inst. for Competition Economics, Discussion Paper No. 218, 2016), *http://www.dice.hhu.de/fileadmin/redaktion/Fakultaeten/Wirtschaftswissenschaftliche_Fakultaet/DICE/Discussion_Paper/218_Haucap_Stiebale.pdf.*

[3] Interview with Commissioner Thomas B. Leary, 19 (3) A.B.A. Antitrust Health Care Chronicle 1, 5 (2005), *https://www.ftc.gov/public-statements/2005/09/health-care-interview-commissioner-thomas-b-leary.*

[4] I have previously noted that the agency can enhance its assessments of the likelihood of entry by new innovators, as well as its approach to vetting the financial condition of divestiture buyers. Statement of Commissioner Rohit Chopra, In the Matter of Fresenius Medical Care AG & Co. KGaA and NxStage Medical, Inc. (Feb. 19, 2019), *https://www.ftc.gov/public-statements/2019/02/statement-commissioner-chopra-matter-fresenius-medical-care-ag-co-kgaa;* Statement of Commissioner Rohit Chopra, In the Matter of Linde AG, Praxair, Inc., and Linde PLC (Oct. 22, 2018), *https://www.ftc.gov/public-statements/2018/10/statement-commissioner-chopra-matter-linde-ag-praxair-inc-linde-plc.*

[5] This transaction will lead to changes in the merged firm's capital structure, as well as an acceleration of share buybacks. I fear that these changes will alter the firm's incentives in ways that might increase the likelihood of anticompetitive conduct. *See* Bristol-Myers Squibb, Press Release, Bristol-Myers Squibb Announces Agreement Between Celgene and Amgen to Divest OTEZLA® for $13.4 Billion (Aug. 26, 2019, 6:30 a.m.), *https://news.bms.com/press-release/corporatefinancial-news/bristol-myers-squibb-announces-agreement-between-celgene-and-a.*

[6] Tax avoidance appears to be one of the primary motivations of the deal, rather than a meaningful increase in the firms' ability to innovate or operate effectively. *See, e.g.,* Siri Bulusu, *Celgene Holders May See Tax Benefit From Bristol-Myers Deal (1),* Bloomberg Tax (Jan. 4, 2019, 4:43 p.m.), *https://news.bloombergtax.com/daily-tax-report/celgene-holders-may-see-tax-benefit-from-bristol-myers-deal-1* (noting that the buyer went out of its way to make sure the stock component of the merger will be taxable and describing how that tax would be deductible by Celgene shareholders). Tax considerations were also relevant to Amgen, the Commission's approved buyer of a divested asset. Amgen publicly disclosed that it would recognize $2.2 billion in tax benefits, on a present value basis. *See* Michael Erman & Manas Mishra, *Amgen to buy Celgene psoriasis drug Otezla for $13.4 billion,* Reuters (Aug. 26, 2019), *https://www.reuters.com/article/us-bristol-myers-divestiture-amgen/amgen-to-buy-celgene-psoriasis-drug-otezla-for-13-4-billion-idUSKCN1VG102.*

[7] For example, I noted with great interest that two-thirds of Bristol-Myers Squibb's 100 largest shareholders also have stakes in Celgene, according to data assembled by Refinitiv. *See, e.g.,* Svea Herbst-Bayliss & Michael Erman, *Starboard joins opposition to Bristol-Myers' $74 billion Celgene*

Continued

In addition, there are also concerns about a history of anticompetitive conduct.[8] Expansive investigation for mergers like these is time well spent.

Again, with a few exceptions,[9] many FTC Commissioners have primarily scrutinized pharmaceutical mergers based on an examination of whether there are any product overlaps between the merging corporations, or where there may be clear-cut incentives to foreclose rivals with the ability to compete.[10] When there are no obvious overlaps or foreclosure possibilities, the Commission typically does not challenge any aspect of the transaction.[11]

I am deeply skeptical that this approach can unearth the complete set of harms to patients and innovation, based on the history of anticompetitive conduct of the firms seeking to merge and the characteristics of today's pharmaceutical industry when it comes to innovation. Will the merger facilitate a capital structure that magnifies incentives to engage in anticompetitive conduct or abuse of intellectual property? Will the merger deter formation of biotechnology firms that fuel much of the industry's innovation? How can we know the effects on competition if we do not rigorously study or investigate these and other critical questions? Given our approach, I am not confident that the Commission has sufficient information to determine the full scope of potential harms to competition of this massive merger.

Conclusion

The financial crisis and the Great Recession taught our country a tough lesson: When watchdogs wear blindfolds or fail to evolve with the marketplace, millions of American families can suffer the consequences. The regulators and enforcers of the mortgage industry failed to stop the widespread abuses that plagued the marketplace. And there are many more examples every year, from the opioid crisis to the failures of the Boeing 737 Max, where blindfolded regulators and the absence of rigorous investigation proved to be catastrophic to human life, despite so many warning signs.

When enforcers conduct wide-ranging, intensive inquiries that do not uncover unlawful conduct, then, of course, they cannot take action. However, when they wear blindfolds or cling to the status quo, they cannot assume that the public is protected.

For these reasons, I respectfully dissent.

[FR Doc. 2019–26074 Filed 12–2–19; 8:45 am]

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deal, Reuters (Feb. 28, 2019, 6:59 a.m.), *https://www.reuters.com/article/us-celgene-m-a-bristol-myers-wellington/starboard-joins-opposition-to-bristol-myers-74-billion-celgene-deal-idUSKCN1QH1K7.*

[8] For example, last year, the Food & Drug Administration published a list of drug makers that were the subject of complaints that they had restricted generic drug companies from accessing drug samples, which enable generic firms to develop viable alternatives. Celgene was a top recipient of these complaints. Alison Kodjak, *How a Drugmaker Gamed The System To Keep Generic Competition Away,* NPR (May 17, 2018; 5:00 a.m.), *https://www.npr.org/sections/health-shots/2018/05/17/571986468/how-a-drugmaker-gamed-the-system-to-keep-generic-competition-away.*

[9] *See, e.g.,* Statement of the Federal Trade Commission, In the Matter of Teva Pharmaceuticals Industries Ltd. and Allergan plc (July 27, 2016), *https://www.ftc.gov/public-statements/2016/07/statement-federal-trade-commission-matter-teva-pharmaceuticals-industries; cf.* Concurring Statement of Commissioner J. Thomas Rosch, Federal Trade Commission v. Ovation Pharmaceuticals, Inc. (Dec. 16, 2008), *https://www.ftc.gov/public-statements/2008/12/concurring-statement-commissioner-j-thomas-rosch-federal-trade-commission.*

[10] In this matter, the Analysis of Agreement Containing Consent Orders to Aid Public Comment focuses primarily on a specific product market overlap. This is similar to many past analyses contained in public notices seeking comment on proposed consent orders in the FTC's pharmaceutical merger actions. *See, e.g.,* Analysis Of Agreement Containing Consent Orders To Aid Public Comment, *In the Matter of Boston Scientific Corporation,* File No. 191–0039, *https://www.ftc.gov/system/files/documents/cases/191_0039_boston_scientific_aapc.pdf;* Analysis Of Agreement Containing Consent Orders To Aid Public Comment, *In the Matter of Amneal Holdings, LLC, Amneal Pharmaceuticals LLC, Impax Laboratories, Inc., and Impax Laboratories, LLC,* File No. 181–0017, *https://www.ftc.gov/system/files/documents/cases/1810017_amneal_impax_analysis_4-27-18.pdf. See also* Markus Meier et al., Fed. Trade Comm'n, Overview of FTC Actions In Pharmaceutical Products and Distribution (2019), *https://www.ftc.gov/system/files/attachments/competition-policy-guidance/overview_pharma_june_2019.pdf.*

[11] For example, in January 2015 the Commission granted early termination of the Hart-Scott-Rodino waiting period and took no enforcement action against the proposed $66 billion merger between Actavis plc and Allergan, Inc. *See* Fed. Trade Comm'n, Early Termination Notices, *20150313: Actavis plc; Allergan, Inc.* (Jan. 9, 2015), *https://www.ftc.gov/enforcement/premerger-notification-program/early-termination-notices/20150313.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2019–0112]

Priority Topics for the Community Preventive Services Task Force (CPSTF); Request for Information

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Request for information.

SUMMARY: The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) announces the opening of a docket to obtain public comment to identify topics of public health importance that will form the basis of Community Preventive Services Task Force (CPSTF) evidence-based recommendations. CDC will use this information to support the CPSTF in its selection of priority topics to guide its work over the next five years. This docket will provide the opportunity to expand the current body of knowledge and identify important evidence gaps.

DATES: Written comments must be received on or before January 23, 2020.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2019–0112, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Julie Zajac, Centers for Disease Control and Prevention, Office of the Associate Director for Policy and Strategy, Community Guide Office, 1600 Clifton Road NE, Mail Stop V25–5, Atlanta, GA 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *http://regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Julie Zajac MPH, Community Guide Office, Office of the Associate Director for Policy and Strategy, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mail Stop V25–5, Atlanta, GA 30329. Phone: 404–498–1827; Email: *cpstf@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. In addition, CDC invites comments specifically on the following questions:

1. What public health topics should be prioritized for CPSTF systematic reviews assessing the effectiveness and economic merits of public health programs, services, and other interventions?

2. What is the rationale for choosing these topics?

3. What are examples of published studies on interventions within these topics?

Possible domains to consider in answering these questions include (but are not limited to):