State of California
Office of the Attorney General
XAVIER BECERRA
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June 11, 2020

Federal Trade Commission
Acting Secretary April Tabor
Office of the Secretary
600 Pennsylvania Avenue, NW
Suite CC-5610 (Annex D)
Washington, D.C. 20580

RE: AbbVie and Allergan; File No. 191 0169

Dear Acting Secretary Tabor:

As the chief law enforcer of the State of California, I have vigorously challenged anticompetitive conduct and mergers in the pharmaceutical industry. Further, California has a long history of working with the FTC on these matters to ensure fair competition. For this reason, I am urging the FTC to conduct a study on the effectiveness of divestitures in addressing the anticompetitive harms of pharmaceutical mergers, which would benefit antitrust enforcement.

The FTC's significant expertise in the complex pharmaceutical marketplace is an invaluable bulwark against anticompetitive harms from mergers in that space. In the current Covid-19 environment, competition in our pharmaceutical markets has a new prominence, as the rapid rise of prescription drug prices over the last decade poses an increasing challenge to governments, employers and consumers to pay for drugs while facing economic uncertainty. At the same time, a growing chorus of lawmakers, scholars, and public health advocates attribute responsibility for the drug price increases, in part, to mergers and consolidation in the industry.[1]

[1] *See e.g.,* Thomas Sullivan, *Bipartisan Senators [Susan Collins and Claire McCaskill] Release Committee Report on Drug Pricing Investigation,* May 4, 2018, available at https://www.policymed.com/2018/01/bipartisan-senators-release-committee-report-on-drug-pricing-investigation.html; U.S. Senate Judiciary Subcommittee on Antitrust, Competition Policy and Consumer Rights, Ranking Member Senator Amy Klobuchar, joined by Senators Richard Blumenthal, Cory Booker, Mazie K. Hirono, Kamala D. Harris, Elizabeth Warren, Tammy Baldwin, Tina Smith, and Bernie Sanders, Letter to Fed. Trade Comm'n, Sept. 17, 2019, available at https://www.klobuchar.senate.gov/public/index.cfm/2019/9/klobuchar-leads-letter-warning-that-pharmaceutical-mergers-may-threaten-drug-competition-increase-prices-and-reduce-patient-access-to-essential-medications; U.S. Government Accountability Office, *Drug*

It is widely recognized that pharmaceutical mergers that burden the public in the form of higher prices, fewer drug choices, drug shortages, or other anticompetitive effects, must not be allowed. This raises the question of whether, and to what extent, mergers that are approved subject to divestitures restore the lost competition from those mergers.

I. The Key Issues in FTC Approval of the AbbVie and Allergan Merger

The FTC conditioned the merger approval of AbbVie and Allergan on the divestiture of three Allergan drugs: Brazikumab to AstraZeneca; and Viokace and ZenPep to Nestle. Before merging to become the world's fourth largest pharmaceutical company, AbbVie and Allergan competed with one another in various therapeutic categories and even in directly competing drugs. The FTC's standard process in pharmaceutical mergers is to identify overlaps where the merging parties' drugs are potential direct substitutes for one another, and then to require divestiture of one product for each overlap as the condition for merger approval.[2] Putting aside the adequacy of this approach from the standpoint of consumer protection or compliance with the Clayton Act's prohibition of mergers and acquisitions that lessen competition or tend to create a monopoly,[3] the

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Industry Profits, Research and Development Spending, and Merger and Acquisition Deals, November 2017, GAO-18-40, available at https://www.gao.gov/assets/690/688472.pdf; Colleen Cunningham, Florian Ederer, and Song Ma, *Killer Acquisitions*, Apr. 19, 2020, available at SSRN: https://ssrn.com/abstract=3241707 or http://dx.doi.org/10.2139/ssrn.3241707; Justus Haucap and Joel Stiebale, *How Mergers Affect Innovation: Theory and Evidence from the Pharmaceutical Industry*, Discussion Paper No. 218, University of Düsseldorf, Düsseldorf Institute for Competition Economics (DICE), Apr. 2016 (hereinafter "DICE Discussion Paper No. 218"), available at https://www.dice.hhu.de/fileadmin/redaktion/Fakultaeten/Wirtschaftswissenschaftliche_Fakultaet/DICE/Discussion_Paper/218_Haucap_Stiebale.pdf; National Nurses United, *Marching Toward Monopoly – Mergers and Acquisitions in the Pharmaceutical Industry*, Institute for Health and Socio-Economic Policy, Oct. 17, 2016, available at https://www.nationalnursesunited.org/sites/default/files/nnu/files/pdf/research/MarchingTowardMonopoly-PharmaMA10-17-16.pdf.

[2] Fed. Trade Comm'n, *The FTC's Merger Remedies 2006-2012: A Report of the Bureaus of Competition and Economics*, pp. 9-10, Jan. 2017 (hereinafter "FTC 2017 Study"), available at https://www.ftc.gov/system/files/documents/reports/ftcs-merger-remedies-2006-2012-report-bureaus-competition-economics/p143100_ftc_merger_remedies_2006-2012.pdf (The FTC "has developed significant expertise in the pharmaceutical industry and follows a standard approach for evaluating these mergers and designing relief.").

[3] *See* Dissenting Statement of Commissioner Rebecca Kelly Slaughter, *In the Matter of Bristol-Myers Squibb and Celgene Commission*, FTC File No. 191-0061 (Nov. 15, 2019) ("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, but I am concerned that it does not fully capture all of the competitive consequences of these transactions

FTC has developed a commendable body of best practices when invoking divestitures. However, the FTC did not follow two of those best practices in approving the AbbVie and Allergan merger. First, the FTC's rule that divestiture of on-market products is preferred over divestiture of pipeline products was disregarded by allowing the divestiture of Allergan's pipeline Brazikumab rather than AbbVie's on-market Skyrizi.[4] This was done despite the FTC's acknowledgment that divestitures of pipeline products have a high rate of failure.[5] Second, despite the FTC's well-

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. . . . 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.") (citations omitted); Robert H. Lande, *A Traditional and Textualist Analysis of the Goals of Antitrust: Efficiency, Preventing Theft from Consumers, and Consumer Choice*, 81 Fordham L. Rev. 2349, 2381 (2013) ("A textualist or 'plain meaning' analysis of [Clayton Act] section 7 straightforwardly leads to the conclusion that if a merger 'may be substantially' likely to lead to a monopoly, or to 'tend to lessen competition,' the merger should be blocked . . . . The statute contains no exception for a merger likely to create an efficient monopoly, so none should be read into section 7 . . . . Nor should an exception be implied for the second part of the statute: if competition is likely to be impaired enough that prices are likely to rise, the merger should be prohibited."); DICE Discussion Paper No. 218, at p. 1 ("Our main result is that after a merger, patenting and R&D of the merged entity and its non-merging rivals declines substantially.").

[4] Both AbbVie and Allergan own IL-23 inhibitor drugs, Skyrizi and Brazikumab. AbbVie's Skyrizi is an on-market product, which had an exceptional launch in 2019, and is estimated to exceed $1.2 billion in annual sales in 2020. Some contend that the launch and market success is a result of AbbVie's use of rebates from Humira to force favorable formulary placement of Skyrizi. (*See e.g.*, *AbbVie Expects 2020 Skyrizi Revenue Of ~$1.2 Bln and Rinvoq Revenue of ~$500 Mln*, Reuters, Feb. 7, 2020, available at https://www.reuters.com/article/brief-abbvie-expects-2020-skyrizi-revenu/brief-abbvie-expects-2020-skyrizi-revenue-of-1-2-bln-and-rinvoq-revenue-of-500-mln-idUSFWN2A70XX); Angus Liu, *AbbVie Pads Humira Follow-up Skyrizi's Blockbuster Potential with Positive 2-Year Data*, FiercePharma June 11, 2019, available at https://www.fiercepharma.com/marketing/abbvie-pads-skyrizi-s-blockbuster-potential-positive-2-year-data.) Meanwhile, Allergan's Brazikumab has not yet completed clinical trials, with no clear launch date even for its phase three trials. (AstraZeneca Press Release, *AstraZeneca to Recover the Global Rights to Brazikumab (MEDI2070) from Allergan*, Jan. 27, 2020, available at https://www.astrazeneca.com/media-centre/press-releases/2020/astrazeneca-to-recover-the-global-rights-to-brazikumab-medi2070-from-allergan-27012020.html.)

[5] Bruce Hoffman, Dir., Bureau of Competition, Fed. Trade Comm'n, *It Only Takes Two to Tango: Reflections on Six Months at the FTC*, pp. 6-7, Feb. 2, 2018, available at https://www.ftc.gov/system/files/documents/public_statements/1318363/hoffman_gcr_live_feb_2018_final.pdf ("Based on a history of problems with divestitures in this area, our view is that divesting ongoing manufacturing rather than products that haven't yet come to market places the greater risk of failure on the merging firms, rather than the American public. Since, in the context of merger remedies, we are considering divestitures or other remedies as a fix to an otherwise anticompetitive merger, it is entirely proper that the risk of failure be placed on the parties to the merger.").

established principle that the divested drug product should go to an experienced competitor ready to compete in the pharmaceutical market, ZenPep was divested to Nestlé Health, maker of chocolates, bottled water, and baby food, rather than to an experienced pharmaceutical company.[6] But even when followed, the FTC's best practices must be supported by rigorous research and evidence-based analysis.

II. The Need for an Empirical Study on Pharmaceutical Divestitures

Given that the FTC's standard remedy for anticompetitive effects of a pharmaceutical merger is ordering divestitures of specific drugs, as it did in approving the AbbVie and Allergan merger, we believe there is an urgent need to rigorously study the effectiveness of divestitures to restore the loss of competitive intensity that result from the mergers.[7] Existing FTC studies provide a starting point from which to understand the effectiveness of pharmaceutical divestitures. For example, studies show that even with an extremely broad and generous definition of "success," divestitures have at least a 35 percent chance of failure,[8] while other studies suggest more broadly

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[6] AbbVie and Allergan own Creon and ZenPep respectively, which are two competing drugs in the Pancreatic Enzyme Replacement Therapy (PERT) market that together comprise more than 95 percent of that market. Though AbbVie's Creon has the dominant share, Allergan's ZenPep, through effective marketing, had seized more than 20 percent of the market and was expanding its market share while the other competitors in the PERT market all have nominal market share of two percent or less. (Beth Snyder Bulik, *Allergan's New Spokescharacter Breaks Down Enzyme Importance in ZenPep Campaign*, FiercePharma, Apr. 2, 2018, available at https://www.fiercepharma.com/marketing/allergan-s-new-spokescharacter-breaks-down-enzyme-importance-zenpep-campaign.) Allergan's ZenPep drug was divested to Nestle, a multinational food and beverage corporation known for chocolate and bottled water. Nestle appears poorly positioned to step into Allergan's place with key customers when the corporation primarily sells to consumers and retail stores and has minimal, if any, existing relationships with health plans and healthcare providers. Nestle's previous attempt to enter the pharmaceutical market during the past five years resulted in a complete sale of their pharmaceutical division to a private equity firm, accompanied by declarations from management that Nestle would "sharpen its focus on food, beverage and nutritional health products" and its pharmaceutical division's products "lie increasingly outside the Group's strategic scope." (Angus Liu, *Nestlé's Pharma Experiment Nears an End with $10B Skin Health Sale Talks*, FiercePharma, May 16, 2019, available at https://www.fiercepharma.com/pharma/nestle-s-pharma-ambition-nears-end-as-it-could-sell-skin-health-unit-for-10b.)

[7] *FTC v. Sysco Corp.*, 113 F. Supp. 3d 1, 72 (D.D.C. 2015) ("Restoring competition requires replacing the *competitive intensity* lost as a result of a merger…" (italics original) (quoting 2004 U.S. Department of Justice's *Policy Guide to Merger Remedies*).

[8] The FTC reports that approximately 20 percent of divestitures in horizontal mergers fail to return competition to the pre-merger state, and another 15 percent are only qualified successes, with consumers experiencing multiple years of sub-normal competition prior to the market returning to pre-merger levels. (FTC 2017 Study, at pp. 18, 15 (defining "qualified success").)

that the use of divestitures is not arresting price increases post-merger.[9] These troubling findings call for deeper evaluation in a study that would help guide and improve antitrust regulators' merger analysis amid the routine use of pharmaceutical divestitures as a remedy.

III. Current Gaps and Vulnerabilities in Merger Analysis

The FTC's studies to date highlight a need for more comprehensive empirical analysis on pharmaceutical divestitures, which would address gaps and vulnerabilities in standard merger analysis, and potentially produce more favorable outcomes. There are three main issues a study should address in order to strengthen the merger analysis and review process of antitrust regulators.

First, existing FTC institutional studies of pharmaceutical divestitures lack the drug sales data that is critical to make a meaningful assessment of whether a drug divestiture was successful in maintaining the competitive intensity of the pre-merger market in that drug.[10] That data would allow the FTC to determine whether the divested drug in the hands of a divestiture buyer maintained or even grew the pre-merger market share of the divesting party. In the absence of that vital data, the FTC is unable to determine if the remedy is truly successful in maintaining pre-merger competition. Instead, existing FTC studies have simply defined a successful divestiture as one that was consummated and resulted in at least a single sale post-merger, or in the case of a pipeline drug, simply determined if the paperwork for the drug purchase was transferred:

> The divestiture of products marketed by both parties to the merger at the time of the divestiture—on-market products—was considered successful if the buyer sold the product in the market post-divestiture . . . . For each divestiture relating to

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Moreover, when the divestiture involves a selected package of assets, as is the case with an individual drug divestiture, there is a much higher potential for failure of the remedy than associated with divestiture of an ongoing business. (*Id.* at pp. 23-24.) The FTC found that of 28 orders that required the divestiture of 33 packages of selected assets to 32 different buyers, only nine out of the 32 buyers succeeded with few, if any, difficulties, even under the FTC's broad definition of success. (*Id.* at p. 23.)

[9] Professor John Kwoka "found that mergers subject to divestitures resulted in price increases of about 5.6 percent, little different from mergers that were outright cleared." (John E. Kwoka, Jr., *Reviving Merger Control: A Comprehensive Plan for Reforming Policy and Practice*, Oct. 9, 2018, at p. 47, available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3332641.) Professor Kwoka reviewed retrospective studies on whether FTC's divestiture remedies are effective and "found that a significant fraction of the FTC's divestiture remedies has failed to preserve competition." (*Id.*)

[10] In the FTC 1999 Study, the FTC conceded it was largely unable to get sales data or market information on a voluntary basis from the parties to assess whether pre-merger competition was maintained. (FTC 2017 Study, at p. 10 (describing FTC 1999 Study).) The FTC 2017 study did not use sales data to evaluate pharmaceutical divestitures. (*Id.* at pp. 4-5, n.12; and 30.)

> pipeline products, . . . the divestiture was considered successful if all assets relating to those products were successfully transferred.[11]

Econometric analysis of the intensity of competition by the divestiture buyer is necessary to ensure a robust and meaningful evaluation of the likelihood of success of a divestiture. Clearly, where the divestiture party is able to achieve only a tiny fraction of the pre-merger sales of the divesting party, the divestiture has not succeeded in maintaining the pre-merger competitive intensity. Additionally, many divestitures have a transition period in which the divesting party provides contract and product support for a set timeframe. Current FTC studies fail to account for sales levels of the divestiture buyer after that transition period when post-merger competition occurs unaided by the contractually obligated support from the divesting party, which would provide a more accurate view of the divestiture's success. With respect to pipeline drugs, the study should determine whether the divested pipeline drug was actually developed and successfully launched and marketed, something that the last FTC remedy review did not assess.[12] In the absence of this data, the FTC cannot provide the public the assurance that the divestiture remedy is actually effective in addressing the anticompetitive effects of the merger.

Second, the study should evaluate the value in and need for a more active role by the FTC in identifying, selecting and approving only those divestiture buyers who are highly likely to replicate the competitive capabilities of the merging parties. The FTC's 1999 divestiture study revealed the FTC's finding that "Staff also learned that respondents often recommended marginally acceptable buyers and, on some occasions, engaged in post-divestiture strategic behavior aimed at minimizing the competitive impact of the buyer's entry into the market."[13] The

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[11] FTC 2017 Study, at p. 30.

[12] *Id.*; Chris Sagers, *The Limits of Divestiture as an Antitrust Remedy*, The New York Times, Feb. 14, 2017, available at https://www.nytimes.com/2017/02/14/business/dealbook/the-limits-of-divestiture-as-an-antitrust-remedy.html.

[13] FTC 2017 Study, at p. 10 (describing FTC 1999 Divestiture Study). The reforms the FTC adopted to address the problem were the imposition of shorter divestiture periods, requiring purchase of a package of assets, requiring the appointment of a monitor and requiring detailed business plans. (*Id*. at pp. 10-11.) None of these reforms, however, blunted the ability of the merging parties to select the least capable competitor for FTC review. While the FTC acknowledged this as an ongoing concern (*id.* at pp. 5, 21), it also noted that the Commission intended to examine whether the buyer had adequate funding sources to ensure success. (*Id.*) The 2017 FTC Study found that respondents in most cases proposed buyers likely to satisfy the Commission's criteria of adequate funding for viable competitors. However, in the case of pharmaceutical markets, the success of a divestiture requires more than financial or cash reserves, as access to drug formularies, relationships with targeted health care officials, and industry know-how are such that even Amazon's ability to break into the sector has been questioned. (*See* Kellie Ell, *Barriers to Entering the Pharmaceutical Industry are Too High Even for Amazon*, CNBC, Apr. 23, 2018, available at https://www.cnbc.com/2018/04/23/pharmaceuticals-industry-barriers-are-too-high-for-amazon-investor.html.)

FTC's 2017 remedy study acknowledged that this problem was an ongoing concern,[14] and the selection of Nestle, an inexperienced pharmaceutical company with a past history of strategic arbitrage of drug products and companies, reinforces the need for a systematic study of measures that might guard against the parties' opportunistic selection of weaker divestiture buyers over stronger divestiture buyers.

Third, the study should evaluate ancillary relief related to the significant role of pharmacy benefit managers (PBMs) in managing or even blocking market access to pharmaceuticals, in order to assure the pharmaceutical divestiture's ability to succeed. PBMs create tiered formularies based on rebates offered by drug manufacturers in order to obtain a higher placement or exclusive placement in a drug formulary. Academics and others have voiced concerns that this tiering process is at times manipulated by the pharmaceutical corporations to foreclose competition and raise prices on consumers.[15] For example, drug manufacturers' use of rebate walls and exclusive contracting on specific drugs creates barriers to entry and expansion. This practice can preclude the success of a drug divestiture no matter how it is structured, and increases the failure rate for riskier divestitures. The FTC has often used ancillary remedies in non-pharmaceutical mergers by restricting the contracting or other conduct of the merged parties to ensure a divestiture succeeds.[16] By contrast, the FTC rarely devises ancillary remedies for divestitures in pharmaceutical mergers. Such a remedy could be essential for the success of drug divestitures like Brazikumab, which is a pipeline drug that, once and if it gets to market, would need to compete against AbbVie's incumbent drug for PBM formulary access. The FTC should include in its study of pharmaceutical mergers whether ancillary remedies can aid in the success of divestitures, particularly for pipeline products or in markets where entry is difficult because of market structure or prevailing contracting and formulary practices.

We sincerely appreciate your consideration of our comments.

Sincerely,

XAVIER BECERRA
Attorney General

[14] 2017 FTC Study, at pp. 5, 21.
[15] Feldman, Robin, *The Devil in the Tiers*, UC Hastings Research Paper No. 379, Nov. 19, 2019, available at https://ssrn.com/abstract=3490065 or http://dx.doi.org/10.2139/ssrn.3490065.
[16] *See e.g., In the Matter of Simon Property Group, Inc.*, FTC File No. 101-0061 (Jan. 13, 2011); *In the Matter of CoStar Group, Inc., Lonestar Acquisition Sub, Inc., and LoopNet, Inc.*, FTC File No. 111-0172 (Aug. 29, 2012).