

HOLDINGS, LLC, KZTM(FM), Fac. ID No. 33829, FROM: CENTRALIA, WA, TO: MCKENNA, WA, File No. 0000121551; FAMILY LIFE MINISTRIES, INC., WCGT(FM), Fac. ID No. 172665, FROM: TIDIOUTE, PA, TO: CLINTONVILLE, PA, File No. 0000124533; FAMILY LIFE MINISTRIES, INC., WCOT(FM), Fac. ID No. 20653, FROM: JAMESTOWN, NY, TO: TIDIOUTE, PA, File No. 0000124532; PRAISE COMMUNICATIONS, INC., WTUA(FM), Fac. ID No. 23895, FROM: PINOPOLIS, SC, TO: ST. STEPHEN, SC, File No. 0000125220, and OMNI BROADCASTING, LLC, WTKP(FM), Fac. ID No. 67579, FROM: PORT ST. JOE, FL, TO: YOUNGSTOWN, FL, File No. 0000124529. The full text of these applications is available electronically via the Media Bureau's Consolidated Data Base System, https://licensing.fcc.gov/prod/cdbs/pubacc/prod/app_sear.htm or Licensing and Management System (LMS), <https://apps2int.fcc.gov/dataentry/public/tv/publicAppSearch.html>.

Federal Communications Commission.

Nazifa Sawez,

Assistant Chief, Audio Division, Media Bureau.

[FR Doc. 2020-24961 Filed 11-10-20; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at <https://www.federalreserve.gov/foia/request.htm>. Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551-0001, not later than November 27, 2020.

A. Federal Reserve Bank of Dallas (Robert L. Triplett III, Senior Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. *Laurie Lewis Saunders, John T. Saunders III, Steve C. Lewis, Richard S. Lewis II, A.J. Lewis III, A.J. Lewis, IV, Frances M. Lewis, and Sallie W. Lewis, all of San Antonio, Texas; all individually, and as trustee or voting appointee for one or more of the following trusts: the Laurie Lewis Saunders Family 2007 Trust One, the Laurie Lewis Saunders Family 2007 Trust Two, the A.J. Lewis Jr. Trust FBO Laurie Lewis Saunders, the Peggy W. Lewis Article III GST Exempt Trust FBO Laurie Lewis Saunders, the Christina M. Saunders Trust, the John T. Saunders III Trust, the Virginia G. Saunders Trust, the Steve C. Lewis Family 2007 Trust One, the Steve C. Lewis Family 2007 Trust Two, the A.J. Lewis, Jr. Trust FBO Steve C. Lewis, the Peggy W. Lewis Article III GST Exempt Trust FBO Steve C. Lewis, the Barclay C. Adams Grantor Trust, the Richard S. Lewis II Grantor Trust, the Adams Family 2019 GST—Exempt Trust, the Richard S. Lewis 11 Family 2018 Trust, the A.J. Lewis III Family 2007 Trust One, the A.J. Lewis III Family Trust Two, the A.J. Lewis, Jr. Trust FBO A.J. Lewis III, the Peggy W. Lewis Article III GST Exempt Trust FBO A.J. Lewis III, the Frances Marguerite Lewis Grantor Trust, the A.J. Lewis IV Grantor Trust, the Sallie Wolff Lewis Grantor Trust, the A.J. Lewis IV Family Trust One, the A.J. Lewis IV Family Trust Two, the Frances M. Lewis Family Trust One, the Frances M. Lewis Family Trust Two, the Sallie W. Lewis Family Trust One, the Sallie W. Lewis Family Trust Two, all of San Antonio Texas, and*

Susan C. Lewis, Christina M. Saunders, Barclay C. Adams, all of San Antonio, Texas; and Kenneth S. Adams IV, Nashville, Tennessee; to become members of the Lewis Family Group, a group acting in concert, to retain the voting shares of Jefferson Bancshares, Inc., and thereby indirectly retain the voting shares of Jefferson Bank, both of San Antonio, Texas.

2. *Paul E. McSween III, Linda Lewis McSween, Juliet McSween Zacher, Jennifer McSween Canavan, Linda McSween Satel, all of San Antonio, Texas; all individually, and as grantor, trustee, or voting appointee for one or*

more of the following trusts: the Paul E. McSween III Family 2011 Trust One, the Paul E. McSween III Family 2011 Trust Two, the Paul E. McSween IV Grantor Trust, the Thomas D. McSween Grantor Trust, the Benjamin Lewis McSween Grantor Trust, the Linda Lewis McSween Trust, the Jennifer McSween Canavan Family 2011 Trust One, Jennifer McSween Canavan Family 2011 Trust Two, the Jennifer McSween Canavan Management Trust, the Juliet W. McSween Zacher Family 2011 Trust One, Juliet W. McSween Zacher Family 2011 Trust Two, the Juliet McSween Zacher Management Trust, the Linda G. McSween Satel Family 2011 Trust One, the Linda G. McSween Satel Family 2011 Trust Two, the Linda McSween Satel Management Trust, the Katherine Ann Satel Grantor Trust, the Emily Grace Satel Grantor Trust, and the Caroline McSween Satel Grantor Trust, all of San Antonio, Texas; and

Caroline M. Satel, Katherine Ann Satel, Emily Grace Satel, Joseph S. Satel, Jr., Paul E. McSween IV, Thomas D. McSween, Benjamin Lewis McSween, Crain McSween Canavan, William Jackson Canavan, Josephine Grace Canavan, Walker Cole Canavan, August Andrew Zacher, Annabelle McSween Zacher, and the Richard Spencer Lewis Memorial Foundation, all of San Antonio, Texas; to become members of the McSween Family Control Group, a group acting in concert, to retain the voting shares of Jefferson Bancshares, Inc., and thereby indirectly retain the voting shares of Jefferson Bank, both of San Antonio, Texas.

Board of Governors of the Federal Reserve System, November 6, 2020.

Ann Misback,

Secretary of the Board.

[FR Doc. 2020-25010 Filed 11-10-20; 8:45 am]

BILLING CODE P

FEDERAL TRADE COMMISSION

[File No. 191-0182]

Pfizer Inc. and Mylan N.V.; 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 to Aid Public Comment describes both the allegations in the complaint and the terms of the consent order—embodied

in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before December 14, 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: “Pfizer Inc. and Mylan N.V.; File No. 191 0182” 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, please 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: Jasmine Rosner (202–326–3558), 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 of Agreement Containing Consent Orders 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 website at this web address: <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 December 14, 2020. Write “Pfizer Inc. and Mylan N.V.; File No. 191 0182” 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.

Due to the public health emergency in response to the COVID–19 outbreak and the agency’s heightened security screening, postal mail addressed to the Commission will be subject to delay. We

strongly encourage you to submit your comments online through the <https://www.regulations.gov> website.

If you prefer to file your comment on paper, write “Pfizer Inc. and Mylan N.V.; File No. 191 0182” 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 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 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 your comment does not include 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 <https://www.regulations.gov>—as legally

required by FTC Rule 4.9(b)—we cannot redact or remove your comment from that 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 this matter. 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 December 14, 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 Consent Orders To Aid Public Comment

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from Pfizer Inc., Upjohn Inc., Viatris Inc., Mylan N.V., and Utah Acquisition Sub Inc., that is designed to remedy the anticompetitive effects resulting from the proposed combination of Upjohn and Mylan. Under the terms of the Consent Agreement, the parties are required to divest Upjohn’s generic drug rights and assets related to six products to Prasco, LLC. The Consent Agreement also requires the parties to divest Mylan’s rights and assets related to eplerenone tablets to Prasco. Further, the Consent Agreement requires prior Commission approval before Upjohn, Mylan, or Viatris may gain an interest in or exercise control over any third party’s rights to (1) levothyroxine sodium tablets, (2) sucralbate tablets, and (3) varenicline tartrate tablets.

The Consent Agreement has been placed on the public record for thirty days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again evaluate the Consent Agreement, along with the comments received, to make a final decision as to whether it should withdraw the Consent Agreement, modify it, or make final the proposed Decision and Order (“Order”).

Pursuant to agreements dated July 29, 2019, Pfizer proposes to spin off its Upjohn business, which includes legacy Pfizer branded products and the authorized generic business,

Greenstone, LLC. Upjohn will combine with Mylan to form a new entity, Viatrix ("Proposed Combination"). The Commission alleges in its Complaint that the Proposed Combination, if consummated, would violate Section 7 of the Clayton Act, 15 U.S.C. 18, as amended, and Section 5 of the Federal Trade Commission Act, 15 U.S.C. 45, as amended, by lessening current competition in the following seven U.S. markets: (1) Amlodipine besylate/atorvastatin calcium tablets, (2) eplerenone tablets, (3) gatifloxacin ophthalmic solution, (4) medroxyprogesterone acetate injectable solution, (5) phenytoin chewable tablets, (6) prazosin hydrochloride ("HCl") capsules, and (7) spironolactone hydrochlorothiazide ("HCTZ") tablets. The Commission also alleges that the Proposed Combination would violate the aforementioned statutes by lessening future competition in the markets for: (1) Levothyroxine sodium tablets, (2) sucralfate tablets, and (3) varenicline tartrate tablets. The Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be eliminated by the Proposed Combination.

I. The Products and Structure of the Markets

In human pharmaceutical markets, price generally decreases as the number of generic competitors increases. Prices continue to decrease incrementally with the entry of the second, third, fourth, and even fifth generic competitor. And in markets prone to supply shortages, additional entry after the fifth generic competitor continues to affect price and ensures more stable supply. Accordingly, the reduction in the number of suppliers within each relevant market has a direct and substantial effect on pricing.

The Proposed Combination would reduce current competition in the markets for seven products where Greenstone distributes the authorized generic version of the branded drug:

- Amlodipine besylate/atorvastatin calcium tablets combine a calcium channel blocker to treat hypertension with a lipid-lowering agent to treat high cholesterol. Only four companies sell generic amlodipine besylate/atorvastatin calcium tablets: Greenstone, Mylan, Dr. Reddy's Laboratories Ltd., and Apotex Inc.

- Eplerenone is a diuretic that is prescribed as an adjunctive therapy when treating hypertension or congestive heart failure after a heart attack. Significant sellers of eplerenone include Greenstone, Mylan,

Breckenridge Pharmaceutical, Inc., and Accord Healthcare Inc.

- Gatifloxacin ophthalmic solution is an eye drop that treats bacterial conjunctivitis caused by susceptible strains of certain bacteria. The market for gatifloxacin has faced historical supply disruptions. Five companies supply this product today: Greenstone, Mylan, Sandoz International GmbH, Akorn, Inc., and Lupin Ltd.

- Medroxyprogesterone acetate is an injectable solution used to treat certain types of dysfunctional uterine bleeding. Injectable products, such as medroxyprogesterone acetate, have recently experienced shortages and supply disruptions. Greenstone, Mylan, Amphastar Pharmaceuticals, Inc., Teva Pharmaceutical Industries Ltd., and Sun Pharmaceutical Industries Ltd. currently supply medroxyprogesterone acetate.

- Phenytoin chewable tablets are an anti-epileptic drug that slows down impulses in the brain that cause seizures. Only three suppliers provide phenytoin chewable tablets today: Greenstone, Mylan, and Taro Pharmaceutical Industries Ltd.

- Prazosin HCl capsules are an alpha-adrenergic blocker that treats hypertension by relaxing the veins and arteries so that blood can more easily pass. The market for prazosin HCl capsules is supplied by four companies: Greenstone, Mylan, Teva, and Novitium Pharma LLC.

- Spironolactone HCTZ tablets are a diuretic used to treat hypertension. Only three suppliers provide spironolactone HCTZ tablets: Greenstone, Mylan, and Sun.

The Proposed Combination also would reduce future competition in the following generic markets:

- Levothyroxine sodium tablets are offered in a host of strengths and are prescribed to treat hypothyroidism or as an adjunct therapy for patients undergoing treatment for thyroid cancer. Suppliers for levothyroxine sodium tablets vary by strength. Should Upjohn or Greenstone launch an authorized generic of Pfizer's levothyroxine sodium branded product (Levoxyl®), the Proposed Combination likely would reduce the number of independent suppliers from three to two in some strengths.

- Sucralfate tablets are used to treat and prevent ulcers in the small intestines. Three companies sold sucralfate tablets historically: Greenstone, Mylan, and Teva. Mylan recently discontinued sales of sucralfate. The Proposed Combination likely alters Mylan's incentives to relaunch sucralfate tablets and would reduce the number of firms capable of

selling sucralfate tablets from three to two.

- Varenicline tartrate tablets are a smoking cessation aid offered under Pfizer's brand Chantix®. Currently, only branded Chantix® is available in the market. Mylan is one of a limited number of companies likely to share the Hatch-Waxman 180-day exclusivity period when the generic market forms. Should Upjohn or Greenstone launch an authorized generic of Pfizer's Chantix®, the Proposed Combination would significantly reduce the number of independent generic suppliers.

II. Entry

Entry into the markets at issue would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Proposed Combination. The combination of drug development times and regulatory requirements, including approval by the FDA, is costly and time-consuming.

III. Competitive Effects

The Proposed Combination would likely cause significant anticompetitive harm to consumers in the relevant generic pharmaceutical markets by eliminating current and/or future competition in concentrated existing generic markets or in future generic markets. In generic pharmaceuticals markets, price is heavily influenced by the number of participants with sufficient supply. Market participants consistently characterize generic drug markets as commodity markets in which the number of generic suppliers has a direct impact on pricing. Customers and competitors alike have confirmed that the prices of the generic pharmaceutical products at issue continue to decrease with new entry even after a number of suppliers have entered these generic markets.

The evidence shows anticompetitive effects are likely because the Proposed Combination will reduce the number of independent competitors in the markets at issue. In each of the current generic drug markets, industry participants have indicated that the presence of Greenstone and Mylan as independent competitors has allowed them to negotiate lower prices and, in some markets, has improved surety of supply.

In five of the markets where Upjohn and Mylan currently compete (amlodipine besylate/atorvastatin calcium tablets, eplerenone tablets, phenytoin chewable tablets, prazosin HCl capsules, and spironolactone HCTZ tablets), the Proposed Combination likely would reduce competition by combining two of only four or fewer

current suppliers, likely leading to higher prices. In two of the markets where Upjohn and Mylan currently compete and where significant product shortages have occurred (gatifloxacin ophthalmic solution and medroxyprogesterone acetate injectable solution), the Proposed Combination would eliminate an independent supplier. Customers have indicated that preserving competition between Upjohn and Mylan, particularly in markets prone to shortages, is important to maintaining adequate supplies and competitive prices.

In addition, the Proposed Combination likely would delay or forego the introduction of beneficial competition, and subsequent price decreases, by eliminating future competition in the markets for generic levothyroxine sodium tablets, sucralfate tablets, and varenicline tartrate tablets.

Absent the Consent Agreement, the Proposed Combination would eliminate significant current and future competition between the parties and likely cause U.S. consumers to pay higher prices for the aforementioned generic pharmaceutical products.

IV. The Consent Agreement and Order

The proposed Order effectively remedies the competitive concerns raised by the Proposed Combination for the ten generic pharmaceutical product areas at issue. Pursuant to the proposed Order, the parties are required to divest to Prasco Upjohn's authorized generic rights and assets related to six products. The proposed Order also requires the parties to divest Mylan's rights and assets related to eplerenone tablets to Prasco. The parties must accomplish these divestitures and relinquish their rights no later than ten days after the Proposed Combination is consummated. The proposed Order further allows the Commission to appoint a trustee in the event the parties fail to divest the products.

Further, the proposed Order requires prior Commission approval before Upjohn, Mylan, or Viatriis may gain an interest in, or exercise control over, any third party's rights to the following products: (1) Levothyroxine sodium tablets, (2) sucralfate tablets, and (3) varenicline tartrate tablets.

The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the Proposed Combination. Prasco is a capable purchaser with management and employees who have experience marketing and distributing generic pharmaceutical products. It will be able

to replicate the competition otherwise lost from the Proposed Combination.

The proposed Order contains several provisions to help ensure that the divestitures are successful. As to the products and rights being divested to Prasco, generic drug manufacturing will continue to be performed by the same entity as prior to the Proposed Combination, reducing the risk of any interruption in supply to Prasco. In some instances, Pfizer—which will be an independent entity, separate from Viatriis after the Proposed Combination—will serve as Prasco's contract manufacturer, allowing Prasco to step into the shoes of Upjohn/Greenstone. Should Prasco decide to move manufacturing to another contract manufacturer, the proposed Order requires the parties to provide transitional services to assist Prasco or its designated contract manufacturer in establishing manufacturing capabilities and securing all necessary FDA approvals. These transitional services include technical assistance to manufacture the currently marketed products in substantially the same manner and quality employed or achieved by the parties. To the extent that Pfizer will manufacture relevant products on behalf of both Viatriis and Prasco, the proposed Order requires that supply to Prasco is provided at a pre-determined cost and is prioritized over supply to Viatriis. For amlodipine besylate/atorvastatin calcium tablets, Viatriis will provide the active pharmaceutical ingredient ("API") used in Prasco's product. The proposed Order requires that Viatriis provide Prasco with API at a pre-determined cost and that it prioritizes Prasco's use of API over its own. Moreover, the proposed Order requires a firewall between Viatriis's API business and its commercial business to prevent the sharing of commercially sensitive information. Under the proposed Order, the Commission also will appoint two Monitors.

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, Commissioner Chopra and Commissioner Slaughter dissenting.

April J. Tabor,
Acting Secretary.

Statement of Commissioner Christine S. Wilson

Today, the Commission announces that it has voted 3–2 to issue a complaint and accept a settlement to

remedy the threats to competition arising from Mylan's proposed acquisition of Pfizer's off-patent drug business.

The experienced staff of the Federal Trade Commission thoroughly investigated all cognizable theories of harm to competition during more than a year of review. Their extensive investigation put to rest some concerns and produced grounds for other concerns. Staff negotiated comprehensive remedies to address the potential anticompetitive effects identified during their exhaustive investigation—as they have done in many transactions in the pharmaceutical sector, including Bristol-Myers Squibb/Celgene and AbbVie/Allergan. Yet, as Commissioners Slaughter and Chopra did in those merger reviews, they are again opposing the settlement of this enforcement action.

Prices for pharmaceuticals and biologics deserve the attention of the American public and the federal government. As I stated in connection with the announcement of the FTC's settlement with Bristol-Myers and Celgene, within its limited civil authority as a competition agency, the Commission vigorously pursues a comprehensive agenda to address anticompetitive mergers and unlawful conduct in the pharmaceutical industry.¹ I continue to encourage those government entities with the appropriate mandates to fix the many problems in this sector that lie beyond our jurisdiction.

Dissenting Statement of Commissioner Rohit Chopra Joined by Commissioner Rebecca Kelly Slaughter

Summary

- The FTC's record when it comes to reviewing pharmaceutical mergers suggests that the agency will simply never seek to block a merger. Instead, the agency's approach is to strike narrow settlements. This encourages market actors to propose even more unlawful mergers.

- Both Pfizer and Mylan have been accused of collusion in the generic drug business. We must assess whether this merger will enhance their ability to conspire and collude.

- Rajiv Malik, who will be president of the merged entity, is currently a defendant charged with antitrust

¹ Statement of Commissioner Christine S. Wilson, *In the Matter of Bristol-Myers Squibb Company/Celgene Corporation*, File No. 191–0061, Nov. 15, 2019, available at https://www.ftc.gov/system/files/documents/public_statements/1554278/bms-celgene-wilson-statement.pdf.

misconduct. The Commission's silence about his role is deeply problematic.

Drug prices are out of control, and in too many instances, are out of reach for patients who depend on them. Competition from generic drugs pushes down high prices. That's why it's critical to combat abuse of intellectual property that allows branded drug makers to block generic entry. But we should also be deeply concerned that patients can't reap the full benefits from generic competition, given the alleged collusion in the generic drug industry to drive up prices. Any investigation of massive mergers in the generic business must take this into account.

Today, the Federal Trade Commission has voted to settle allegations that Mylan's (NASDAQ: MYL) proposed \$12 billion acquisition of Pfizer's (NYSE: PFE) generic drug business is unlawful.¹ The combined firm would become the largest generic pharmaceutical firm in the world and offer approximately 3,000 drug products that treat a broad range of diseases and conditions.² The FTC's proposed settlement requires divestiture of seven individual products, as well as other provisions.

When it comes to pharmaceutical mergers, I am unable to identify a single instance in recent history where the agency has filed a complaint in federal court seeking to halt a prescription drug company merger. This lack of litigation creates the strong impression that the FTC simply looks to strike settlement deals involving individual product divestitures. Virtually every market participant I have spoken to in this industry believes that there is simply no risk of the FTC blocking an unlawful pharmaceutical merger outright.

I respectfully disagree with the status quo approach the Commission applied to this pharmaceutical merger. The use here is especially concerning, since both firms and two of Mylan's top executives have been accused of a wide-ranging price fixing and market allocation conspiracy in the generic drug

industry.³ With an expanded empire of generic drug products, these alleged antitrust crimes may be even easier to perpetrate by the new entity.⁴

In this statement, I focus on how mergers involving companies competing across a large number of product lines can exacerbate the risk of collusive conspiracies, particularly in industries where middlemen may not have an incentive to keep prices low.⁵ I also focus on issues we must always confront. For example, the Commission should always look to testimony from top executives at companies proposing to merge in order to fully understand the range of potential effects on competition. The Commission can only make a conclusion about the risk of collusion and any impacts on competition when it has a full range of data and evidence.

Conditions for Collusion

When competitors enter into agreements to fix prices, rig bids, and divvy up markets, they can face civil and criminal charges. Pfizer and Mylan are defendants in several state attorneys general and private plaintiff lawsuits alleging market allocation and price fixing in the generic drug industry.⁶ They are also under investigation for criminal market allocation and price fixing by the Department of Justice.⁷ Over thirty additional generic drug companies are defendants in the same state attorneys general suits, including

³ See Compl., *Connecticut v. Teva Pharms. USA, Inc.*, Case No. 3:19-cv-00710 (D. Conn. filed May 10, 2019) ¶ 50; *In re Generic Pharms. Pricing Antitrust Litig.* ¶ 34, Civ. Action No. 17-3768 (E.D. Pa. filed June 15, 2018).

⁴ The Department of Justice also charged Teva with criminally conspiring to fix prices, rig bids, and allocate customers for generic drugs. Five previous corporate cases were resolved by deferred prosecution agreements; Teva and its co-conspirator Glenmark are awaiting trial. Four executives have also been charged; three have entered guilty pleas, and one is awaiting trial. See Press Release, Dep't. of Just., Seventh Generic Drug Manufacturer Is Charged In Ongoing Criminal Antitrust Investigation (Aug. 25, 2020), <https://www.justice.gov/opa/pr/seventh-generic-drug-manufacturer-charged-ongoing-criminal-antitrust-investigation>.

⁵ Most generic drugs are sold by their manufacturers to group purchasing organizations and large retail purchasers, who negotiate pricing contracts for their members that ultimately purchase the products. These contracts typically have inflation-based provisions that allow for potentially greater compensation when prices are higher. See *In re Generic Pharms. Pricing Antitrust Litig.* ¶ 74.

⁶ See e.g., Pl. States' Consol. Am. Compl., *In re Generic Pharms. Pricing Antitrust Litig.*; Compl., *Connecticut v. Teva Pharms.*; Compl., *Connecticut v. Sandoz, Inc.*, Civ. Action No. 3:20-cv-802 (D. Conn. filed June 10, 2020).

⁷ See Pfizer Inc., Current Report (Form 8-K) (Aug. 6, 2020) at 175; Mylan N.V., Annual Report (Form 10-K) (Dec. 31, 2019) at 153.

well-known drug firms Sandoz, Actavis, Teva, and Allergan, among others. Patients have allegedly paid many billions of dollars in overcharges for the generic drugs involved, causing a significant negative impact on our national health and economy.⁸

Typically, collusion is easier to pull off when a market has only a few big players, since coordination is more difficult with more actors.⁹ However, there are many generic drug companies that operate in the United States. So why might there be widespread misconduct?

One potential explanation is that these companies compete with each other in multiple different product markets. The enormous profit potential for these firms from collusion likely contributes to their incentives to engage in mutually beneficial coordination. By trading favorable competitive terms in one market for favorable competitive terms in another market, it may be easier for competing firms to reach mutually beneficial terms of trade and punish each other for any deviations.¹⁰

Pfizer and Mylan allegedly did just that.¹¹ In addition to colluding within individual generic drug product markets, Pfizer's Greenstone division, Mylan, and others are charged with trading customers across *different* drug markets.¹² They allegedly allowed price increases on generic drugs without competing, based on a quid pro quo from competitors on different drug products.¹³ Given these allegations, it is important that we closely investigate how this transaction could increase the ability of the merged entity to engage in similar—or even more harmful—collusive conduct. For example, the merged entity would become the top supplier of generic drugs by global revenues, with an enormous number of

⁸ Compl., *Connecticut v. Teva Pharms. USA, Inc.* ¶ 5.

⁹ This concept is reflected in the FTC's Horizontal Merger Guidelines. U.S. DEPT OF JUST. & FED. TRADE COMM'N, HORIZONTAL MERGER GUIDELINES § 7.2 (Aug. 19, 2010), <https://www.justice.gov/sites/default/files/atr/legacy/2010/08/19/hmg-2010.pdf>.

¹⁰ See Federico Ciliberto & Jonathan W. Williams, Does multimarket contact facilitate tacit collusion? Inference on conduct parameters in the airline industry, 45 RAND J. OF ECON. 764–791 (2014) (noting that such multimarket contact facilitates tacit collusion in the U.S. airline industry).

¹¹ Compl., *In re Generic Pharms. Pricing Antitrust Litig.* ¶¶ 103–105 (describing Defendant Malik's willingness to “play fair” and give up two large customers to Heritage because Heritage had previously allowed Mylan to enter another market without competition); see also Compl., *Connecticut v. Sandoz, Inc.* ¶ 1299.

¹² *Id.*

¹³ Compl., *In re Generic Pharms. Pricing Antitrust Litig.* ¶ 101; see also Compl., *Connecticut v. Teva Pharms* ¶ 12.

¹ Pfizer, Press Release, Mylan and Upjohn, a Division of Pfizer, to Combine, Creating a New Champion for Global Health Uniquely Positioned to Fulfill the World's Need for Medicine (July 29, 2019, 2:45 a.m.), https://www.pfizer.com/news/pressrelease/pressreleasedetail/mylan_and_upjohn_a_division_of_pfizer_to_combine_creating_a_new_champion_for_global_health_uniquely_positioned_to_fulfill_the_worlds_need_for_medicine.

² See Mylan & Upjohn Investor Presentation, A New Champion for Global Health at 17 (July 29, 2019), <https://www.championforglobalhealth.com/media/championforglobalhealth/pdf/mylanupjohninvestorpresentation072919.pdf>; see also Mylan & Upjohn Fact Sheet, A New Champion for Global Health (n.d.a.), <https://www.championforglobalhealth.com/media/championforglobalhealth/pdf/MylanUpjohnFactsheet072919.pdf>.

products and a broad range of competitors with which to engage in quid pro quo collusive arrangements.¹⁴ With more generic drugs in the hands of one competitor, it may be easier to form a cartel and punish those who don't adhere to its terms. Despite this risk, the Commission's analysis is silent with respect to the alleged price fixing conduct.¹⁵

The FTC often acts without the benefit of the experience of other law enforcement partners.¹⁶ In all matters, the Commission should avoid a go-it-alone approach and collaborate with other agencies to help shed light on the mechanisms involved in the allegations. Together, we should closely assess whether the likelihood of harm increases post-merger.

Investigating Executives

In any matter where a company has a history of potential wrongdoing, a key method to determine the motivations for a merger and to predict how it will affect competition is to seek sworn testimony from key executives. This is especially critical to understand how sales, pricing, and market forces are working. This evidence is also helpful if the agency must prepare a lawsuit.

While filings submitted by merging parties shed light on many aspects of a transaction, they do not always provide a complete picture of the deal rationale, pricing models, and boardroom behavior. The state allegations of price fixing and market allocation make clear that individual executives play a key role in sales and price setting, so it is critical that we fully understand this element of the competitive process. For example, what is their involvement in developing a pricing model? Do they approve deviations from this pricing model? How do they decide which new markets to enter? In what contexts do they interact with their competitors? There are a long list of questions that are

absolutely essential in an inquiry like this.

In this transaction, one of the alleged masterminds of the ongoing price fixing and market allocation schemes is Rajiv Malik, Mylan's current president, who is a named defendant in one of the state lawsuits.¹⁷ A second Mylan executive, Vice President of Sales James Nesta, is also a named defendant in one of the cases.¹⁸ The merging parties have publicly announced that Mr. Malik will retain the top executive role in the expanded generic drug empire, if the transaction closes.¹⁹ As president, he will be in charge of the merged entity's sales and marketing operations.²⁰ He will also serve on the merged company's board.²¹

Mr. Malik's role in the alleged price fixing scheme is significant. He allegedly conceived and directed many of the schemes.²² In one example, he is alleged to have agreed to cede market share in one market to a specific competitor in exchange for an agreement from that competitor to allow Mylan to enter a different market without competition.²³

Despite the alarm bells raised by Mr. Malik's planned role in the merged firm, the Commission's analysis does not discuss his involvement in the ongoing price fixing and market allocation allegations in the industry or his plans for the company. In my view, the Commission owes the public a clear explanation about Mr. Malik's role. In matters like this, it is critical that the Commission rely on a wide range of data and evidence, including testimony from key executives.²⁴

Conclusion

I am concerned that executives in the pharmaceutical industry routinely propose anticompetitive mergers without any fear that their transactions will ever be blocked. In my view, the status quo approach of seeking settlements through divestitures of

individual products is myopic and misses some of the fundamental elements of how firms compete in this industry. I am also not aware of any instance where the Commission publicly relied on the testimony under oath of a pharmaceutical executive in approving a pharmaceutical divestiture settlement.

Unless we change our approach, anticompetitive mergers in the pharmaceutical industry will continue unabated, and we will all suffer for it. I appreciate the diligence of our staff, who work at the direction of the Commission. Unfortunately, the directives of the Commission are deeply flawed, favoring routine over rigor. For all these reasons, I respectfully dissent.

[FR Doc. 2020-25021 Filed 11-10-20; 8:45 am]

BILLING CODE 6750-01-P

FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Proposed Collection; Comment Request; Extension

AGENCY: Federal Trade Commission.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 ("PRA"), the Federal Trade Commission ("FTC" or "Commission") is seeking public comment on its proposal to extend for an additional three years the Office of Management and Budget clearance for information collection requirements in its rule governing Care Labeling of Textile Wearing Apparel and Certain Piece Goods As Amended ("Care Labeling Rule"). The current clearance expires on May 31, 2021.

DATES: Comments must be filed by January 11, 2021.

ADDRESSES: Interested parties may file a comment online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write "Care Labeling Rule: FTC File No. P072108," 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 J), 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 J), Washington, DC 20024.

¹⁴ Beth Snyder Bulik, Mylan and Pfizer roll out tricolor branding for their giant generics combo, Viatrix, FIERCEPHARMA (July 9, 2020, 10:06 a.m.), <https://www.fiercepharma.com/marketing/mylan-and-pfizer-debuts-new-viatrix-generics-merged-brand-unveils-tri-color-logo-for>.

¹⁵ See, e.g., Analysis Of Agreement Containing Consent Orders To Aid Public Comment, *In the Matter of Pfizer Inc./Mylan N.V.*, File No. 191 0182 (Oct. 29, 2020).

¹⁶ See Statement of Commissioner Rohit Chopra *In the Matter of AbbVie, Inc./Allergan plc*, File No. 191 0169, 2, 19 (May 5, 2020), https://www.ftc.gov/system/files/documents/public_statements/1574583/191_0169_dissenting_statement_of_commissioner_rohit_chopra_in_the_matter_of_abbvie-allergan_redacted.pdf; see also Statement of Commissioner Rohit Chopra *In the Matter of Social Finance, Inc.*, File No. 162 3917 (Oct. 29, 2018), https://www.ftc.gov/system/files/documents/public_statements/1418711/162_3197_statement_of_commissioner_chopra_on_sofi_10-29-18.pdf.

¹⁷ Compl., *In re Generic Pharms. Pricing Antitrust Litig.* ¶ 34.

¹⁸ See Compl., *Connecticut v. Teva Pharms. USA, Inc.* ¶ 50.

¹⁹ See Pfizer Press Release, *supra* note 1.

²⁰ Compl., *In re Generic Pharms. Pricing Antitrust Litig.* ¶ 34.

²¹ See Pfizer Press Release, *supra* note 1.

²² Compl., *In re Generic Pharms. Pricing Antitrust Litig.* ¶ 10.

²³ *Id.* ¶ 188.

²⁴ This is particularly important in industries where the Commission cannot rely on evidence and testimony from customers who act as middlemen. We know from the allegations in the state attorneys general lawsuits that drug wholesalers and large retailers allegedly benefit when generic drug prices are higher. These firms have contractual provisions allowing for potentially greater compensation when prices are higher. *Id.* ¶¶ 71-75.