

DAVID A. BALTO
ATTORNEY AT LAW
8030 Ellingson Drive
Chevy Chase, Maryland 20815

PHONE: (202) 577-5424
Email: david.balto@dcantitrustlaw.com

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Ian Conner
Director
Bureau of Competition
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. Conner:

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 rein in excessive drug costs and raised concerns in our September 12, 2019 letter to the Commission that AbbVie Inc.'s ("AbbVie") proposed acquisition of Allergan plc ("Allergan") would substantially harm competition.² We write to raise considerable concerns whether any proposed divestiture can remedy the clear anticompetitive effects from the merger.

We are skeptical that the divestiture to AstraZeneca of Allergan's brazikumab, a drug in development,³ can adequately address the anticompetitive effects of the merger. Reportedly, the parties propose divesting Allergan's pipeline IL-23 inhibitor product, brazikumab, to resolve competition concerns related to the overlap in biologic treatments for ulcerative colitis and Crohn's disease. As we detail below, this divestiture raises a number of serious concerns. First, the divestiture of a pipeline product should be disfavored, as suggested by former Director Bruce

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 AbbVie Press Release, *AbbVie and Allergan Announce Agreements to Divest Brazikumab and Zenpep*, January 27, 2020, available at <https://news.abbvie.com/news/press-releases/abbvie-and-allergan-announce-agreements-to-divest-brazikumab-and-zenpep.htm>.

Hoffman’s remarks at a conference in 2018, since pipeline drug divestitures face a “startlingly high” rate of failure and 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.⁴ The divestiture of brazikumab is inconsistent both with Director Hoffman’s concerns, the Commission’s past actions,⁵ and the Commission’s actions in divesting the incumbent product in the Bristol Myers/Celgene merger.⁶ 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.

Moreover, a divestiture of brazikumab faces substantial risks. As detailed below, the immunology product space is dominated by AbbVie which uses a variety of exclusionary tactics to hamper rivals. Current AbbVie rivals face daunting obstacles to competition from these exclusionary contracting practices and have had difficulty overcoming these obstacles. Any acquirer of brazikumab will need a strong market position, including a strong immunology product portfolio, to effectively restore competition. Based on the limited public information, we believe there are signs that AstraZeneca may lack the incentive and ability to fully restore competition. AstraZeneca is the former owner of these assets and was not successful in bringing them to market. It lacks the product portfolio in immunology to adequately compete. The transaction is reportedly structured to place little risk of failure on AstraZeneca. For all of these reasons, AstraZeneca as a potential buyer of the brazikumab assets should be carefully scrutinized.

Finally, AbbVie’s use of rebate walls creates substantial barriers to AstraZeneca’s commercial success in bringing brazikumab to the market and the success of competing products in these therapeutic categories. AbbVie has and is currently engaged in restrictive contracting practices that have enabled the creation of so called “rebate walls” to protect its blockbuster drugs, Humira and Skyrizi, that not only lead to higher prescription drug prices, but foreclose rival drugs from obtaining access to payors’ formularies, resulting in reduced consumer choice.⁷ These strategies are currently used to place Skyrizi in an increasingly dominant position, stifling the ability of current and potential rivals to effectively compete.

As we emphasized in our earlier letter, this merger, by giving AbbVie additional blockbuster drugs, may increase AbbVie’s bargaining leverage including its incentive and ability to engage in even more restrictive contracting practices that will harm competition and consumers by blocking access to new lower-priced more efficacious drugs, inhibiting innovation,

⁴ *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.

⁵ *Amneal Pharmaceuticals LLC/Impax Laboratories Inc.*, C-4650, FTC File No. 1810017 (final order approved on July 10, 2018) (<https://www.ftc.gov/enforcement/casesproceedings/181-0017-c-4650/amneal-holdings-impax-laboratories-matter>) (“Impax Consent Order”) (requiring divestitures of on-market products instead of pipeline products).

⁶ 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.

⁷ For a description of the anticompetitive effect of rebate walls, see Robin Feldman, *Drugs, Money and Secret Handshakes: The Unstoppable Growth of Prescription Drug Prices*, (2019) at 3.1.1. See also, *Profits Over Consumers: How Pharmaceuticals Game the System*, Testimony of Jeffrey K. Francer, Senior VP General Counsel of Association of Accessible Medicines, Before the Subcommittee on Consumer Protection and Commerce of the House Committee on Energy and Commerce, September 19, 2019.

and distorting competition. (We note that both the DOJ and FTC have brought enforcement actions in the past where a merger increased a firm's bargaining leverage even where there was not a direct product overlap.)⁸ As nine U.S. Senators observed in writing to the Commission:

[p]ost-merger, the combined firm would have greater ability to condition buyers' access to these multi-billion dollar drugs on purchases of less popular drugs in their portfolios. They could also use their increased leverage to secure favorable positions on buyers' drug formularies by offering volume-based rebates that competitors with rival products cannot match; these "rebate traps" or "rebate walls" can have the effect of preventing alternative drugs, including more affordable biosimilars and generics, from competing.⁹

Any buyer of brazikumab faces a daunting task in bringing the product to the market and fully restoring competition. Consistent with past enforcement actions, we believe it is absolutely crucial that the Commission impose restrictions on AbbVie's use of rebate walls, to give any buyer of the divested assets a fighting chance to be an effective competitor in the relevant markets and fully restore competition.¹⁰

⁸ The antitrust agencies can bring enforcement actions to challenge acquisitions or enter into settlement agreements that prohibit certain contracting practices 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. The FTC has also 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, e.g., FTC v. OSF Healthcare Sys.*, 852 F. Supp.2d 1069, 1084 (N.D. Ill. 2012) ("[T]he proposed merger in this case would give the combined entity significant bargaining leverage, which would in turn allow the combined entity to extract higher prices from [insurers]."); *FTC v. ProMedica Health Sys., Inc.*, 2011 WL 1219281 (N.D. Ohio Mar. 29, 2011).

⁹ On September 19, 2019, nine senators (Klobuchar, Booker, Baldwin, Smith, Hirono, Sanders, Harris, and Warren) 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>.

¹⁰ FTC consent orders often impose non-structural remedies along with a divestiture requirement to ensure the divestiture is successful. These hybrid remedies are often required to allow the divestiture buyer to successfully integrate the divested assets and begin competing successfully in the relevant market. *CoStar Group Inc*, Docket No. C-4368, Decision and Order (August 29, 2012) ("CoStar Consent Order"). www.ftc.gov/sites/default/files/documents/cases/2012/08/120830costardo.pdf (requiring CoStar to refrain from bundling its products together in ways that could impede its competitors including the divestiture buyer.). *See also, Teva Pharmaceutical Industries Ltd./Barr Pharmaceuticals, Inc.*, C-4242, FTC File No. 081 0224 (final order issued February 9, 2009) (<http://www.ftc.gov/enforcement/cases-45-proceedings/081-0224/teva-pharmaceutical-industries-ltd-corporation-barr>)(*requiring Teva and Barr to provide transitional services to enable the acquirer to obtain all necessary FDA approvals*); *Victrex, plc, Invibio, Inc. and Invibio Limited*, C-4586 FTC File No. 1410042 (July 13, 2016)(consent order in Section 5 case prohibiting Victrex from entering into exclusive supply contracts and from preventing current customers from using alternate products). *see also United States v. Charter Communications Inc, Time Warner Cable Inc, Advance/Newhouse Partnership and Bright House Networks LLC*, (No. 1:16-cv-00759) (D.D.C. April 25, 2016)(prohibiting New Charter from entering into any agreement forbidding, limiting or creating

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.¹¹ This potential remedy cannot meet that standard.

I. Divestitures of a Pipeline Product Alone Are Unlikely to Fully Restore Competition

We are unsure where the Commission is in its investigation of the transaction, however, it appears as if the parties are proposing a divestiture of pipeline assets to resolve the competitive overlaps of IL-23 inhibitors and a divestiture of Allergan’s Zenpep, which competes with AbbVie’s Creon, to Nestle to resolve the overlap in pancreatic enzyme therapy for exocrine pancreatic insufficiency.¹² As indicated previously, we are concerned that divestitures of pipeline drugs may not fully restore competition.

Divestitures of pipeline assets raise significant competitive concerns. After all, divestitures of pipeline assets in the pharmaceutical industry are often unsuccessful in terms of actual product launches, especially in a situation like the immediate one where the overlap involves an on-market drug, Skyrizi, and brazikumab, a pipeline product.¹³ Indeed, former Director Bruce Hoffman explained that an internal study at the Commission revealed that the rate of failure was “startlingly high” for divestitures of certain pharmaceutical pipeline products.¹⁴ He 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.¹⁵ We agree with Mr. Hoffman that consumers should not bear the risk of an unsuccessful divestiture and that divestiture of pipeline assets should be strongly disfavored.

We note that the FTC staff studied pharmaceutical pipeline divestitures in its 2017 merger remedy study. It 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. We respectfully

incentives to retaliate against a video programmer for providing content to online video distributors); *United States v. Anheuser Busch InBev SA/NV*, No. 16-1483 Modified Final Judgment (October 22, 2018)(prohibiting 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.”); *United States v. Ticketmaster Entertainment Inc.*, No. 1:10-cv-00139-RMC, Amended Final Judgment (January 28, 2020) (prohibiting Live Nation from threatening to withhold concerts from a venue if the venue chooses a ticketer other than Ticketmaster.)

¹¹ “[R]estoring competition requires replacing the *competitive intensity* lost as a result of a merger...” rather than just maintaining premerger levels. *Fed. Trade Comm’n v. Sysco Corp.*, 113 F. Supp. 3d 1, 72 (D.D.C. 2015) (emphasis in original).

¹² Nestlé Press Release, *Nestlé acquires Zenpep, expanding its medical nutrition business*, January 27, 2020. <https://www.nestle.com/media/pressreleases/allpressreleases/nestle-medical-nutrition-business-acquisition-zenpep>. We are not addressing this divestiture in this letter, but we raise the question of whether Nestle can step into the shoes of Allergan and provide the same competitive intensity that Allergan was able to provide and whether it has the same incentive and ability to do so. *Sysco*, 113 F. Supp. 3d at 72.

¹³See Impax Consent Order.

¹⁴ *It Only Takes Two to Tango*.

¹⁵ *Id.*

suggest the FTC staff was asking the wrong question.¹⁶ There was no analysis of whether the pipeline assets were used or used effectively or whether they ultimately resulted in a product coming to market.

Mr. Hoffman’s observation that the rate of failure for pipeline assets was “startling high” strongly suggests there should be a strong preference for divestiture of the in-market product. As buyers of drugs for Crohn’s disease and ulcerative colitis and as representatives of thousands of patients and consumers suffering from these diseases, we strongly believe that the Commission should divest the on-market drug, Skyrizi. History has demonstrated that divestiture of pipeline assets often fail. There is too much at stake for these vulnerable patients and payors to have them bear the risk of a failed remedy.

The FTC has a significant burden to make sure that the divestiture buyers have the incentive and ability to fully restore competition and replace the competitive intensity lost by the merger of two rivals.¹⁷ In order to meet these goals, a superior approach is the divestiture of the in market product, which was recently required in the FTC’s Consent Order approving Bristol-Myers Squibb Company’s acquisition of Celgene Corporation. In that Order, Celgene’s Otezla was sold to Amgen instead of BMS’ pipeline product.¹⁸

II. AstraZeneca is a Questionable Divestiture Buyer

We believe there are important questions that raise concerns whether AstraZeneca is a suitable buyer and would have the incentive and ability to fully restore competition. As we detailed in our earlier letter, AbbVie dominates the immunology product space and other firms face significant challenges in entering and competing, in part, because of AbbVie’s exclusionary contracting practices. Major pharmaceutical firms, such as Valeant Pharmaceutical, Eli Lilly, Novartis Pharmaceutical Corporation, Sun Pharmaceutical Industries Ltd, and Johnson & Johnson have struggled to secure market acceptance. Entering this product space is a daunting

¹⁶ *FTC’s Merger Remedies 2006-2012: A Report of the Bureaus of Competition and Economics*, January 2017, at 31 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. According to the Remedies Study, “For each divestiture relating to pipeline products, i.e. products in development, the divestiture was considered successful if all assets relating to those products were successfully transferred. Staff did not attempt to assess whether the buyer of assets related to pipeline products replaced the acquired firm, in part because there was no but-for baseline from which to compare the buyer’s efforts with those of the acquired firm, nor did staff measure success by determining if the buyer succeeded in launching a product.” So, the Remedies Study is not helpful in determining whether pipeline products were ever approved by the FDA, let alone successfully launched.

¹⁷ *Sysco Corp.*, 113 F. Supp. 3d at 72.

¹⁸ 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. A similar approach was taken in *Amneal/Impax. In the Matter of Amneal Holdings, LLC, Amneal Pharmaceuticals LLC, Impax Laboratories, Inc., and Impax Laboratories, LLC*, File No. 181-0017, Analysis of Agreement Containing Consent Orders to Aid Public Comment, (“Impax”) April 27, 2018 available at https://www.ftc.gov/system/files/documents/cases/1810017_amneal_impax_analysis_4-27-18.pdf “Additionally, in mergers involving complex pharmaceutical products that are difficult to manufacture, the Commission generally will require the divestiture of an on-market product over a pipeline product to place the greater risk on the merging parties rather than the public.”

task because for an entrant to get on to a preferred position on a formulary against AbbVie's rebate wall, it would have to essentially give its product away for free, and even in those cases, the economic incentive for the payor is to keep AbbVie's products in the preferred position.¹⁹

There are serious reasons to raise questions whether AstraZeneca can succeed in this marketplace. AstraZeneca does not actually have any existing portfolio of drugs that treat inflammatory bowel diseases or other autoimmune diseases. It may have other products in the pipeline but that does not improve their position in getting market acceptance. Unlike Allergan, which has related products which might strengthen its ability to secure market access, AstraZeneca does not appear to have any immunology drugs or related drugs. AstraZeneca's commitment to immunology is uncertain. While AstraZeneca owned the brazikumab assets in the past, it made a financial decision to withdraw from commercialization and chose to license the global rights of brazikumab to Allergan in October 2016.²⁰ In other words, AstraZeneca gave up on the assets some three and a half years ago and has conducted none of the development since that time. It is crucial that a buyer of divested assets has the incentive and ability to fully restore competition and AstraZeneca's lack of a product portfolio and their decision to withdraw from this market a few years ago raises concerns over their long-term commitment. We also believe payors may be reluctant to choose a producer with an uncertain commitment.

Moreover, according to AstraZeneca's press release on January 27, 2020, "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."²¹ This is potentially problematic in that Allergan has no incentive to aid the development of a competing product any more than it is contractually obligated to do.²² And once that well of R&D funds runs dry, how much of its own resources will AstraZeneca commit to the project? On the flip side, Allergan is agreeing to invest hundreds of millions to develop a rival product meaning that AstraZeneca may be taking on very little financial risk. The Commission should take a close look because if AstraZeneca is getting a sweet-heart deal, it may lack the financial incentive to commercialize brazikumab. Indeed, a low purchase price may suggest that a firm will lack the full incentive to compete aggressively.²³ The Commission should question whether AstraZeneca is truly invested in these assets not only in the effort to obtain FDA approval, but to actually market brazikumab against the merged firm.

¹⁹ See Aaron Hakim and Joseph S. Ross, *Obstacles to the Adoption of Biosimilars for Chronic Diseases*, JAMA, vol. 317, no. 21 (June 6, 2017).

²⁰ 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#>.

²¹ 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>.

²² *Sysco*, 113 F. Supp. 3d at 77 (A divestiture that calls for a "continuing relationship between the seller and buyer of divested assets" is problematic as it "may increase the buyer's vulnerability to the seller's behavior.")

²³ *United States v. Aetna*, 240 F. Supp. 3d 1, 72 (D.D.C. 2017) (noting that "an extremely low purchase price reveals the divergent interest between the divestiture purchaser and the consumer: an inexpensive acquisition could still 'produce something of value even if it does not become a significant competitor.'")

In this product space with substantial barriers to entry and expansion, any divestiture must be to a firm that possesses the product portfolio and clear commitment to this product space.

III. For Any Divestiture to be Effective AbbVie's Use of Rebate Walls Needs to be Restricted as Part of the Consent Order

AbbVie's use of rebate walls must be addressed as part of any consent order regarding the sale of brazikumab.²⁴ AbbVie's rebate wall involves the coupling of volume-based rebates across multiple indications with penalty provisions, resulting in the withholding of hundreds of millions of dollars from payors that put rival drugs on their formularies.²⁵ AbbVie's rebate wall has kept Humira in the preferred position on formularies while impeding the ability of rival IL-17 and IL-23 inhibitors such as Valeant Pharmaceutical's Siliq; Eli Lilly's Taltz; Novartis Pharmaceutical Corporation's Cosentyx; Sun Pharmaceutical Industries Ltd's Ilumya, and Johnson & Johnson's Tremfya from obtaining the preferred position on formularies for many indications including for moderate to severe psoriasis even though many of these new drugs are clinically superior and lower cost than Humira.²⁶

AbbVie has also used rebate walls based off of Humira's prescription volume to compel payors to put Skyrizi, the IL-23 inhibitor, that will directly compete with brazikumab, in a preferred position on payors' drug formularies.²⁷ These arrangements prevented other competitors from being placed on the formulary or they were permitted only if patients were forced to go through costly step therapy because the rival drugs were in a second or third line position.²⁸ These step therapies can cause significant consumer harm as consumers are prevented from using the most efficacious drug. AbbVie's rebate wall was essentially used to

²⁴ We note that the FTC currently has an ongoing investigation into Johnson & Johnson's use of rebate walls to exclude rivals and protect its blockbuster drug, Remicade. See, Eric Sagonowski, *J&J boasted about defending Remicade from biosims. Now it's under FTC investigation*, Fierce Pharma, July 30, 2019, available at <https://www.fiercepharma.com/pharma/j-j-has-boasted-about-its-remicade-defense-and-now-it-s-under-ftc-investigation>; Johnson & Johnson, Form 10 Q dated June 30, 2019 at 44 ("FTC issued a Civil Investigative Demand to Johnson & Johnson in connection with its investigation of whether Janssen's REMICADE® contracting practices violate federal antitrust laws.") available at <https://johnsonandjohnson.gcs-web.com/static-files/3c846c82-8c94-405c-a707-c32100438f42>.

²⁵ See, e.g., Citron Research, *Citron Research Explains Why AbbVie is on its Way to \$60*, July 24, 2018 available at <https://citronresearch.com/wp-content/uploads/2018/07/Citron-Research-Explains-Why-AbbVie-is-on-its-way-to-60.pdf>; Letter to FTC, September 12, 2019.

²⁶ 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.

²⁷ ZITTER HEALTH INSIGHTS, THE MANAGED CARE MESSAGE MONITOR: PSORIASIS DATA SPOTLIGHT (June 2018), at 6. In June 2018, Zitter reported that "AbbVie continues to promote portfolio contracting opportunity for risankizumab [*i.e.*, Skyrizi] that provides enhanced Humira rebates in exchange for exclusively preferring its pipeline agents".

²⁸ *Id.* A Blue Shield of California representative stated to Zitter that "he/she was 'dubious' of a portfolio contract for Humira in rheumatoid arthritis since AbbVie 'created the Humira contracting monster that shuts all competitors out' and is 'notorious for price increases'".

preserve a formulary spot for Skyrizi until it received FDA approval for moderate to severe psoriasis or other indications.²⁹

Largely because of AbbVie's rebate strategy, Skyrizi, which launched in May of 2019, has been a huge commercial success. Skyrizi now holds the largest position in the psoriasis market, garnering about a 25% share of second and third-line prescriptions³⁰ and is the market share leader for new and switching patients seeking treatment for psoriasis as it has been placed in a preferred formulary position along-side Humira.³¹ Thus, Skyrizi's commercial access is now at parity to Humira on all payors' formularies.³² AbbVie with Humira and Skyrizi has almost 50% of the moderate to severe psoriasis market even though they compete with a handful of IL-17 and IL-23 inhibitors.³³

AbbVie's rebate wall strategy has worked so well that Humira has lost very little share since the introduction of Skyrizi meaning Skyrizi is taking share from other IL-17 and IL-23 inhibitors that have been on the market for several years but have had little success in obtaining preferred formulary access.³⁴ As AbbVie's CEO, Rick Gonzalez puts it, "[w]hen you step back and you look at Rinvoq (AbbVie's JAK inhibitor) and you look at Skyrizi, those two assets will have all of the major indications that Humira have when fully built out, plus one that Humira doesn't have, which is atopic dermatitis. So, if pricing were to stay the same ... you should be able to build these assets to be \$20 bn combined or greater."³⁵ In other words, as Skyrizi continues to grow volume in moderate to severe psoriasis and any new indications, AbbVie will be able to use the same volume-based rebate strategy to foreclose the entry of rival IL-23s including brazikumab, which are not likely to be launched for several years, from ever getting on a payor's formulary as a medicine for Crohn's disease and ulcerative colitis.

Given AbbVie's current exclusionary contracting strategies to protect Humira's and Skyrizi's preferred position on drug formularies, the Commission must address AbbVie's use of rebate walls because left unchecked, they will be used to prevent AstraZeneca from effectively restoring competition and in turn will increase entry barriers for other IL-23 inhibitors. Simply put, without a restriction on rebate walls, AstraZeneca's entry is unlikely to be successful.

Imposing restrictions on AbbVie's anticompetitive contracting practices is consistent with past merger enforcement actions where the Commission and the DOJ have imposed

²⁹ 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."

³⁰ J.P. Morgan Day 3: Skyrizi Momentum Builds, What's Next For Amarin, Viatris Debuts And More, Pink Sheet available at <https://pink.pharmaintelligence.informa.com/PS141500/JP-Morgan-Day-3-Skyrizi-Momentum-Builds-Whats-Next-For-Amarin-Viatris-Debuts-And-More>.

³¹ AbbVie Inc. CEO Rick Gonzalez Presents at 38th Annual J.P. Morgan Healthcare Conference (Transcript) January 15, 2020.

³² AbbVie Q4 2019 Earnings Call Transcript, February 7, 2020.

³³ 38th Annual J.P. Morgan Healthcare Conference.

³⁴ *Id.*; Taltz was superior to Humira in the percentage of patients who achieved both ACR50 and PASI 100 at week 24 available at <https://www.taltz.com/hcp/rheumatology/taltz-vs-adalimumab/primary-endpoint>.

³⁵ J.P. Morgan Day 3.

restrictions on merging parties to facilitate the entry and success of the divested assets.³⁶ Moreover, restrictions on exclusivity are consistent with the FTC action in *Surescripts* last year challenging exclusionary contracts with loyalty and bundled discounts.³⁷ The FTC's complaint describes Surescripts' contracts as including a penalty provision that would discourage customers from using multiple networks or switching away from Surescripts by requiring them to repay loyalty incentives that they previously earned.³⁸ AbbVie's contracting practices appear to be very similar to the exclusionary contracts at issue in *Surescripts*.³⁹

The Commission has the authority and flexibility to craft a consent order in a way to ensure that the relevant markets are competitive.⁴⁰ 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; allow innovative therapies to gain formulary coverage, which will help patients get the prescription drugs they need to better manage their immunology conditions; and 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, rival IL-23 inhibitors 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. Specifically, AbbVie should be prohibited from: entering into or enforcing rebate agreements with payors that limit, or forbid, IL-23 inhibitors access to those payors' drug formularies; entering into rebate agreements that create financial incentives for payors to limit access of rival IL-23 inhibitors; and discriminating

³⁶ CoStar Consent Order (prohibiting bundling its products together in ways that could impede its competitors); see also *United States v. Charter Communications Inc, Time Warner Cable Inc, Advance/Newhouse Partnership and Bright House Networks LLC*, (No. 1:16-cv-00759) (D.D.C. April 25, 2016); *United States v. Anheuser Busch InBev SA/NV*, No. 16-1483 Modified Final Judgment (October 22, 2018); *United States v. Ticketmaster Entertainment Inc.*, No. 1:10-cv-00139-RMC, Amended Final Judgment (January 28, 2020); *Victrex, plc, Invibio*, Consent Order.

³⁷ FTC Press Release, *FTC Charges Surescripts with Illegal Monopolization of E-Prescription Markets*, April 24, 2019, available at <https://www.ftc.gov/news-events/press-releases/2019/04/ftc-charges-surescripts-illegal-monopolization-e-prescription>.

³⁸ *Id.*

³⁹ Pharmaceutical rebates raise even greater concern than rebates or discounts in other industries. Pharmaceutical rebates often lead to higher list prices, which result in higher co-insurance payments by consumers. That is why major consumer groups supported the Administration's proposal to eliminate the antikickback safe harbor for pharmaceutical rebates. 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.”).

⁴⁰ *Victrex, plc, Invibio*, Consent Order. The FTC's consent order prohibited Invibio from entering into exclusive supply contracts; preventing current customers from using alternate products; and using pricing terms in new contracts that could effectively result in an exclusive arrangement between Invibio and a device maker. These prohibited terms include setting minimum purchase requirements; conditioning discounts or important services on a device maker's purchase from Invibio of a specified percentage of its PEEK requirements; and providing retroactive volume discounts.

against, retaliating against, or punishing any payor for providing formulary access to any rival IL-23 inhibitor.

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.

IV. 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 request an opportunity to meet with you to more fully explain our concerns.

Please contact our counsel David Balto at 202-577-5424 at your earliest convenience.

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: Chairman Joseph Simons
Commissioner Noah Joshua Phillips
Commissioner Rohit Chopra
Commissioner Rebecca Kelly Slaughter
Commissioner Christine S. Wilson
Daniel Zach, Acting Assistant Director, Mergers I
Eric Rohlck, Deputy Assistant Director, Compliance
Kari A. Wallace, Mergers I