

April 2, 2020

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

Re: AbbVie/Allergan's Proposed Divestiture of Brazikumab to AstraZeneca is Inadequate Without Restrictions on AbbVie's Use of Anticompetitive Rebate Walls

Dear Mr. Simons:

As you know, we represent the undersigned unions, with over 10 million subscribers and members, and consumer groups and public interest organizations.¹ These organizations work tirelessly to try to reign in excessive drug costs and raised concerns in our September 12, 2019² and February 18, 2020 letters to the Commission that AbbVie Inc.'s ("AbbVie") proposed acquisition of Allergan plc ("Allergan") would substantially harm competition and that the proposed divestiture of brazikumab to AstraZeneca without restrictions on AbbVie's use of rebate walls is inadequate to maintain competition.³ As your staff requested, we write this letter to supplement our other two letters and to respond to several issues that have arisen in our meetings with staff and other Commissioner offices.

I. Background – Rebate Walls are a Significant Competitive Problem

As you know a critical concern, we have raised involves rebate walls, the bundling of rebates across indications and products, which we believe are used by AbbVie to foreclose competition in the immunology product space. We believe these rebate walls must be addressed because they will severely impair any remedy chosen by the Commission.

Some people might question whether rebates can be anticompetitive since they may appear to be price discounts. As a preliminary matter, pharmaceutical rebates raise even greater concern than rebates or discounts in other industries. There is increasing evidence that rebates drug manufacturers offer pharmacy benefit managers and health plans ("payors") to get expensive biologics on their formularies actually raise the cost of prescription drugs. This is why

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 Letter to Chairman Joseph Simons raising concerns about AbbVie's acquisition of Allergan, dated September 12, 2019 available at https://docs.wixstatic.com/ugd/1859d0_92f865639fc74293a62fef5c4fe1c62c.pdf.

³ Letter to Director of Bureau of Competition, Ian Conner raising concerns about Allergan's divestiture of brazikumab to AstraZeneca, dated February 18, 2020 available at https://b5dbfb83-9c74-47bd-bd60-30480423303a.filesusr.com/ugd/1859d0_68ca515ec90649b0bfe99d56eb368fec.pdf.

the Administration proposed eliminating rebates,⁴ a reform supported by major consumer groups.⁵ What is important to understand about these rebates is that they are not discounts for patients. Because the rebates go to payors, rather than to consumers, payors have perverse incentives to negotiate higher list prices so they can secure higher rebates – without regard to patient wellbeing or patient cost.⁶ The Administration’s proposal clearly documented that rebates lead to higher list prices and deter innovation. These rebates actually increase patients’ costs because the patients’ coinsurance is based on the inflated list price of the branded drug. If the patients had access to lower cost branded drugs, their coinsurance costs would go down.

A rebate wall or trap has even worse implications for patients. They are erected when an incumbent manufacturer uses existing market power to secure preferred formulary access for its drug by offering volume-based rebates to payors, on the condition that they deny or limit the formulary access of rival drugs.⁷ The rebate is bundled across multiple products, indications, and/or therapeutic specialties, the breadth of which cannot be matched by a new rival.⁸ Through a rebate wall, a manufacturer with a dominant incumbent drug can prevent entry of a newly approved branded drug even if it is offered at a greater rebate or for free. That is because the new branded drug has few prescriptions, if any, so even a larger rebate will not overcome the potential loss of the rebate dollars from the market-leading product. Branded drugs lose because offering them at a lower price does not guarantee them a position on a plan’s formulary, which means that they are unlikely to gain early acceptance by doctors and patients.

The impact on patients can be severe. They can lose access to more efficacious and lower cost drugs. Even if a rival drug is not entirely excluded, it is often put on an inferior tier of the formulary, and a patient must undergo a costly and painful step therapy in order to secure the drug. In other words, a patient must continue treatment on a less efficacious drug, often leading to continued illness, increased pain, and other adverse results.

⁴ 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).

⁵ 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.”).

⁶ Robin Feldman, *Why Prescription Drug Prices Have Skyrocketed*, *Washington Post*, November 26, 2018.

⁷ 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/>

⁸ 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.

II. AbbVie's Rebate Wall Is a Merger Specific Concern

Questions have arisen whether AbbVie's rebate wall agreements with payors are a merger specific concern. We believe that they absolutely are, as AbbVie's acquisition of Allergan's strong portfolio of drugs in numerous therapeutic areas increases AbbVie's bargaining leverage over payors so it has an increased ability and incentive to use rebate contracts based on the prescription volume of the portfolio of drugs - now greatly expanded - as well as its immunology franchise to protect its new and weaker drugs and stifle the entry and expansion of any rival drugs. AbbVie has aggressively used rebates to protect its dominant position in the immunology space.

Some might suggest that payors typically seek rebates only for a certain therapeutic area and that AbbVie already has the power through Humira to financially coerce payors into agreements whereby rivals are kept off of payors' formularies. While that may often be true, we believe the acquisition will increase the merged firm's leverage to promulgate new anticompetitive rebate tactics to keep rivals off of formularies. This includes not only bundling across indications, which AbbVie has done in the past with respect to Humira, but to bundle across a number of products, and potentially other therapeutic areas. We believe that some payers like Express Scripts are open to doing portfolio contracting across therapeutic areas if there is enough rebate volume at stake. If the financial incentive exists, payors would give up the flexibility required of a cross therapeutic area bundle in order to benefit from AbbVie's incremental rebate volume. This merger combines significant blockbuster drugs of the two companies. Thus, the newly merged firm will have the increased ability and incentive to continue with this strategy on a much larger scale by erecting rebate walls in other therapeutic areas other than autoimmune to create even stronger rebate walls because AbbVie needs to fill the void as its prized franchise, Humira, will lose exclusivity in 2023.

Clearly combining AbbVie and Allergan's blockbuster drugs will increase their bargaining leverage. Both the Commission and the Department of Justice ("DOJ") have brought enforcement actions against mergers that increase a merged firm's bargaining leverage.⁹ Indeed, the FTC has successfully demonstrated that mergers are anticompetitive when the merged hospital's bargaining leverage over insurers would be great enough to effectively force an insurer to provide coverage because it cannot afford to lose the merged hospital from its network. *See, FTC v. OSF Healthcare Sys.*, 852 F.Supp.2d 1069, 1084 (N.D. Ill. 2012). And, the DOJ has challenged cable mergers where the merged firm would have an increased ability and incentive to use its leverage with video programmers (producers of TV shows and programs) to limit the access of rival online video distributors such as Netflix, Hulu, and Amazon, to important content. In its investigation of Charter's acquisition of Time Warner Cable ("TWC"), the DOJ learned that prior to the merger, TWC had already used its power to set up roadblocks for its new rivals

⁹ 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>. *See also, FTC v. OSF Healthcare Sys.*, 852 F. Supp.2d 1069, 1084 (N.D. Ill. 2012); *FTC v. ProMedica Health Sys., Inc.*, 2011 WL 1219281 (N.D. Ohio Mar. 29, 2011).

by aggressively securing clauses in its contracts with programmers that either prevented the programmer from distributing its content to online video distributors or placed certain restrictions on such online distribution.¹⁰ The DOJ acknowledged in its Competitive Impact Statement that no horizontal overlap existed between the merging parties, but it made clear that “the Clayton Act is also 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.”¹¹ The DOJ’s complaint alleged that the newly merged firm because it was growing even larger through the acquisition would have even more to gain from imposing restrictive contractual provisions that would make these new emerging rival online video distributors less competitive.¹² Accordingly, the DOJ sought comprehensive behavioral relief to ensure that the merged firm would not have the ability to foreclose online video distributor competition and deny customers the benefit of innovation and new services through restrictive contracting provisions.¹³

There are several parallels between the Charter/TWC and the AbbVie/Allergan transactions. Both deals involve multiple tiers between the producers, middlemen, and the customers. Both combinations involve dominant firms that already had the ability and incentive to pressure companies in other tiers to enter into contracts that have the effect of restricting rivals’ access to consumers, and as a result of the merger, the newly merged firm would have greater incentive and ability to impose restrictions and/or incentives that could raise entry barriers or foreclose its new emerging rivals. The competitive concerns in the AbbVie/Allergan merger are largely the same as the concerns in the Charter/TWC complaint. To the extent a transaction, such as the one at issue here, enhances AbbVie’s ability or incentive to restrain rival branded drugs’ access to payors’ drug formularies, and thus to prevent rival branded drugs from becoming a meaningful new competitive option, consumers lose.

Along the same lines, the Commission has required behavioral relief when a merger enhanced a merged firm’s ability to coordinate to delay the introduction of a product. In Perrigo/Paddock, the Commission sought to preserve competition in the testosterone gel market by prohibiting Perrigo from entering into any “reverse payment” arrangements with Abbott, the branded drug manufacturer of Androgel, a testosterone gel, or accepting any payments from Abbott relating to Androgel.¹⁴ The Commission was concerned that the acquisition increased the likelihood and degree of coordination between Perrigo and Abbott even though there was no real connection between the two. Apparently, Perrigo was one of a limited number of suppliers

¹⁰ See *Competitive Impact Statement, U.S. v. Charter Communications, Inc., Time Warner Cable, Inc.*, No. 16-0795 (D.D.C. 2016) available at <https://www.justice.gov/atr/file/850161/download>.

¹¹ *Id.*; 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.”).

¹² See, *Complaint, U.S. v. Charter Communications, Inc., Time Warner Cable, Inc.*, No. 16-0795 (D.D.C. 2016) available at <https://www.justice.gov/atr/file/844831/download>.

¹³ See, *U.S. v. Charter Communications, Inc., Time Warner Cable, Inc.*, No. 16-0795 (D.D.C. 2016) (Final Judgment) available at <https://www.justice.gov/atr/file/844851/download>. The behavioral remedies are outlined on pages 5-7.

¹⁴ Perrigo Company/Paddock Laboratories, Inc., C-4329, FTC File No. 1110083 (final order issued June 21, 2012) (<https://www.ftc.gov/enforcement/cases-proceedings/111-0083/perrigocompany-paddock-laboratories-inc-matter>).

capable of entering this future generic market. Pursuant to an agreement between Par Pharmaceutical Companies, Inc. (“Par”), Paddock, and Solvay Pharmaceuticals, the former owner of Androgel, Par agreed to delay introducing a generic version of Androgel in exchange for, among other things, payments under a backup supply agreement. That agreement was transferred to Paddock. According to the Commission, the proposed acquisition would make Perrigo a party to that agreement, thereby enhancing Abbott’s and Perrigo’s ability to coordinate to delay the introduction of Perrigo’s future product.

In sum, the Commission has legal authority to bring an enforcement action in a merger like this one that increases a merged firm’s bargaining leverage and incentive and ability to enter into rebate wall agreements with payors that foreclose competition.

III. Divestiture of Skyrizi, the On-Market Drug Is Preferred Over Brazikumab, a Pipeline Drug

There have been suggestions that there might be reduced competitive concerns because the overlap between Skyrizi and brazikumab is of two IL-23 inhibitor pipeline products as opposed to an overlap of an on-market IL-23 inhibitor and an IL-23 pipeline product. While it is true that neither Skyrizi nor brazikumab have been approved for Crohn’s disease and ulcerative colitis, Skyrizi is already a product that is in a preferred position on drug formularies for moderate to severe psoriasis. It is already gaining acceptance and prescription volume, which makes it a much more desirable asset. Given the circumstances regarding AbbVie’s rebate wall, we believe the FTC should require a divestiture of Skyrizi. If a divestiture buyer had Skyrizi, it would have a better chance of succeeding in future indications for Crohn’s disease and ulcerative colitis given Skyrizi’s prescription volume in moderate to severe psoriasis.

IV. AstraZeneca Is Not A Suitable Divestiture Buyer

Finding a suitable buyer in this market is a daunting task. There are significant barriers to entry in any pharmaceutical market, but the barriers here are far more intense because of AbbVie’s ongoing anticompetitive conduct, especially its use of rebate walls. As we noted in our earlier letter, several major manufacturers have been unable to overcome these barriers, and AbbVie has used these walls to compel market acceptance of Skyrizi.

We believe that AstraZeneca is not a suitable buyer because it does not have the incentive nor ability to fully restore competition.

First, AstraZeneca’s commitment to the immunology space is uncertain. In 2016, AstraZeneca made a financial decision to exit the space with the divestiture of brazikumab to Allergan. At the time, AstraZeneca claimed that brazikumab was “outside of AstraZeneca’s three main therapy areas,” which it identified as (1) oncology, (2) cardiovascular and metabolic diseases and (3) respiratory.¹⁵ Prior to the divestiture of brazikumab, AstraZeneca divested its non-U.S. global rights to Entocort, a medicine for ulcerative colitis and Crohn’s disease, in a

¹⁵ 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#>

move to sharpen its focus on its core areas.¹⁶ In 2018, when AstraZeneca divested non-U.S. rights to Nexium and Vimovo, its press release reiterated the point that the divestments were made so that it could focus on its three main therapy areas.¹⁷ And now, all of a sudden, AstraZeneca is interested in taking over the brazikumab assets to compete with AbbVie's Humira and Skyrizi. It cannot be underscored enough that AstraZeneca simply gave up on the brazikumab assets some three and a half years ago and has conducted none of the development since that time. It is also worth noting that AstraZeneca had no interest in acquiring Zenpep, a gastroenterology product. Because of their uncertain commitment, we believe payors will be uncertain about courting disfavor with AbbVie and choosing AstraZeneca.

Second, AstraZeneca appears to be getting a sweet-heart deal as it does not appear to be paying anything at all for the brazikumab assets and Allergan is fronting the development costs. Indeed, AstraZeneca's press release states that "Allergan will fund up to an agreed amount, estimated to be the total costs expected to be incurred by AstraZeneca until completion of development for brazikumab in CD and UC, including the development of a companion diagnostic."¹⁸ In a situation like this, where a divestiture buyer does not have any "skin in the game," it is unlikely that it will put forth a financially aggressive effort to do what is necessary to get on payors' formularies. We are particularly concerned that the reason AstraZeneca is not paying anything for the development of brazikumab is because its own internal assessment suggests that the competitive conditions are such that the likelihood of success is dubious.

Third, AstraZeneca lacks a product portfolio in the immunology product space. It has less than a handful of products, all in gastroenterology. It lacks a set of immunology products to satisfy payors who want to deal with a limited set of buyers. Moreover, payors will look to a manufacturer's success with similar products in the product category before it commits to a new product. As currently envisioned, AstraZeneca would have to go it alone in trying to secure access for brazikumab.

Finally, the lack of an immunology product portfolio raises concerns about whether it will have an effective counterstrategy to AbbVie's rebate walls. Very powerful manufacturers such as Novartis Pharmaceutical Corporation, Eli Lilly, Valeant Pharmaceutical, and Sun Pharmaceutical Industries have not been able to overcome the barriers to acceptance created by AbbVie's rebate walls. It is difficult to envision how AstraZeneca can succeed in overcoming these barriers. (We discuss this in further detail below).

AstraZeneca's decision to withdraw from this market only a few years ago to focus on its three core areas that do not include immunology, and lack of financial investment into

¹⁶ AstraZeneca Press Release, *AstraZeneca sharpens focus on main therapy areas through agreement with gastroenterology specialist Tillotts Pharma for Entocort*, July 9, 2015 available at <https://www.astrazeneca.com/media-centre/press-releases/2015/astrazeneca-tillotts-pharma-entocort-gastroenterology-09072015.html#>.

¹⁷ AstraZeneca Press Release, *Agreement with Grünenthal for rights to Nexium in Europe and Vimovo worldwide (ex-US)*, October 30, 2019 available at <https://www.astrazeneca.com/media-centre/press-releases/2018/agreement-with-grunenthal-for-rights-to-nexium-in-europe-and-vimovo-worldwide-ex-us-30102018.html>.

¹⁸ AstraZeneca Press Release, *AstraZeneca to recover the global rights to brazikumab (MEDI2070) from Allergan*, January 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>.

brazikumab assets raises serious doubts over AstraZeneca's incentives and long-term commitment to commercially marketing brazikumab in the future.

V. For a Divestiture of Brazikumab To Be Effective, the Commission Must Impose Restrictions on AbbVie's Ability to Implement Rebate Walls

We do not believe that the sale of brazikumab pipeline assets to AstraZeneca fully restores competition. Competition can only be restored if AstraZeneca can market brazikumab without having to face AbbVie's rebate wall. In short, AbbVie should be prohibited from using rebate walls that would impede any IL-23 inhibitor including the brazikumab assets from gaining access to drug formularies.

AbbVie has demonstrated an ability to bundle its rebates across Humira's ten indications, which not only protect Humira, but have allowed AbbVie to prop up Skyrizi to a preferred position alongside Humira on payors' drug formularies.¹⁹ Payors also claim that AbbVie is incentivizing them to save a preferred position for Rinvoq, AbbVie's new oral JAK inhibitor, indicated for rheumatoid arthritis.²⁰ Part of AbbVie's rebate strategy has been to put these two drugs in a strong position in terms of prescription volume before biosimilar competition for Humira arrives in 2023,²¹ and the same rebate wall strategy will likely be used to get Skyrizi in the preferred position on drug formularies for Crohn's disease and ulcerative colitis whenever Skyrizi is approved for those indications. Thus, AbbVie's rebate strategy will likely inhibit the ability of any buyer of brazikumab to compete in Crohn's disease and ulcerative colitis in the future.

Indeed, AbbVie's rebate wall has successfully kept both Lilly and Novartis's IL-17 inhibitors, Taltz and Cosentyx, at bay the last several years even though both drugs were more efficacious than Humira for the treatment of moderate to severe psoriasis.²² By the time AstraZeneca obtains FDA approval for brazikumab in 2024 or 2025, for which the timing of the approval will be in the hands of Allergan, AbbVie's rebate wall will have been transferred from Humira to Skyrizi and Rinvoq, which will have both built up very sizable prescription volume.²³

We believe that some pharmaceutical companies may have counterstrategies to address rebate walls. For example, Johnson & Johnson ("J&J") has offered payors rebates on a bundle of immunology products such as Remicade (infusion therapy for chronic diseases such as rheumatoid arthritis, plaque psoriasis, and Crohn's disease), Simponi (used for rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and ulcerative colitis), Simponi Aria (used for

¹⁹ 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."

²⁰ *Id.*

²¹ AbbVie Inc. CEO Rick Gonzalez Presents at 38th Annual J.P. Morgan Healthcare Conference (Transcript) January 15, 2020.

²² Lilly Press Release, *Lilly Announces Positive Top Line Results for Taltz (ixekizumab) vs. Humira in a Head to Head (SPIRIT-H2H) Superiority Study in Patients with Active Psoriatic Arthritis*, December 17, 2018. *Targeted Immunomodulators for the Treatment of Moderate to Severe Plaque Psoriasis: Effectiveness and Value*, Institute for Clinical and Economic Review, Final Evidence Report, August 3, 2018 at 32-34.

²³ AbbVie Inc. CEO Rick Gonzalez Presents at 38th Annual J.P. Morgan Healthcare Conference (Transcript) January 15, 2020.

rheumatoid arthritis), and Stelara (used for plaque psoriasis, psoriatic arthritis, and Crohn's disease). This essentially means that J&J may be able to guarantee its products, including its IL-23 inhibitor Tremfya, a preferred position on payors' formularies. With respect to this merger, Allergan may have been in a stronger position to devise a counterstrategy than AstraZeneca. While both have a modest presence in the autoimmune space – mainly through gastroenterology, Allergan has approximately 12 products in this space, including Zenpep²⁴ compared to AstraZeneca, which only has three products and nothing in the pipeline.²⁵

To be sure, AstraZeneca does not have anything in its portfolio that is similar to the volume of Humira or to what Skyrizi will have in three or four years. We do not believe that AstraZeneca will have a counterstrategy to combat AbbVie's rebate wall because it is more difficult to bundle its therapeutic areas against immunology players such as AbbVie and J&J because payors know that most patients will remain on their existing autoimmune therapy if it is working for them. In other situations, where a drug is interchangeable, such as insulin for diabetes, patients can easily switch medications if there is a formulary change. But, if a payor were to make a formulary change for an immunology drug, the incumbent product still provides a rebate stream to the payor because patients are unlikely to switch. Because of this fundamental difference between almost all other therapeutic areas and immunology, AstraZeneca will have a very difficult time overcoming AbbVie's rebate wall meaning that it is unlikely that AstraZeneca will successfully commercialize brazikumab.

In situations like this, 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, in 2012, the Commission's CoStar/LoopNet consent order contained what the FTC characterized at the time as "conduct relief that is unusual in a merger settlement."²⁶ In addition to requiring that the parties divest LoopNet's interest in Xceligent, the consent contained several conduct provisions designed to facilitate Xceligent's ability to compete and to lower entry barriers.

An important point about the Commission's consent order in CoStar/Loopnet is that LoopNet faced many of the same hurdles remedied by the consent when it was competing against CoStar. Still, the Commission required comprehensive behavioral relief to facilitate competition and entry and expansion into new markets. The consent (1) prohibited the merged firm from restricting customers' ability to support Xceligent; (2) required the merged firm to allow customers to terminate their existing long term contracts, without penalty, with one year's prior notice to prevent long term subscriptions commitments from hindering competition; (3) barred the merged firm from requiring customers to buy any of its products as a condition for receiving other products, and from requiring customers to subscribe to multiple geographic

²⁴ Allergan website available at <https://www.allergan.com/gastroenterology>.

²⁵ AstraZeneca website available at <https://www.astrazeneca.com/our-therapy-areas/medicines.html>.

²⁶ Press Release, Fed. Trade Comm'n, *FTC Places Conditions on CoStar's \$860 Million Acquisition of LoopNet* (Apr. 26, 2012), available at <http://www.ftc.gov/opa/2012/04/costar.shtm>.

coverage areas to gain access to a single area in which they are interested and (4) required the merged firm to offer their customers certain core products on a stand-alone basis.²⁷

Unfortunately, Xceligent was unable to survive even with these additional protections because CoStar was relentless in its efforts to compete against Xceligent.²⁸ The failure of Xceligent serves as a reminder that a merged firm will vigorously compete with a divestiture buyer, and in situations, like this one, where AbbVie is known to have used a number of anticompetitive strategies to stifle competition, it is essential that the Commission impose comprehensive behavioral relief to assist the divestiture buyer.

The Commission has the authority and flexibility to craft a consent order in a way to ensure that the relevant markets are competitive. Prohibiting AbbVie from using a rebate wall would allow payors to contract at the indication level, thereby increasing the number of drug manufacturers competing for access for each indication. It would allow innovative therapies to gain formulary coverage, which will help patients get the prescription drugs they need to better manage their immunology conditions. And, it would allow payors to engage in contracting strategies that focus on clinical outcomes.

At minimum, conditions should apply to the sale of brazikumab and the relevant markets at issue here, such that, if it is ever approved by the FDA, a rival IL-23 inhibitor can market newly approved drugs for ulcerative colitis and Crohn's disease without being foreclosed from getting on a formulary by AbbVie's rebate wall.

In sum, the conditions should prohibit exclusionary contracting practices that foreclose competition, which would provide further incentive for the divestiture buyer of brazikumab to actually market it in competition with Skyrizi.

VI. The Commission Should Separately Investigate AbbVie's Use of Rebate Walls

AbbVie has a long history of engaging in anticompetitive practices that harm competition and cost consumers in higher prices and lost innovation. The Commission has appropriately focused attention on AbbVie's anticompetitive cookbook and has successfully challenged AbbVie's illegal patent settlements and sham litigation.²⁹ AbbVie has added a new recipe to its cookbook – the use of rebate walls.

²⁷ In the Matter of CoStar Group, Inc., Lonestar Acquisition Sub, Inc., and LoopNet, Inc., Docket No. C-4368 Final Judgment, August 29, 2012 available at <https://www.ftc.gov/sites/default/files/documents/cases/2012/08/120830costardo.pdf>.

²⁸ Steve Vockrodt, CoStar Competitor Xceligent Shuts Down, The Kansas City Star, December 15, 2017 available at <https://www.kansascity.com/news/business/article190318374.html>.

²⁹ FTC Press Release, Statement FTC Chairman Joe Simons Regarding Federal Court Ruling, June 29, 2018 available at <https://www.ftc.gov/news-events/press-releases/2018/06/statement-ftc-chairman-joe-simons-regarding-federal-court-ruling>.

Congressmen, experts, and key enforcers have raised significant concerns over rebate walls. Congressman³⁰ and Senators³¹ have noted these practices prevent alternative drugs from effectively competing. Rebate walls were also raised by a number of speakers, at the FDA/FTC Workshop on a Competitive Market for Biosimilars on March 9, 2020, as an anticompetitive practice that has stifled the entry and expansion of biosimilars. High-ranking members of the Administration including Alex Azar, Secretary of Health & Human Services,³² and, former Food & Drug Administration Commissioner Scott Gottlieb have called for action to stop branded drug companies from using rebate-based contracts that foreclose competition.³³

Given the widespread acknowledgement that rebate walls have become an obstacle to competition for alternative branded drugs, biosimilars, and generics from getting on payors' formularies, we believe that the Commission should open an investigation into AbbVie's contracting practices in the immunology markets. An investigation and an enforcement action will protect the millions of immunology consumers that are suffering from higher prices and less choice and innovation.

VII. Concluding Thoughts

We appreciate the considerable work of the Commission's staff in evaluating this merger. Past history suggests that meaningful divestitures in this area are very difficult to craft. In order to effectively restore competition and protect the thousands of patients using these vital drugs we hope the Commission clearly addresses the problem of rebate walls and secures a remedy that fully protects competition.

We hope that if the Commission does not impose any additional behavioral relief, it will at least issue a statement indicating that it will continue to monitor anticompetitive contracting practices in the pharmaceutical industry very closely, and will pay particular attention to rebate walls and how they may raise barriers to entry and foreclose competition.

³⁰ In January 2019, in response to the proposed merger of Celgene and Bristol-Meyers Squibb, Congressmen Peter Welch (D-Vt.) and Francis Rooney (R-Fla.) sent a letter urging the FTC and DOJ to investigate the proposed merger and its impact on competition, including the use of rebate walls.
<https://welch.house.gov/sites/welch.house.gov/files/Letter%20to%20FTC%20and%20DOJ%20on%20BMS%20Celgene%20Merger.pdf>

³¹ On September 19, 2019, nine senators (Klobuchar, Booker, Baldwin, Smith, Hirono, Sanders, Harris, and Warren) wrote a letter to the FTC 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>.

³² HHS Secretary Alex Azar Testimony to the Senate Health, Education, Labor and Pensions (HELP) Committee, June 12, 2018 ("I am very much aware that these rebate walls can prevent 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.") available at <https://www.c-span.org/video/?446791-1/secretary-azar-testifies-prescription-drug-pricing-plan>.

³³ Scott Gottlieb, *Don't Give Up on Biosimilars—Congress Can Give Them a Boost*, Wall Street Journal, August 24, 2019. He argued for the need to "stop branded drug companies from using 'rebates' to squelch competition from biosimilars... If there's one situation where rebates are anticompetitive, it's when they're being used to block competition from a low-cost generic."

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

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
Ian Conner, Director of Bureau of Competition
Gail Levine, Deputy Director of Bureau of Competition
Daniel Zach, Acting Assistant Director, Mergers I
Eric Rohlck, Deputy Assistant Director, Compliance
Kari A. Wallace, Mergers I