

September 12, 2019

The Honorable Joseph J. Simons
Chairman
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

Re: AbbVie's Acquisition of Allergan Will Likely Harm Consumers

Dear Chairman Simons:

The undersigned unions, representing over 10 million subscribers and members, consumer and public interest organizations¹ have watched with concern as the pharmaceutical drug industry has become increasingly concentrated in recent years, often resulting in higher prices and reduced choice. We write to express our concerns over AbbVie Inc.'s ("AbbVie") proposed acquisition of Allergan plc ("Allergan") which would "create the fourth largest global biopharmaceutical company, with leadership positions in immunology, hematological oncology, medical aesthetics, neuroscience, women's health, eye care, and virology."² In light of the problems arising from this growing market concentration, we request that the Commission investigate this proposed merger thoroughly and take all necessary action, including blocking the merger, to prevent further harm to consumers.

We are particularly concerned because both companies have engaged in a wide variety of anticompetitive conduct to stifle competition including restrictive contracting practices and intellectual property abuse. We urge the Commission to thoroughly investigate that conduct, such as the use of contracting practices that have enabled the creation of so-called "rebate walls" which lead to increased prices and reduced consumer choice. The merger may enable AbbVie to engage in even more restrictive practices that will harm competition and consumers by blocking access to new lower-priced more efficacious drugs, inhibiting innovation, and distorting markets.

¹ The groups are Families USA, Public Citizen, U.S. PIRG Education Fund, Services Employees International Union (SEIU), American Federation of State, County, and Municipal Employees (AFSCME), UNITE HERE, Consumer Action, American Federation of Teachers, Alliance for Retired Americans, American Family Voices, Doctors for America, End AIDS Now, Prescription Justice, Social Security Works, the Other 98, Treatment Action Group, and NextGen California.

² AbbVie Inc. CEO Rick Gonzalez on Acquisition of Allergan Conference Call Transcript, June 25, 2019 ("AbbVie/Allergan Transcript") available at <https://seekingalpha.com/article/4272066-abbvie-inc-abbv-ceo-rick-gonzalez-acquisition-allergan-conference-call-transcript>. (Mr. Gonzalez stated that the acquisition would create the fourth largest global biopharmaceutical company). See Jason Woleben and Michael Gibney, *AbbVie heads for no. 5 spot on list of top drug makers with 84.2 billion Allergan buy*, S&P Global Market Intelligence, June 27, 2019, available at <https://www.spglobal.com/marketintelligence/en/news-insights/trending/7exo662zn8hya30ljjzew2>.

I. AbbVie's Acquisition of Allergan Continues the Trend Towards Consolidation Resulting in Higher Drug Prices and Less Innovation

AbbVie's acquisition of Allergan continues a trend of big pharma companies spending financial resources on acquisitions to grow their drug portfolios, rather than on research and development ("R&D") to develop new drugs or reducing drug prices.

Increasing consolidation in the pharmaceutical drug industry has led to higher prices for prescription drugs, less consumer choice, and less innovation. Between 1993 and 2015, there were approximately 2,500 deals, of which twenty firms were responsible for 74% of the merger and acquisition spending.³ Drug prices are skyrocketing to new heights, and R&D spending has dropped. Pfizer, Inc.⁴ and Valeant Pharmaceuticals, Inc.,⁵ for example, cut their R&D spending after completing acquisitions, and focused on increased sales of their expanded existing drug portfolios to increase revenues. Academic studies confirm that mergers tend to reduce innovation, as the companies in the more concentrated marketplace cut back on R&D.⁶ Indeed, the share of new drugs coming from the top twenty big pharma firms has dropped every year since 2013, from over 60% to just above 30% in 2018.⁷

II. The AbbVie/Allergan Merger Would Reduce Competition in a Number of Specific Product Markets

AbbVie's global blockbuster brand name biologic, Humira, is the best-selling drug in the world, generating approximately \$20 billion in revenue in 2018. Humira currently has FDA approval for the treatment of ten different medical conditions, including rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, plaque psoriasis, Crohn's disease, and ulcerative colitis, among others. AbbVie has engaged in a wide range of anticompetitive practices, including intellectual property abuse and restrictive contracting, to stifle competition and this has enabled them to more than triple Humira's list price from 2006 to 2017, with the list price for a one-year supply soaring from \$16,636 to \$58,612; and from 2012 to 2018, it increased in price by 144%. Neither inflation nor higher manufacturing costs explain these price increases. Given AbbVie's history of price increases, it is easy to predict what could be expected if AbbVie acquires control of Allergan's drug portfolio.

³*Marching Toward Monopoly – Mergers and Acquisitions in the Pharmaceutical Industry*, Institute for Health and Socio-Economic Policy, October 17, 2016, available at <https://www.nationalnursesunited.org/sites/default/files/nnu/files/pdf/research/MarchingTowardMonopoly-PharmaMdearA10-17-16.pdf>.

⁴ Mathew Herper, *Former Pfizer Research Chief Says Pharmaceutical Mergers Cripple Science*, Forbes, August 1, 2011 available at <https://www.forbes.com/sites/matthewherper/2011/08/01/former-pfizer-research-chief-says-pharmaceutical-mergers-cripple-science/#66e2d89420c3>.

⁵ Jonathan D. Rockoff and Dana Mattioli, *Bid for Allergan Puts Valeant's Research and Development Cuts Under Scrutiny*, Wall Street Journal, June 10, 2014 available at <https://www.wsj.com/articles/bid-for-allergan-puts-valeants-research-and-development-cuts-under-scrutiny-1402443053>.

⁶ 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>.

⁷ Mukherjee, *Protect at All Costs*.

The Commission should carefully examine the various overlaps of currently competing products that would be consolidated by the merger. Information about these overlaps is not generally publicly available. AbbVie executives on the investor call announcing the Allergan merger acknowledged antitrust concerns that would require divestitures.⁸ As noted above, AbbVie’s mega blockbuster, Humira, is already indicated for both Crohn’s disease and ulcerative colitis, and has a strong presence in inflammatory bowel disease, controlling over one third of the gastroenterology market.⁹ Press articles note that both AbbVie and Allergan have two investigative biologic drugs working their way through the U.S. Food and Drug Administration (“FDA”) approval process that are indicated to treat Crohn’s disease and ulcerative colitis.¹⁰ AbbVie currently has Skyrizi, an IL-23, which is currently approved to treat moderate to severe psoriasis and is currently being investigated for the treatment of multiple inflammatory diseases, including psoriatic arthritis, Crohn’s disease, ulcerative colitis, and atopic dermatitis. Allergan’s brazikumab is an IL-23 inhibitor that is currently being investigated to treat Crohn’s disease and ulcerative colitis. Press articles also suggest that AbbVie and Allergan currently compete in the manufacture and sale of pancreatic enzyme therapies for exocrine pancreatic insufficiency and drugs to treat uterine fibroids, among others.¹¹

The Commission should carefully scrutinize these overlaps and consider extensive divestitures to fully resolve competitive concerns. We are concerned that divestitures in the pharmaceutical industry are often unsuccessful especially in a situation like this one where there is an overlap between an actual and pipeline product because too often an inadequate set of pipeline assets may be divested in an effort to restore competition. Indeed, Bruce Hoffman, Director of the Bureau of Competition, [speaking at the Global Competition Review Seventh Annual Antitrust Law Leaders Forum on February 2, 2018](#), explained that an internal study at the FTC revealed that the rate of failure was “startlingly high” for divestitures of certain pharmaceutical pipeline products, such as inhalants or injectables.¹² Mr. Hoffman blamed the high failure rate on the difficulty in actually getting the pipeline pharmaceutical to market by a divestiture buyer. He noted further that when considering merger remedies “it is entirely proper that the risk of failure be placed” on the merging parties and not consumers.¹³

Accordingly, the divestiture of a pipeline product may be a poor choice. Unless a comprehensive remedy is secured the Commission should consider blocking the transaction. Consumers should not bear the risk of an unsuccessful divestiture especially where the acquiring firm has a long history of substantial price increases.

⁸ AbbVie/Allergan Transcript. “There are a few small product overlaps that we’ve agreed to divest.”

⁹ *Id.*

¹⁰ Angus Lui, After Roche, BMS Surprises, what does AbbVie need to do to win FTC clearance for Allergan buy, FiercePharma, June 26, 2019 available at <https://www.fiercepharma.com/pharma/after-roche-s-spark-delay-and-bristol-s-otezla-sale-what-does-abbvie-need-to-let-go-to-win>.

¹¹ *Id.*

¹² *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.

¹³ *Id.*

III. The Combination Will Exacerbate Competitive Problems in the Industry

As important as these direct product overlaps are, the Commission should not limit its focus to them in assessing whether the merger would substantially lessen competition in violation of the Clayton Act. Indeed, the combination of these three blockbuster drugs – AbbVie’s Humira and Allergan’s Botox and Restasis– will enable the merged company to more broadly leverage market power to force health insurers and pharmacy benefit managers (PBMs) to agree to exclusionary conditions that hamper the ability of rivals to compete.¹⁴

For example, the merger would enable AbbVie to use exclusionary practices such as rebate walls to limit the ability of rivals to expand and enter. A rebate wall is when a manufacturer leverages its market-dominant position to secure preferred formulary access for its products by offering lucrative incentives to PBMs and health insurers in the form of volume-based rebates.¹⁵ These rebates are often offered across multiple products, indications, and therapeutic specialties, the breadth of which cannot be matched by new and innovative therapies. Both AbbVie and Allergan have used rebate walls to stifle competition. It is well-known that part of Humira’s success is linked to rebates.¹⁶ And Allergan has been sued for bundling rebates for its drug Restasis together with rebates for other drugs in its portfolio, to keep rivals from coming to market.¹⁷

The Administration has also shown concern regarding rebate walls. Secretary Alex Azar of the Department of Health & Human Services (“HHS”) told the Senate Health, Education, Labor, and Pensions Committee that “I am very much aware that these rebate walls can prevent

¹⁴ The antitrust agencies can bring enforcement actions even when there are not direct overlaps, where a merger may increase a firm’s bargaining leverage. *Cf.* Comcast Corporation Abandons Proposed Acquisition of Time Warner Cable After Justice Department and the Federal Communications Commission Informed Parties of Concerns, Department of Justice, April 24, 2015, at <https://www.justice.gov/opa/pr/comcast-corporation-abandons-proposed-acquisition-time-warner-cable-after-justice-department>; Justice Department Allows Charter’s Acquisition of Time Warner Cable and Bright House Networks to Proceed with Conditions, Department of Justice, April 25, 2016, at <https://www.justice.gov/opa/pr/justice-department-allows-charter-s-acquisition-time-warner-cable-and-bright-house-networks>. In both of these cases, the Department of Justice’s Antitrust Division recognized that the merger would harm competition by increasing the merged company’s bargaining leverage to negotiate terms with video programmers that would limit online video distributors such as Netflix from obtaining important content.

¹⁵ The competitive concerns in these practices are described in “David Balto, *FTC Must Tackle Anti-Competitive Drug Rebate Practices*, Law360, May 17, 2019; Robin Feldman, *Why Prescription Drug Prices Have Skyrocketed*, Washington Post, November 26, 2018. According to Professor Robin Feldman, law professor at University of California Hastings Law and an expert on drug pricing, “the name of the game is volume. The more volume a drug company has with a particular PBM or hospital, the better deal it can offer as a temptation to exclude rival drugs.” Former FDA Chairman Scott Gottlieb has recognized that volume-based rebates on biologics allow the manufacturers and middlemen to split the monopoly profits. Speech, Brookings Institute, available at <https://www.brookings.edu/events/u-s-market-for-biosimilars-fda-scott-gottlieb/>

¹⁶ *See, e.g., Global Pharmaceuticals: Future of US Rebates Under Review*, Credit Suisse Analyst Report, April 29, 2019, at 6, 29; Citron Research, Citron Research Explains Why AbbVie is on its Way to \$60, July 24, 2018.

¹⁷ Shire sued Allergan in 2017 alleging a pattern of anticompetitive conduct related to Allergan’s exclusionary arrangements and bundled rebate conditional pricing practices in the \$1.5 billion market for drugs for dry eye disease used in Medicare Part D plans. *Shire v. Allergan, Inc.*, No. 2:17-cv-7716 (D.N.J. October 2, 2017). On March 22, 2019, the district court dismissed the case because the Medicare Part D plan market was too narrow to be a relevant product market and Shire failed to allege that Allergan had monopoly power. [*Shire US, Inc. v. Allergan, Inc.*, No. 17-cv-7716 \(D.N.J. Mar. 22, 2019\)](#).

competition and new entrants into the system ... I do not like that practice. I think it's using their market power in ways that are not appropriate. I want to make sure we are looking at that. I think Congress could look at that question as part of this whole initiative.”¹⁸

We share Secretary Azar's concern because pharmaceutical rebates raise more profound competitive problems than discounts in other industries. In fact, there is increasing evidence that rebates actually inflate prices paid by consumers and do not decrease prices which is why HHS sought to eliminate rebates from the Medicare prescription drug program.¹⁹ Many consumer groups supported this proposal because pharmaceutical rebates actually increase drug costs and do not ultimately benefit consumers.²⁰ We are further concerned that combining AbbVie's blockbuster drugs with Allergan's is likely to exacerbate this anticompetitive conduct, because the merged firm will have an increased ability to bundle rebates across its enlarged drug portfolio in order to keep competing branded drugs, generics, and biosimilars off of PBMs' and insurers' preferred position on their drug formularies.²¹

We are also concerned that the merger could exacerbate anticompetitive patent practices. AbbVie and Allergan have engaged in such practices to prolong their monopolies and exclusive patent periods, in order to keep prescription drug prices high. To protect Humira, AbbVie created a vast “patent estate” of approximately 247 patent applications and 136 patents, which it used to sue each of its prospective biosimilar competitors.²² As a result of these lawsuits, AbbVie entered into anticompetitive settlements that prevent these new rivals from entering and competing in the United States until 2023.²³ Allergan attempted to protect its blockbuster dry eye drug, Restasis, by transferring its patents to a Native American tribe, in an effort to block patent challenges from competing generics.²⁴

¹⁸ On June 12, 2018, HHS Secretary Alex Azar told the Senate Health, Education, Labor and Pensions (HELP) Committee that the administration is aware of rebate walls and how they can prevent competition from new entrants. Hearing Transcript Available at <https://www.c-span.org/video/?446791-1/secretary-azar-testifies-prescription-drug-pricing-plan>.

¹⁹ Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees, 84 Fed. Reg. 2,340 (Feb. 6, 2019) (to be codified at 42 C.F.R. pt. 1001).

²⁰ See Consumer Action, Consumer Federation of America, Consumer Reports, NETWORK Lobby for Catholic Social Justice, and U.S. PIRG, Comment on Proposed Rule on Fraud and Abuse: Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees (Apr. 8, 2019), <https://www.regulations.gov/document?D=HHSIG-2019-0001-19975> (“[W]e support HHS' proposed rule changes to eliminate rebates, thereby encouraging prices that more closely reflect actual costs, with competitive incentives to offer any discounts directly to patients at the pharmacy counter.”).

²¹ See, e.g., Aaron Hakim and Joseph S. Ross, *Obstacles to the Adoption of Biosimilars for Chronic Diseases*, Journal of the American Medical Association, May 2, 2017.

²² Samantha DiGrande, IMAK Report Takes on Humira's Patent Estate, September 29, 2018 available at <https://www.centerforbiosimilars.com/news/imak-report-takes-on-humiras-patent-estate>, and Mukherjee, *Protect at All Costs*.

²³ Susanna Luthi, *AbbVie Sued over Humira 'Patent Thicket'*, Modern Healthcare, March 19, 2019, at <https://www.modernhealthcare.com/politics-policy/abbvie-sued-over-humira-patent-thicket>.

²⁴ Katie Thomas, *How To Protect a Drug Patent? Give It to a Native American Tribe*, New York Times, September 8, 2017, at <https://www.nytimes.com/2017/09/08/health/allergan-patent-tribe.html>. Fortunately, the federal courts

These practices should receive careful attention as part of the Commission's investigation into the effects of this proposed merger and if an adequate remedy can not be found, the Commission should challenge this acquisition.

IV. Concluding Thoughts

We urge the Commission to carefully investigate the potential for this merger to substantially lessen competition, and to take effective enforcement action to ensure that competition is protected and that consumers will have full access to effective and lower-cost branded drugs as well as effective and lower-cost biosimilars and generics, for their individualized needs. And we hope this investigation will be part of a reinvigorated broader look at pharmaceutical drug mergers.

If you have questions about this letter please contact our counsel David Balto at 202-577-5424 or david.balto@dcantitrustlaw.com.

Thank you for your consideration.

Respectfully,

Families USA

Public Citizen

U.S. PIRG Education Fund

Service Employees International Union (SEIU)

American Federation of State, County, & Municipal Employees (AFSCME)

UNITE HERE

Consumer Action

American Federation of Teachers

Alliance for Retired Americans

American Family Voices

Doctors for America

End AIDS Now

Prescription Justice

[rejected the sham agreement, which would have kept generics out of the market.](https://www.reuters.com/article/us-usa-court-allergan/u-s-supreme-court-rejects-allergan-bid-to-use-tribe-to-shield-drug-patents-idUSKCN1RR1FD) Lawrence Hurley, *U.S. Supreme Court Rejects Allergan Bid to Use Tribe to Shield Drug Patents*, Reuters, April 15, 2019, at <https://www.reuters.com/article/us-usa-court-allergan/u-s-supreme-court-rejects-allergan-bid-to-use-tribe-to-shield-drug-patents-idUSKCN1RR1FD>.

Social Security Works

The Other 98

Treatment Action Group

NextGen California

cc: Commissioner Noah Joshua Phillips
Commissioner Rohit Chopra
Commissioner Rebecca Kelly Slaughter
Commissioner Christine S. Wilson
Bruce Hoffman, Director, FTC Bureau of Competition