



June 11, 2020

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

Re: AbbVie and Allergan; File No. 191 0169

Dear Secretary:

The undersigned unions, consumer groups and public interest organizations are concerned about the high cost of prescription drugs, escalating healthcare costs, and lack of meaningful patient choice.¹ These organizations work to rein in excessive drug prices and are concerned that the proposed consent order that allowed AbbVie Inc. (“AbbVie”) to close its acquisition of Allergan plc (“Allergan”) will ultimately harm consumers and not restore competition.² We believe the Federal Trade Commission’s proposed consent will fail to fully restore competition. These comments make five points.

First, the Federal Trade Commission (“FTC”) failed to address rebate walls which is an exclusionary practice AbbVie will use to further forestall competition in critical immunology markets and vanquish AstraZeneca’s efforts to effectively restore competition. Both Alex Azar, Secretary of Health & Human Services, and former Food & Drug Administration Commissioner Scott Gottlieb have raised substantial concerns over the use of rebate walls. AbbVie currently uses these practices to stifle competition from important rivals ultimately leading to higher prices

¹ The groups are Families USA, American Federation of State, County, and Municipal Employees, American Federation of Teachers, Alliance for Retired Americans, American Family Voices, Consumer Action, Coalition to Protect Patient Choice, Doctors for America, End AIDS Now, Services Employees International Union, Social Security Works, Treatment Action Group, UNITEHERE, and U.S. PIRG Education Fund.

² We submitted three separate letters to the Commission raising antitrust concerns regarding the transaction and questioning whether the remedies proposed would restore competition.

and less innovation. To fail to address rebate walls will enable AbbVie to undermine the proposed consent order and is fundamentally to ignore the elephant in the room.

Second, the divestiture of a pipeline drug is a risky alternative, one that places the risks of failure – less competition leading to higher prices and less choice – clearly on the shoulders of the hundreds of thousands of patients who need these vital drugs. Significantly, in 2018, the former Director of the Bureau of Competition, Bruce Hoffman, noted that pipeline drug divestitures face a “startlingly high” rate of failure.³ Further, the Commission cites to no evidence that pipeline divestitures have ever resulted in any product launches or commercial success. While the 2017 FTC Merger Remedy Study noted that pipeline divestitures have been 100% successful, it narrowly defined success as to whether the intellectual property assets were successfully transferred to the divestiture buyer.⁴ We do not believe that is the proper way to measure success. For a pipeline divestiture to fully restore competition, the divested assets should result in the entry and commercial success of a new product. This is why a divestiture of a pipeline product should be disfavored, as suggested by Hoffman’s remarks at a 2018 conference, since such a divestiture places “a greater risk of failure . . . on the American public” and loss of competition on consumers, inconsistent with the law and sound antitrust policy.⁵

Third, Nestle and AstraZeneca are inappropriate divestiture buyers making it less likely that competition will be restored.

Fourth, to the extent that the Commission requires divestitures of pipeline assets, it should not simply require a transfer of the assets; rather, it should require additional conditions to support a divestiture buyer’s ability to market the product.

Finally, we strongly agree with Commissioner Chopra’s sound proposals for reform of the review of pharmaceutical mergers. The Commission expends tremendous resources on pharmaceutical merger review, but we respectfully ask, “what concrete evidence is there that the Commission’s consent orders actually restore competition?” There is no evidence that any divestiture has actually succeeded in a firm successfully restoring competition, nor does the Commission ask the tough questions when it evaluates divestitures. Nor has the Commission sued to block a pharmaceutical merger. The lack of litigation or concrete results from enforcement raise serious questions.

Nine U.S. Senators raised significant concerns about this acquisition, concerns not addressed in the proposed consent order. This proposed consent order raises very serious questions and we respectfully request that the Commission provide a substantive response to these concerns, the concerns of the Senators, and the other public comments.

³ *It Only Takes Two to Tango: Reflections on Six Months at the FTC*, Remarks at GCR Live 7th Annual Antitrust Law Leaders Forum, D. Bruce Hoffman, Acting Director, Bureau of Competition, U.S. Federal Trade Commission, February 2, 2018.

⁴ FTC’s Merger Remedies 2006-2012: A Report of the Bureaus of Competition and Economics, January 2017, at 31 (“FTC Remedy 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.

⁵ *It Only Takes Two to Tango: Reflections on Six Months at the FTC*.

I. The Commission Should Have Imposed Conditions to Prohibit Rebate Walls Because the Merger Increased the Merged Firm’s Incentive and Ability to Use Them to Foreclose Competition

The FTC’s analytical approach to evaluating pharmaceutical mergers can sometimes fail to address wide-ranging issues of competitive harm. The Supreme Court has held that “the Clayton Act is . . . concerned with mergers that threaten to reduce the number or quality of choices available to consumers by increasing the merging parties’ incentive or ability to engage in conduct that would foreclose competition.”⁶ AbbVie is clearly an antitrust recidivist with countless government and private antitrust suits filed challenging a panoply of anticompetitive practices. Not only have AbbVie and Allergan engaged in a laundry list of egregious anticompetitive practices that have resulted in higher prices and less consumer choice, but the merger threatens to reduce choices further by increasing the merged firm’s incentive and ability to foreclose competition.

AbbVie has engaged in a number of anticompetitive practices to protect its blockbuster drug, Humira, including the use of a contracting practice whereby it bundles rebates across its ten indications to payors on the condition that they favor Humira and its new drugs, Skyrizi and Rinvoq, and keep rival drugs off of the preferred position on drug formularies.⁷ We are concerned that the merged firm could strengthen those rebate walls and use the same strategy to prop up Allergan’s migraine assets, Ubrelvy and Atogepant, to preferred positions on payors’ drug formularies.

Though Allergan already had its blockbuster, Botox, which is approved for the treatment of chronic migraine, Allergan could not use Botox to prop up Ubrelvy and Atogepant through rebate walls because Botox is reimbursed through the medical benefit channel not the pharmacy benefit channel. Because these migraine assets are reimbursed through the pharmacy benefit channel just like AbbVie’s autoimmune portfolio, the merged firm will have an increased incentive and ability to leverage Humira’s and/or Skyrizi’s and Rinvoq’s prescription volume to benefit Ubrelvy and Atogepant in the future.⁸

For example, AbbVie could offer a rebate on Humira’s prescription volume on the condition that Allergan’s Ubrelvy is given preferred positions on payors’ drug formularies for the treatment of acute migraines over its rivals including Biohaven’s Nurtec and Lilly’s Reyvow. AbbVie could also use the same strategy for Allergan’s Atogepant, which is an oral medication that is completing final clinical trials. It is expected to launch sometime later in 2021 or early 2022. AbbVie could offer a rebate on Humira’s or Skyrizi’s prescription volume on the

⁶ See *Brown Shoe Co. v. United States*, 370 U.S. 294, 317 (1962) (noting that the Clayton Act intended to make illegal “not only [] mergers between actual competitors, but also [] vertical and conglomerate mergers whose effect may tend to lessen competition in any line of commerce in any section of the country.”); *FTC v. Procter & Gamble Co.*, 386 U.S. 568, 577 (1967) (“All mergers are within the reach of § 7, and all must be tested by the same standard, whether they are classified as horizontal, vertical, conglomerate.”).

⁷ ZITTER HEALTH INSIGHTS, THE MANAGED CARE MESSAGE MONITOR: PSORIASIS DATA SPOTLIGHT (Mar. 2019), at 7. Prior to Skyrizi’s launch, a payor, SelectHealth, told Zitter: “In terms of Humira, there would be increased rebates for . . . place-holding for the future AbbVie product launches.”

⁸ John Wilkerson, Inside Health Policy, May 11, 2020 available at <https://insidehealthpolicy.com/inside-drug-pricing-daily-news/consumers-abbvieallergan-merger-hurts-migraine-drug-competition>.

condition that Atogepant, when it is finally approved, is ensured a preferred position on payors' drug formularies as a prevention medication for migraine over rivals already in the market including Amgen's Aimovig; Lilly's Emgality; and Teva's Ajovy.

Given AbbVie's past history of engaging in practices that foreclose competition and the fact that the merger increases AbbVie's ability and incentive to engage in rebate wall strategies to inhibit the ability of rival drugs to get on a preferred position on drug formularies, the Commission should have prohibited AbbVie from implementing rebate walls. We continue to urge the Commission to investigate these practices, because of the substantial harm to thousands of vulnerable consumers.

II. Merger Remedies Involving the Divestiture of Pipeline Assets Increasingly Fail to Restore Competition

The proposed consent is unlikely to resolve the competitive concerns raised in the Commission's Complaint regarding the overlap between AbbVie's Skyrizi and Allergan's brazikumab. Both IL-23 inhibitors are currently in development to treat ulcerative colitis and Crohn's disease. While the FTC does its best to construct effective divestiture remedies, the government can never be certain how the divestiture buyer will perform with the divested assets in the future. Not surprisingly, the existing empirical evidence suggests that structural remedies often fail to prevent harm to competition. In fact, consumers face fewer choices and pay higher prices in several industries because of failed merger remedies in the grocery store,⁹ dollar store,¹⁰ and rental car industries.¹¹

There is even more reason to be skeptical when the Commission requires the divestiture of a drug in development, such as brazikumab, instead of a drug that is already in the market, such as Skyrizi. Indeed, the Commission failed to cite to any evidence that divestitures of drugs in development have ever resulted in any product launches or commercial success. We note that the FTC staff studied pharmaceutical pipeline divestitures in its 2017 merger remedy study and concluded that it had a success rate of 100% because in all 32 matters in which pipeline assets were divested, the assets were successfully transferred.¹² Respectfully, that is not the proper

⁹ In 2015, the FTC approved Safeway's acquisition of Albertson's, a large grocery merger, on the condition that the merged company divest 146 stores to Haggens, a small chain of 18 stores. Within months, that small chain filed for bankruptcy and the merged company wound up buying back about 36 stores. Ana Marum, Failed divestiture: Albertsons is bidding on 36 Hagggen stores, including some it used to own, *The Oregonian*, November 10, 2015. https://www.oregonlive.com/window-shop/index.ssf/2015/11/albertsons_bids_on_36_haggen_s.html

¹⁰ In 2015, the FTC conditioned Dollar Tree's acquisition of Family Dollar, a merger of dollar stores, on a divestiture of stores to Sycamore, a private equity firm. The private equity buyer sold the assets to the other large national dollar store player, Dollar General, within 21 months. FTC Press Release, "FTC Approves Sycamore Partners II, L.P. Application to Sell 323 Family Dollar Stores to Dollar General", April 27, 2017. <https://www.ftc.gov/news-events/press-releases/2017/04/ftc-approves-sycamore-partners-ii-lp-application-sell-323-family>

¹¹ In 2012, the FTC conditioned Hertz's acquisition of Dollar Thrifty on a divestiture of Advantage and other assets to a small rental car company, FSNA, backed by a private equity fund. The Advantage buyer filed for bankruptcy within a year only to have some of the assets auctioned back to Hertz. Bret Kendall, How the FTC's Hertz Antitrust Fix Went Flat, *Wall Street Journal*, December 8, 2013. <https://www.wsj.com/articles/how-the-ftc8217s-hertz-antitrust-fix-went-flat-1386547951?ns=prod/accounts-wsj>

¹² FTC Remedy Study at 31.

measure of success. **Just because assets are transferred does not mean competition is restored.** What is critical is whether a firm actually restores competition.

According to Director Hoffman, divestitures of pipeline drugs face a “startlingly high” rate of failure and such a divestiture places “a greater risk of failure ... on the American public.”¹³ Director Hoffman blamed this high failure rate on the difficulty of the divestiture buyer in actually getting the pipeline pharmaceutical to market and noted that it is “entirely proper that the risk of failure be placed” on the merging parties and not consumers.¹⁴ The divestiture of brazikumab is inconsistent with Director Hoffman’s concerns, the Commission’s past actions with respect to Amneal and Impax,¹⁵ and its actions in divesting the incumbent product in the Bristol Myers/Celgene merger.¹⁶ Thousands of Crohn’s disease and ulcerative colitis patients will be ill-served by a remedy that places the risk of failure on their shoulders as there is no guaranty that brazikumab will ever be launched, let alone obtain FDA approval. For these reasons, the Commission should adopt a policy that requires a divestiture of the in-market product over a divestiture of a drug in development.

III. Nestle and AstraZeneca Are Inappropriate Divestiture Buyers

Finding a suitable buyer in pharmaceutical drug markets is a daunting task. Under the law, a remedy is permissible only where it fully restores competition and “restoring competition requires replacing the competitive intensity lost as a result of a merger...” rather than just maintaining premerger levels.¹⁷ The divestitures to Nestle and AstraZeneca do not meet this standard. First, Nestle is not a pharmaceutical manufacturer with a portfolio of drugs that comes anywhere close to what Allergan had. There is no comparison. The Commission’s majority statement dances around this point. Second, AstraZeneca, which is a formidable pharmaceutical manufacturer, is nevertheless not a suitable buyer because it does not have the incentive or ability to fully restore competition.

The Commission is requiring Allergan to transfer the brazikumab assets to AstraZeneca for nothing while Allergan fronts the development costs. The Commission’s statement notes that “AstraZeneca’s incentive to develop brazikumab does not depend on how much AstraZeneca paid for those rights but how much money it can make going forward.” That is exactly the point. The fact that AstraZeneca is not paying anything reflects its assessment that the commercial success of the product is dubious. Without any substantial financial investment, it lacks the incentives to bring the product to market. Moreover, AstraZeneca has shown that it lacks a

¹³ *It Only Takes Two to Tango: Reflections on Six Months at the FTC.*

¹⁴ *Id.*

¹⁵ *Amneal Pharmaceuticals LLC/Impax Laboratories Inc.*, C-4650, FTC File No. 1810017 (final order approved on July 10, 2018) (<https://www.ftc.gov/enforcement/cases-proceedings/181-0017-c-4650/amneal-holdings-impax-laboratories-matter>) (“Impax Consent Order”) (requiring divestitures of on-market products instead of pipeline products).

¹⁶ See FTC Press Release, *FTC Requires Bristol-Myers Squibb Company and Celgene Corporation to Divest Psoriasis Drug Otezla as a Condition of Acquisition*, November 15, 2019.

¹⁷ *Fed. Trade Comm’n v. Sysco Corp.*, 113 F. Supp. 3d 1, 72 (D.D.C. 2015) (emphasis in original).

commitment to the immunology space by divesting most of its immunology products.¹⁸ Thus, it lacks a product portfolio in immunology, which puts it at a disadvantage to come up with an effective counter strategy to AbbVie's rebate walls if AstraZeneca ever decides to market brazikumab.

IV. For a Divestiture of Brazikumab, a Pipeline Drug, To Be Effective, the Commission Should Have Imposed Restrictions on AbbVie's Ability to Use Rebate Walls

Allergan's transfer of brazikumab pipeline assets to AstraZeneca does not restore competition because when brazikumab finally comes to market, if it ever does, it will be unable to break through AbbVie's rebate wall. In situations like this one, where the Commission knows that certain industry characteristics and practices as well as the merged firm's contracts are likely to stifle the entry and expansion of rivals including the divested asset, the Commission has taken action to enhance the likelihood that the remedy will succeed often by imposing a variety of behavioral conditions to support a divestiture buyer. For instance, the Commission's consent orders with respect to *CoStar/LoopNet* and *Simon Property/Prime Outlet* in 2012 and 2010, respectively, contained conduct provisions prohibiting the merged firm from using restrictive contracts that increased entry barriers of rivals along with a divestiture. The Department of Justice ("DOJ") has also imposed conduct conditions in addition to divestitures to protect competition in its consents. In *Anheuser Bush InBev/SABMiller*, the DOJ prohibited ABI from "instituting and continuing practices and programs that limit the ability and incentives of independent beer distributors to sell and promote the beers of ABI's rivals."¹⁹ Given that the Commission has the authority and flexibility to craft consent orders in ways to ensure that the relevant markets are competitive, we are disappointed that the Commission did not prohibit AbbVie from using rebate walls to foreclose brazikumab from getting on a drug formulary.

V. We Strongly Support Commissioner Chopra's Recommendations

We urge the Commission to embrace Commissioner Chopra's recommendations. We agree that the Commission should use a reinvigorated and broader look when evaluating pharmaceutical drug mergers in the future, which expands beyond the identification of overlaps but includes an analysis of whether innovation will be reduced. Academic studies confirm that mergers tend to reduce innovation, as the companies in the more concentrated marketplace cut back on R&D.²⁰ If the Commission finds that a merger is unlikely to create this harm it should be transparent in its analysis and the basis for its decision.

We also agree with Commissioner Chopra that the FTC needs to enhance its capabilities to analyze prospective buyers and remedies. Crafting an effective remedy to an anticompetitive merger is always difficult especially in pharmaceutical mergers as divestitures in this area are

¹⁸ AstraZeneca Press Release, MedImmune out-licenses potential medicine for inflammatory diseases to Allergan, October 3, 2016, available at <https://www.astrazeneca.com/media-centre/press-releases/2016/medimmune-out-licenses-potential-medicine-for-inflammatory-diseases-to-allergan-03102016.html#>

¹⁹ See *United States v. Anheuser Busch InBev SA/NV*, No. 16-1483 Modified Final Judgment (October 22, 2018).

²⁰ E.g., Justus Haucap and Joel Stiebale, Research: Innovation Suffers When Drug Companies Merge, *Harvard Business Review*, August 3, 2016, available at <https://hbr.org/2016/08/research-innovation-suffers-when-drug-companies-merge>.

fraught with tremendous uncertainty. It was only two years ago when former Director Hoffman said that the rate of failure of pipeline divestitures was “startingly high” so the FTC is aware that divestitures of drugs in development rarely work. To reverse the trend of failed divestitures, the FTC needs to strengthen its process wherever it can. Hoffman suggested that the FTC should demand divestitures of in-market drugs over pipeline drugs as the divestiture of an in-market drug provides more certainty, and we agree. The Commission must go further and demand more of its divestiture buyer candidates because it is critical that they have the proper infrastructure and incentives to succeed. Evaluating divestiture buyers is not an easy task. Thus, the Commission should add more financial analysts who have the capabilities to conduct the due diligence required to make an appropriate decision as to whether divestiture buyers have everything that is necessary to make a divestiture successful.

We also agree that the FTC should work closely with the states in merger investigations because the states have a wealth of information gained from their own investigations. The sharing of information could help FTC lawyers and economists with their review. The states have numerous pharmaceutical enforcement actions and have the unique expertise that comes from being close to the concerns of consumers.

Finally, as many current and former Commissioners have observed transparency is essential to effective enforcement. We believe the Commission can provide much greater transparency as outlined in Commissioner Chopra’s statement. In particular, we request the Commission respond, **in a substantive fashion**, to this and other comments filed in this matter as well as the letter submitted in September 2019 from nine senators regarding this merger review.²¹ The Department of Justice routinely responds to public comments regarding its consent decrees as part of its compliance with the Tunney Act, and the FTC should do the same. This transparent process not only better informs the public but requires the Commission to carefully evaluate the basis of its decisions.

VI. Concluding Thoughts

We appreciate the considerable work of Commission staff in evaluating this merger, but we believe that the consent order will not restore competition. In order to effectively restore competition and protect consumers, the Commission should always take steps to prohibit the merged firm from engaging in exclusionary conduct when there is evidence that the transaction increases the merged firm’s incentive and ability to foreclose competition. It is also necessary for the Commission to demand behavioral conditions along with divestitures of pipeline products to ensure that its remedy will fully restore competition especially in pharmaceutical markets where the Commission lacks evidence that divestiture remedies have been successful. Finally, numerous enforcement officials including Commissioners have talked about the critical importance of transparency in its merger reviews. As such, we respectfully request that the

²¹ The Commission occasionally provides detailed responses to public comments. *See, In the Matter of Sycamore Partners II, L.P., Staples, Inc., and Essendant Inc.*, File No. 181-0180 (filed January 28, 2019); *In the Matter of Your Therapy Source, LLC, Neeraj Jindal, and Sheri Yarbray*, Commission File No. 1710134 (filed July 31, 2018).

Commission provide a detailed response to our comments, other comments, and to the letter submitted by nine senators in September of 2019.²²

Thank you for considering our comments. If you have any questions regarding these comments, please contact David Balto at david.balto@dcantitrustlaw.com.

Respectfully submitted,

Families USA,
American Federation of State, County, and Municipal Employees,
American Federation of Teachers,
American Family Voices,
Alliance for Retired Americans,
Coalition to Protect Patient Choice,
Consumer Action,
Doctors for America,
End AIDS Now,
Services Employees International Union,
Social Security Works,
Treatment Action Group,
UNITE HERE, and
U.S. PIRG Education Fund

²² On September 19, 2019, nine senators (Klobuchar, Booker, Baldwin, Smith, Hirono, Sanders, Harris, and Warren) wrote a letter to the FTC expressing concerns about this merger. 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>.