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]

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[14] Beth Snyder Bulik, Mylan and Pfizer roll out tricolor branding for their giant generics combo, Viatris, FIERCEPHARMA (July 9, 2020, 10:06 a.m.), *https://www.fiercepharma.com/marketing/mylan-and-pfizer-debuts-new-viatris-generics-merged-brandunveils-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.

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.

FOR FURTHER INFORMATION CONTACT: Hampton Newsome, Attorney, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Mail Code CC–9528, 600 Pennsylvania Ave. NW, Washington, DC 20580, (202) 326–2889.

SUPPLEMENTARY INFORMATION: *Title of Collection:* Care Labeling of Textile Wearing Apparel and Certain Piece Goods As Amended, 16 CFR 423.

OMB Control Number: 3084–0103.

Type of Review: Extension of currently approved collection.

Affected Public: Private Sector: Businesses and other for-profit entities.

Estimated Annual Burden Hours: 27,489,476 hours.

Estimated Annual Labor Costs: $187,184,518.

Abstract: The Care Labeling Rule requires manufacturers and importers of textile wearing apparel and certain piece goods to attach labels to their products disclosing the care needed for the ordinary use of the product. The Rule also requires manufacturers or importers to possess a reasonable basis for care instructions, and allows the use of approved care symbols in lieu of words to disclose those instructions.

Burden Statement: Staff estimates that approximately 10,744 manufacturers or importers of textile apparel, producing about 18.4 billion textile garments annually, are subject to the Rule's disclosure requirements. Staff estimates the burden of determining care instructions to be 100 hours each year per firm, for a cumulative total of 1,074,400 hours. Staff further estimates that the burden of drafting and providing labels is 80 hours each year per firm, for a total of 859,520 hours. Staff believes that the process of attaching labels is fully automated and integrated into other production steps for about 50 percent (approximately, 9.2 billion) of the approximately 18.4 billion garments that are required to have care instructions on permanent labels. For the remaining 9.2 billion items, the process is semi-automated and requires an average of approximately ten seconds per item, for a total of 25,555,556 hours per year. Thus, the total estimated annual burden for all firms is 27,489,476 hours.

The chart below summarizes the total estimated costs.

Task	Hourly rate [1]	Burden hours	Labor cost
Determine care instructions	$29.00	1,074,400	$31,157,600
Draft and order labels	18.00	859,520	15,471,360
Attach labels	[2] 5.50	25,555,556	140,555,558
Total	.....	.....	187,184,518

Staff believes that there are no current start-up costs or other capital costs associated with the Care Labeling Rule. Because the labeling of textile products has been an integral part of the manufacturing process for decades, manufacturers have in place the capital equipment necessary to comply with the Rule's labeling requirements. Based on knowledge of the industry, staff believes that much of the information required by the Rule would be included on the product label even absent those requirements.

Request for Comment: Pursuant to Section 3506(c)(2)(A) of the PRA, the FTC invites comments on: (1) Whether the disclosure requirements are necessary, including whether the information will be practically useful; (2) the accuracy of our burden estimates, including whether the methodology and assumptions used are valid; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of providing the required information to consumers. All comments should be filed as prescribed in the **ADDRESSES** section above, and must be received on or before January 11, 2021.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before January 11, 2021. Write ''Care Labeling Rule: FTC File No. P072108'' on your comment. 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. To make sure that the Commission considers your online comment, you must file it through the *https://www.regulations.gov* website by following the instructions on the web-based form provided. Your comment, including your name and your state—will be placed on the public record of this proceeding, including the *https://www.regulations.gov* website.

If you file your comment on paper, write ''Care Labeling Rule: FTC File No. P072108'' 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 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, Washington, DC 20024. If possible, please submit your paper comment to the Commission by courier or overnight service.

Because your comment will be placed on the public record, 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

[1] All hourly rates except for ''Attach labels'' are rounded to the nearest dollar and drawn from the U.S. Dep't of Labor, Bureau of Labor Statistics, ''Table 1. National employment and wage data from the Occupational Employment Statistics survey by occupation, May 2019,'' at *https://www.bls.gov/news.release/ocwage.t01.htm.* The hourly labor cost estimate for determining care instructions is based on mean hourly rates for Office and Administrative Support Supervisors and the estimate for drafting and ordering labels is based on mean hourly rates for Information and Record Clerks.

[2] For imported products, the labels generally are attached in the country where the products are manufactured. According to information compiled by an industry trade association using data from the U.S. Department of Commerce, International Trade Administration and the U.S. Census Bureau, approximately 97.5% of apparel purchased in the United States is imported. With the remaining 2.5% attributable to U.S. production at an approximate domestic hourly wage of $12 to attach labels (derived from the U.S. Dep't of Labor, Bureau of Labor Statistics, ''Occupational Employment Statistics—May 2019'' which is cited in footnote 1), staff has calculated a weighted average hourly wage of $5.50 per hour attributable to U.S. and foreign labor combined. Wages in major textile exporting countries, factored into the above hourly wage estimate, were based on data from the U.S. Department of Labor, Bureau of Labor Statistics, available at: *http://www.bls.gov/fls/#compensation.*

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.

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 11, 2021. 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*.

Josephine Liu,

Assistant General Counsel for Legal Counsel.

[FR Doc. 2020–25035 Filed 11–10–20; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Malnutrition in Hospitalized Adults

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for supplemental evidence and data submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *Malnutrition in Hospitalized Adults,* which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before December 14, 2020.

ADDRESSES:

Email submissions: epc@ahrq.hhs.gov.

Print submissions:

Mailing Address: Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E53A, Rockville, MD 20857.

Shipping Address (FedEx, UPS, etc.): Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E77D, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Jenae Benns, Telephone: 301–427–1496 or Email: *epc@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for Malnutrition in Hospitalized Adults. AHRQ is conducting this systematic review pursuant to Section 902 of the Public Health Service Act, 42 U.S.C. 299a.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (*e.g.,* details of studies conducted). We are looking for studies that report on *Malnutrition in Hospitalized Adults,* including those that describe adverse events. The entire research protocol is available online at: *https://effectivehealthcare.ahrq.gov/products/malnutrition-hospitalized-adults/protocol*.

This is to notify the public that the EPC Program would find the following information on *Malnutrition in Hospitalized Adults* helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*
- *For completed studies that do not have results on ClinicalTrials.gov,* a summary, including the following elements: Study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.
- *A list of ongoing studies that your organization has sponsored for this indication.* In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: *https://www.effectivehealthcare.ahrq.gov/email-updates.*

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

Key Questions (KQs)

Key Question 1. What is the association between malnutrition and clinical outcomes among hospitalized patients?

a. How do outcomes vary depending on measures or tools used to detect malnutrition?

b. Are patient-related risk factors, such as increased age or certain pre-existing health conditions, associated with poorer clinical outcomes?