June 25, 2021

Federal Trade Commission
Office of the Secretary
Room H-113 (Annex X)
600 Pennsylvania Avenue, NW
Washington, D.C. 20580

Re: Pharmaceutical Task Force, Project No. P212900

Dear Secretary:

The undersigned unions, consumer groups and public interest organizations , which represent over 20 million covered lives and millions of consumers, are concerned about the high cost of prescription drugs, escalating healthcare costs, and lack of meaningful patient choice.[1] These organizations work to rein in excessive drug prices and write to support the Federal Trade Commission's ("FTC") pharmaceutical merger review project. We believe that the FTC's current approach to pharmaceutical merger enforcement is too lax and fails to consider the full range of potential harm from the massive consolidation that has occurred over the past several years. Consequently, the FTC's current approach fails to fully protect American consumers and patients and the pharmaceutical industry has become increasingly concentrated, resulting in higher prices and reduced choice.[2]

We write to urge the FTC to adopt a new paradigm on how it evaluates the competitive effects of pharmaceutical mergers. As we describe below, the Commission has been able to adopt new paradigms in several markets when its existing approach failed to fully protect competition and those examples should serve as a model for the task at hand. Our basic points are:

- The FTC should use a reinvigorated and broader look when evaluating pharmaceutical mergers, which expands beyond the limited examination of therapeutic overlaps that has historically resulted in either divestitures of individual products or no action at all.

[1] The groups are Families USA, Public Interest Research Group, Services Employees International Union (SEIU), American Federation of State, County and Municipal Employees (AFSCME), Consumer Action, Alliance for Retired Americans, Doctors for America, Social Security Works, and Treatment Action Group. These comments are authored by David Balto, former Assistant Director for Policy in the FTC Bureau of Competition and attorney advisor to Chairman Pitofsky and Andre Barlow a former Trial Attorney in the Healthcare Section of the Antitrust Division of the Justice Department. Both authors have represented merging parties and third parties in FTC pharma merger investigations and these comments in part reflect their personal experiences in these investigations.

[2] On June 11, 2020, Families USA, American Federation of State, County, and Municipal Employees, American Federation of Teachers, Alliance for Retired Americans, American Family Voices, Consumer Action, Coalition to Protect Patient Choice, Doctors for America, End AIDS Now, Services Employees International Union, Social Security Works, Treatment Action Group, UNITE HERE, and U.S. PIRG Education Fund submitted comments raising substantial concerns that the AbbVie/Allergan Consent Order failed to fully protect competition. available at https://www.consumer-action.org/downloads/coalition/Public_comment_to_FTC_re_AbbVie_Allergan_Consent_Order_6.11.20.pdf.

- The FTC should adapt its approach to consider potential "portfolio" effects, that a merger by consolidating groups of drugs, or skill areas, may enhance the ability to exercise market power beyond individual product overlaps. This is especially a concern for overall innovation and research and development ("R&D"). In addition, the FTC should intensely scrutinize potential killer acquisitions.

- The FTC should broaden its analysis and scrutinize potential or ongoing anticompetitive conduct and take action to stop that conduct. Anticompetitive conduct is endemic in the pharmaceutical market, yet the Commission's approach seems to ignore that conduct in its merger investigations. For example, in the recent Abbvie-Allergan merger the staff appeared to ignore the clear evidence of ongoing anticompetitive conduct, which would be exacerbated by the merger in spite of the fact that nine U.S. Senators and numerous unions and consumer groups raised that as a critical competitive concern.

- The FTC should take a stronger, more comprehensive approach to merger remedies. The FTC must assure that remedies are fully effective in restoring competition. Currently, the FTC does not ask the tough questions necessary when it evaluates divestitures and divestiture buyers. Moreover, there is little to no evidence that divestitures of individual products or assets to divestiture buyers restore competition.

- The FTC must have an independent assessment on whether its remedies in pharma mergers actually perform its statutory obligation in fully restoring competition. As we detail within, the FTC misguidedly claims a 100% success record in pharma merger remedies in its 2017 divestiture study. There is simply no systematic analysis of whether pharma remedies work. The FTC must conduct a comprehensive objective review of its merger remedies to determine whether they are truly effective.

- The FTC must litigate. The FTC expends perhaps more resources on pharma mergers than practically any other market. Yet it has almost never gone to court to challenge a merger. This alone suggests the threshold for challenging mergers is too high. Moreover, it means that the FTC, not the courts, are the sole source of pharma merger "jurisprudence."[3]

These comments will elaborate on what new and evolving theories of harm that the agencies should consider when evaluating pharmaceutical mergers; the consideration of anticompetitive practices as part of the merger analysis; what evidence is necessary to support these new theories of harm; and the types and scope of structural and behavioral remedies that

[3] *See* Diana Moss, American Antitrust Institute Comment to Pharmaceutical Task Force, Project No. P212900, June 23, 2021.

should be used to restore competition. And, finally, we strongly agree with Commissioner Rohit Chopra's sound recommendations to increase the rigor of the FTC's merger investigations.[4]

I. Developing a New Paradigm: Past Experience Can Guide the Commission

The Commission is now facing an unprecedented situation in evaluating its approach to pharma mergers. Yet revising an enforcement paradigm is a sound practice for any enforcement agency. We point to three examples where the Commission effectively developed a new paradigm towards enforcement, that may guide this inquiry.

Pharmaceutical innovation/technology markets. Up until the mid-1990s, FTC pharmaceutical merger investigations were strictly limited to existing products in the market. There was relatively little attention to pipeline products or efforts in R&D. That changed in 1996 in *Ciba-Geigy/Sandoz*,[5] where the FTC challenged a $63 billion merger of two pharmaceutical giants that threatened to produce a monopoly in key technologies used in the development of gene therapy products, which then showed substantial promise for the treatment of various cancers and other medical conditions. The investigation found that technology competition was a major form of rivalry. The case was particularly notable in that the loss of R&D competition was the principal focus of the FTC concern. The case spurred the development and analysis of research and development markets and helped create the concept of innovation markets. And based on the Commission's approach, it has brought numerous cases challenging the loss of competition in technology markets, even where there are no direct product overlaps.

Fundamentally, the Commission recognized that its existing product paradigm was myopic and seeing the broader range of competition identified other areas of competitive concern. As we explain below that is precisely what needs to be done on the staff's current approach.

Hospital merger enforcement. In the 1990s, the FTC lost a series of hospital merger cases, in part because the courts took a myopic perspective on issues like geographic markets and competitive effects. In addition, it chose not to challenge several mergers because of litigation risks. The lack of enforcement led to a surge in consolidation, leading to higher prices, and diminished choice.

In 2001, FTC Chairman Tim Muris decided to address this problem through a series of studies and enforcement actions. The Bureau of Economics, supported by outside academic economists, produced several economic studies of consummated hospital mergers to determine the competitive effects of those mergers. The studies found several examples of mergers that led to increased prices. The Commission challenged one of those consummated mergers, Evanston

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[4] Statement of Commissioner Rohit Chopra, Regarding the Review of the FTC's Pharmaceutical Merger Enforcement Program, Federal Trade Commission, May 11, 2021 available at https://www.ftc.gov/system/files/documents/public_statements/1589927/statement_of_commissioner_rohit_chopra_regarding_the_review_of_the_ftcs_pharmaceutical_merger.pdf.

[5] FTC Press Release, FTC Accord in Ciba-Geigy/Sandoz Merger To Prevent Slowdown in Gene Therapy Development & Preserve Competition in Corn Herbicides, Flea-Control Markets, December 17, 1996 available at https://www.ftc.gov/news-events/press-releases/1996/12/ftc-accord-ciba-geigysandoz-merger-prevent-slowdown-gene-therapy.

Northwestern's acquisition of Highland Park Hospital, which it successfully litigated in administrative litigation.[6]

Those studies and the litigation approach in Evanston created a foundation for stronger hospital merger enforcement and a clear guide to future hospital merger litigation. Based on those studies, the FTC was able to change its hospital merger paradigm and since has successfully challenged numerous hospital mergers.

Ongoing anticompetitive conduct. In 2003, the FTC challenged Unocal's enforcement of patents before the California Air Resources Board because Unocal failed to disclose the existence of these patents in a regulatory proceeding.[7] In 2005, Chevron sought to acquire Unocal. Although the merger posed no direct competitive overlap, the Commission sued alleging the merger could facilitate future coordinated interaction through enforcement of the patents. The merger went forward based on Chevron agreeing not to enforce Unocal's intellectual property rights, saving consumers millions of dollars every year.[8] The important point is that the Commission was willing to use a novel approach to its analysis of competitive effects to challenge significant ongoing anticompetitive conduct. And the ongoing anticompetitive conduct was part of the merger investigation.

II. The Current Approach for Pharmaceutical Merger Enforcement is Limited and Fails to Address Wide-Ranging Issues of Competitive Harm

The standard approach to reviewing pharma mergers focuses primarily on existing product overlaps, and sometimes on products in development.[9] This approach is myopic, and, in doing so, the FTC fails to identify the full range of competitive harms resulting from anticompetitive transactions.[10] By focusing on individual therapeutical product overlaps, the FTC has engaged in a pattern of approving large pharmaceutical mergers with typically modest divestitures of individual overlapping products to resolve very narrowly defined competitive

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[6] *In the Matter of Evanston Northwestern Healthcare Corporation and ENH Medical Group, Inc.*, Comm'n File No. 0110234, April 29, 2008, available at https://www.ftc.gov/enforcement/cases-proceedings/0110234/evanston-northwestern-healthcare-corporation-enh-medical-group.

[7] FTC Press Release, *FTC Charges Unocal with Anticompetitive Conduct Related to Reformulated Gasoline*, March 4, 2003, available at https://www.ftc.gov/news-events/press-releases/2003/03/ftc-charges-unocal-anticompetitive-conduct-related-reformulated.

[8] FTC Press Release, Dual Consent Orders Resolve Competitive Concerns About Chevrons $18 Billion Purchase of Unocal, FTCs 2003 Complaint Against Unocal, June 10, 2005, available at https://www.ftc.gov/news-events/press-releases/2005/06/dual-consent-orders-resolve-competitive-concerns-about-chevrons.

[9] As noted earlier the two authors of these comments have been involved in several FTC pharma merger investigations for merging parties and third parties.

[10] Dissenting Statement of Rebecca Kelly Slaughter, *In the Matter of Bristol-Myers Squibb and Celgene,* Comm'n File No. 191-0061 November 15, 2019 available at https://www.ftc.gov/system/files/documents/public_statements/1554283/17_-_final_rks_bms-celgene_statement.pdf; Dissenting Statement of Rohit Chopra, *In the Matter of Bristol-Myers Squibb/Celgene*, Comm'n File No. 191-0061, November 15, 2019 available at https://www.ftc.gov/system/files/documents/public_statements/1554293/dissenting_statement_of_commissioner_chopra_in_the_matter_of_bristol-myers-celgene_1910061.pdf.

problems.[11] The process is flawed because the two merging companies are not simply a collection of products. There are a variety of skill sets, intellectual assets, and other synergies in each company. For instance, the FTC approved Bristol Myers Squibbs' $74 billion acquisition of Celgene with a divestiture to resolve a concern in the treatment of psoriasis[12] without examining whether the massive merger resulted in any adverse long-term effects on innovation or whether the merger would exacerbate anticompetitive problems in the industry.

As noted by Commissioners Rebecca Kelly Slaughter and Rohit Chopra, the FTC's standard approach is insufficient to determine whether a pharmaceutical merger reduces innovation or other forms of competition.[13] The merger wave may have adversely affected R&D. In the past thirty years, big pharma companies have used their financial resources to grow their drug portfolios through acquisitions rather than through its own R&D. Increasing consolidation in the pharmaceutical industry has led to higher prices for prescription drugs, less consumer choice, and less innovation.[14] Between 1993 and 2015, there were approximately 2,500 deals, of which twenty firms were responsible for 74% of the merger and acquisition spending.[15] Drug prices are skyrocketing to new heights, and R&D spending has dropped.

For example, Pfizer, Inc.[16] and Valeant Pharmaceuticals, Inc.,[17] cut their R&D spending after completing acquisitions, and focused on increased sales of their expanded existing drug portfolios to increase revenues. It is not surprising that merged firms would reduce R&D spending, but what is surprising, and troubling is that an academic study confirms that mergers reduce innovation across the board in relevant portfolios of products as companies in the more concentrated market cut back on R&D.[18] The reason this occurs is because acquirers often target firms that have a relatively similar patent portfolio.[19] That means there is less competition for discovering and developing new therapies. If a non-merging rival is also researching similar

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[11] Analysis of Agreement Containing Consent Orders to Aid Public Comment, *In the Matter of Bristol-Myers Squibb Company and Celgene Corporation*, Comm'n File No 191-0061 (Dec. 6, 2019).

[12] *FTC Requires Bristol-Myers Squibb Company and Celgene Corporation to Divest Psoriasis Drug Otezla as a Condition of Acquisition,* Federal Trade Commission, Press Release, November 15, 2019.

[13] *Supra,* note *10.* Slaughter Dissenting Statement, Bristol Myers.

[14] *See* Barak Richman, et al., *Pharmaceutical M&A Activity: Effects on Prices, Innovation, and Competition*, 48 LOY. U. CHI. L. J. 787, 790-91 (2017); Meagan Parrish, *What's Behind all the M&A Deals in Pharma*, PHARMA MANUFACTURING (July 31, 2019).

[15] *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.

[16] 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.

[17] 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.

[18] 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.

[19] *Id.*

therapies, that non-merging rival also now has one less competitor. So, rivals benefit from the reduction in competition and cut back on R&D spending just as the merged firm does.[20]

Unfortunately, the FTC's current approach does not examine whether large pharmaceutical mergers will have long term effects on innovation unless there are specific overlaps in the merging drug manufacturers' pipelines that would raise an innovation concern. While the FTC must always be on the lookout for "killer acquisitions" whereby an incumbent manufacturer buys out a smaller firm that is innovating within the same therapeutic category and mechanism of action of the incumbent,[21] this focus on separate markets may not make sense for large pharmaceutical mergers when examining innovation concerns because some discoveries in the pharmaceutical area may result from R&D efforts in a totally different category.[22] We believe that it is imperative that the FTC broadly examine whether a pharmaceutical merger is likely to hinder innovation. In its merger reviews, the FTC needs to request documents and information that will help the agency understand the extent to which research directed at one particular therapeutic category may or may not have spillover effects into other areas. This type of evidence would help the agency determine whether the merger may reduce innovation in the long term.

The FTC needs to look at a broader range of issues instead of the direct overlaps. For example, a firm may want to acquire a rival because it will acquire bargaining leverage by acquiring complementary non-competing drugs. Or a merger may bring together complementary skill sets that may give it a competitive advantage or cut off access to necessary complementary skill sets. Ultimately, the Commission needs to be engaging in a broader inquiry of why the acquisition is occurring and attempt to identify the competitive rationale.

In addition to failing to identify whether mergers hinder innovation, the current approach fails to address whether a merger is likely to exacerbate or facilitate anticompetitive conduct. This is a significant problem in the pharmaceutical market where anticompetitive conduct is endemic. Most recently, the FTC approved two mergers using the standard approach even when the Commission had information that the merging parties were engaged in ongoing anticompetitive conduct. First, the FTC approved a merger between Pfizer's Upjohn division and Mylan without considering the fact that the companies had been accused of price fixing.[23] Second, the FTC approved AbbVie's acquisition of Allergan using the standard approach even though it was widely known that AbbVie and Allergan were involved in countless government and private antitrust suits challenging an array of anticompetitive practices.[24] We believe that the FTC must carefully consider the facts in each specific merger to understand whether or how it may facilitate anticompetitive conduct.

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[20] *Id.*

[21] Colleen Cunningham, Florian Ederer, and Song Ma, "Killer Acquisitions" Working Paper (Washington Center for Equitable Growth, 2019), available at https://equitablegrowth.org/working-papers/killer-acquisitions.

[22] Interview with Commissioner Thomas B. Leary, 19 (3) A.B.A. Antitrust Health Care Chronicle 1, 5 (2005), https://www.ftc.gov/public-statements/2005/09/health-care-interview-commissioner-thomas-b-leary.

[23] Dissenting Statement of Commissioner Rohit Chopra Joined by Commissioner Rebecca Kelly Slaughter, *In the Matter of Pfizer Inc./Mylan N.V.*, Comm'n File No. 191-0182 (Oct. 30, 2020).

[24] Dissenting Statement of Commissioner Rohit Chopra, *In the Matter of AbbVie/Allergan*, Comm'n File No. 1910169, May 5, 2020 available at https://www.ftc.gov/system/files/documents/public_statements/1574583/191-0169_dissenting_statement_of_commissioner_rohit_chopra_in_the_matter_of_abbvie-allergan_redacted.pdf.

The FTC should be seeking all documents and information related to any alleged misconduct that the merging parties have been involved in or are currently engaged in to determine whether the merger is likely to facilitate anticompetitive conduct in the future. There should be careful scrutiny of any ongoing antitrust litigation and any complaints about ongoing conduct should be fully scrutinized.

III. The FTC Must Broaden Its Approach to Include the Consideration of Whether and How the Merger May Facilitate Anticompetitive Conduct

In pharma merger matters, the FTC has simply focused on competitive overlaps and does not remedy any ongoing anticompetitive conduct. Arguably, the law allows for the scrutiny of ongoing anticompetitive conduct especially when the merger increases the merged firm's incentive or ability to use the alleged misconduct to foreclose competition. Indeed, the Supreme Court has held that "the Clayton Act is … concerned with mergers that threaten to reduce the number or quality of choices available to consumers by increasing the merging parties' incentive or ability to engage in conduct that would foreclose competition."[25] Combining the drug portfolios of two merging firms could increase the bargaining leverage of the merged firm in negotiations with payors regarding the placement of the merged firm's drugs on drug formularies at the expense of its smaller rivals. Besides the Chevron matter, there have been several DOJ and FTC matters in which merger consents sought to prevent ongoing anticompetitive conduct.[26]

The most recent matter in which the Commission chose not to address anticompetitive conduct was AbbVie's acquisition of Allergan. Abbvie is renowned for engaging in a broad range of anticompetitive conduct to protect its Humira monopoly, especially sham patent litigation, pay for delay agreements, and rebate walls. As Commissioner Chopra noted the FTC had some evidence suggesting that "AbbVie's rebating practices are suspicious in their own right, and certain aspects of these practices might be unlawful."[27]

The FTC was clearly on notice of the potential harm to competition from AbbVie's use of rebate walls. Indeed, on September 17, 2019, nine Senators, including then-Senator Kamala Harris, wrote a letter to the FTC regarding the AbbVie/Allergan and Bristol Myers/Celgene

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[25] *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.").

[26] *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; *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) (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 form Abbott relating to Androgel because it was concerned that the merger enhanced the ability of the merged firm to coordinate to delay the introduction of the product.)

[27] *Supra* note 24, Dissenting Statement of Commissioner Chopra, *In the Matter of AbbVie/Allergan*.

mergers and they recognized that rebate walls harm competition and reduce consumer choice.[28] The letter noted that "rebate traps or rebate walls can have the effect of preventing alternative drugs, including more affordable biosimilars and generics, from competing."[29] Numerous unions and consumer groups argued that the merger would enable the merged company to more broadly leverage market power through rebate walls to force health insurers and pharmacy benefit managers to agree to exclusionary conditions that hamper the ability of rivals to compete.[30] Yet, in spite of the concerns expressed by the Senators, unions and consumer groups the FTC staff chose not to make rebate walls part of the Second request investigation.[31]

The concerns were straightforward. A rebate wall involves using rebates over a blockbuster drug to deter competition from other drugs in the same or other indications. The Abbvie acquisition would give Abbvie control over Allergan's blockbuster drugs, putting it in a superior position to execute even stronger rebate walls.

It is important to understand that AbbVie's rebate walls are not procompetitive discounts rather they are exclusionary contracting practices that AbbVie uses to limit the ability of rivals from gaining preferred formulary access or block them from getting on formulary at all.[32] AbbVie's rebate walls foreclose competition and harm patients by increasing out of pocket costs and restricting patient access to more effective and affordable prescription drugs.[33] Dr. Wayne Winegarden, director of Pacific Research Institute's ("PRI") Center for Medical Economics and

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[28] Senator Klobuchar News Release, *Klobuchar Leads Warning that Pharmaceutical Mergers May Threaten Drug Competition, Increase Prices and Reduce Patient Access*, September 17, 2019 available at https://www.klobuchar.senate.gov/public/index.cfm/2019/9/klobuchar-leads-letter-warning-that-pharmaceutical-mergers-may-threaten-drug-competition-increase-prices-and-reduce-patient-access-to-essential-medications.

[29] *Id.*

[30] 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 submitted a letter to the FTC regarding AbbVie's acquisition of Allergan. See, Letter to FTC Chairman Simons regarding AbbVie's acquisition of Allergan, September 12, 2019 available at https://docs.wixstatic.com/ugd/1859d0_92f865639fc74293a62fef5c4fe1c62c.pdf.

[31] AbbVie Presentation at the Wolfe Research Inaugural Healthcare Conference, November 6, 2019. AbbVie CEO Richard Gonzalez explained that after the FTC examined the portfolios of AbbVie and Allergan, it identified two overlaps to investigate during the Second Request investigation.

[32] David Balto, Drug Rebate Walls Should Be Dismantled by the FTC's Antitrust Arm, Stat News, December 4, 2018 available at https://www.statnews.com/2018/12/04/ftc-dismantle-drug-rebate-walls/.

[33] Providers and patient groups have raised concerns about rebate walls. See Let My Doctors Decide Announces Expanded Patient Centered Principles and Issues Call to Action to Drive Access and Affordability, Millions of Americans Face Health Insurance Coverage Barriers; Formulary Contracting Increasingly a Concern for Patients and Doctors, November 6, 2020 (urging CMS, employers, insurers, and other decision-makers to adopt patient-centered principles that would eliminate rebate walls) available at https://www.businesswire.com/news/home/20201106005547/en/Let-My-Doctors-Decide-Announces-Expanded-Patient-Centered-Principles-and-Issues-Call-to-Action-to-Drive-Access-and-Affordability;
see also Global Health Living Foundation's comments at the FTC/FDA Joint Biosimilars Workshop available at https://beta.regulations.gov/comment/FDA-2019-N-6050-0012.

Innovation, has demonstrated that rebate walls cause patients to suffer in the form of artificially inflated prices which results in higher coinsurance payments or out of pocket expenses.[34]

Unfortunately, the FTC failed to address rebate walls which AbbVie has used and will likely continue to use to forestall competition in critical immunology markets. The FTC must commit to considering whether and how mergers facilitate anticompetitive conduct.

A. The Commission Should Impose Behavioral Conditions on Merging Firms to Prohibit Them from Engaging in Anticompetitive Conduct That Is Used to Foreclose Competition

If the Commission decides not to block a merger based on anticompetitive conduct, the Commission should at the very least impose behavioral conditions on merging firms to prohibit them from engaging in the conduct in the future especially when the conduct may foreclose competition. Commissioner Chopra raised concerns in his dissent of the FTC's approval of AbbVie's acquisition of Allergan that the FTC had evidence suggesting that AbbVie used its bargaining leverage and rebates to not only protect its blockbuster drug, Humira, but also to favor its newly launched drugs, Skryizi and Rinvoq.[35] Simply, the chances of the divested assets succeeding are bleak so long as Abbvie can continue to use rebate walls.

Consumer groups raised a similar concern noting how the merged firm could use the same strategy to prop up Allergan's portfolio of assets to preferred positions on payors' drug formularies.[36] It seems clear from the *Unocal* matter and other government enforcement actions that the agencies have the power to remedy ongoing anticompetitive conduct.[37] Yet the FTC chose not to address the concern in its remedy in AbbVie/Allergan. Given AbbVie's history of engaging in rebate practices that foreclose competition and the fact that the merger increased AbbVie's ability and incentive to engage in rebate wall strategies to inhibit the ability of rival drugs to get on a preferred position on drug formularies, the Commission should have crafted a behavioral remedy prohibiting AbbVie from implementing rebate walls. This was a mistake and the FTC should scrutinize the results of the Abbvie merger in the future.

We encourage the FTC to examine mergers that may results in increased bargaining leverage to engage in anticompetitive contracting practices that could foreclose competition, and, in those situations, it should either block the merger or at the very least, use behavioral

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[34] Wayne Winegarden, Tearing Down Drug Rebate Walls Would Save Patients and Improve Healthcare Outcomes, Pacific Research Institute, December 9, 2020 available at https://www.pacificresearch.org/new-brief-tearing-down-drug-rebate-walls-would-save-patients-improve-health-care-outcomes/.

[35] *Supra* note 24, Dissenting Statement of Commissioner Chopra, *In the Matter of AbbVie/Allergan*; 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."

[36] *Supra* note 2. Union and consumer group comment regarding AbbVie/Allergan Consent.

[37] CoStar Group Inc, Docket No. C-4368, Decision and Order (August 29, 2012) ("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).

restrictions to protect consumers. In addition, we urge the Commission to investigate rebate wall practices.[38]

IV. Merger Remedies Increasingly Fail to Restore Competition

We are concerned that the FTC's merger remedies increasingly fail to restore competition. While the FTC does its best to construct effective divestiture remedies, the government can never be certain how the divestiture buyer will perform with the divested assets in the future. Although the FTC has brought more pharmaceutical merger consents (67) than any other area there is little evidence these divestitures succeed in fully restoring competition.

- The FTC has never done a systematic retrospective to see if a remedy in an individual matter worked.

- In its 2017 divestiture study the FTC makes the remarkable claim that it had a success rate of 100% because in all 32 matters in which pipeline assets were divested, the assets were successfully transferred.[39] This is not the proper measure of success. Just because assets are transferred does not mean competition is fully restored. What is critical is whether a firm that acquires the assets fully restores competition. The staff simply failed to ask the meaningful question.

- In generic mergers Commissioner Chopra points out, "there is a 25% failure rate in our generic drug settlements, where the Commission settles an illegal merger by approving a divestiture to another firm, only to find that the buyer abandons the market. This figure may actually be a gross underestimate of failure, since it sets an artificially low bar for success."[40] Commissioner Chopra is exactly right because a divestiture buyer that may still be in the market may not be performing as well as the previous owner was for a number of reasons, but the FTC would count the divestiture of the product overlap as a success even if the divestiture failed to fully restore competition.

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[38] 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.

[39] 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 (FTC Remedy Study).

[40] Statement of Commissioner Rohit Chopra, Regarding the Review of the FTC's Pharmaceutical Merger Enforcement Program, citing to John Kwoka, Controlling Mergers and Market Power: A Program for Revising Antitrust in America 142 (Boston Competition Policy International, 1st ed. 2020) (criticizing the FTC's 2017 Remedies Study for the criteria it uses for claiming a merger remedy was a "success").

- Simply, there is no current basis to measure the success or failure of the FTC pharma merger enforcement program. Nor is there any measure of the public benefits of those 67 enforcement actions.

Not surprisingly, the existing empirical evidence suggests that structural remedies often fail to prevent harm to competition across industries.[41] In fact, consumers face fewer choices and pay higher prices in several industries because of failed merger remedies in the grocery store,[42] dollar store,[43] and rental car industries.[44]

There is even more reason to be skeptical when the Commission requires the divestiture of a drug in development, which is what occurred in the Commission's approval of AbbVie's acquisition of Allergan. There, the FTC required a divestiture of Allergan's brazikumab, instead of a drug that was already in the market, such as AbbVie's drug, Skyrizi. This was a very risky approach. Former Director of the Bureau of Competition, Bruce Hoffman, claimed in a speech that divestitures of pipeline drugs face a "startingly high" rate of failure and such a divestiture places "a greater risk of failure … on the American public."[45] Director Hoffman blamed this high failure rate on the difficulty of the divestiture buyer in actually getting the pipeline pharmaceutical to market and noted that it is "entirely proper that the risk of failure be placed" on the merging parties and not consumers.[46] Yet the Commission ignored Director Hoffman's guidance in Abbvie-Allergan. We believe that the FTC should adopt a policy whereby it demands divestitures of in-market drugs over pipeline drugs as the divestiture of an in-market drug provides more certainty.

The FTC needs to do a better of job of monitoring any consent that it enters into with merging parties and divestiture buyers. We recommend that in the future, the FTC should demand that parties to consent orders report back on at least a quarterly basis on how the remedy

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[41] John Kwoka, Merger Remedies: An Incentives/Constraints Framework, The Antitrust Bulletin, Vo. 62 (2017).
[42] In 2015, the FTC approved Safeway's acquisition of Albertson's, a large grocery merger, on the condition that the merged company divest 146 stores to Haggens, a small chain of 18 stores. Within months, that small chain filed for bankruptcy and the merged company wound up buying back about 36 stores. Ana Marum, Failed divestiture: Albertsons is bidding on 36 Haggen stores, including some it used to own, The Oregonian, November 10, 2015. https://www.oregonlive.com/window-shop/index.ssf/2015/11/albertsons_bids_on_36_haggen_s.html
[43] In 2015, the FTC conditioned Dollar Tree's acquisition of Family Dollar, a merger of dollar stores, on a divestiture of stores to Sycamore, a private equity firm. The private equity buyer sold the assets to the other large national dollar store player, Dollar General, within 21 months. FTC Press Release, "FTC Approves Sycamore Partners II, L.P. Application to Sell 323 Family Dollar Stores to Dollar General", April 27, 2017. https://www.ftc.gov/news-events/press-releases/2017/04/ftc-approves-sycamore-partners-ii-lp-application-sell-323-family
[44] In 2012, the FTC conditioned Hertz's acquisition of Dollar Thrifty on a divestiture of Advantage and other assets to a small rental car company, FSNA, backed by a private equity fund. The Advantage buyer filed for bankruptcy within a year only to have some of the assets auctioned back to Hertz. Brett Kendall, How the FTC's Hertz Antitrust Fix Went Flat, Wall Street Journal, December 8, 2013. https://www.wsj.com/articles/how-the-ftc8217s-hertz-antitrust-fix-went-flat-1386547951?ns=prod/accounts-wsj
[45] *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 *available at* https://www.ftc.gov/system/files/documents/public_statements/1318363/hoffman_gcr_live_feb_2018_final.pdf.
[46] *Id.*

is working for a period of five to ten years. This would help the FTC keep track of whether the remedy is effective and allow for the FTC to intervene if necessary.

A. The FTC Needs to Conduct a Comprehensive Independent Study of its Pharma Merger Remedies

The FTC is well aware of and proud of its work on merger retrospectives. Indeed, one of the unique roles of the Commission is its ability to conduct these studies often with the use of process. As the Evanston example, illustrates, sound careful retrospectives can assist the agency in its merger enforcement mission. As former Chairman Joseph Simons has observed:

> [M]erger retrospective studies can be an important asset in persuading courts to block anticompetitive mergers. … First, merger retrospectives can help validate prospective merger review tools. Testing the efficacy of these tools can demonstrate to the courts that these tools are effective at identifying anticompetitive mergers. Second, retrospective studies can provide an empirical basis for a merger challenge. For example, these studies can help to persuade a court that a merger is anticompetitive by showing that similar mergers in the past resulted in anticompetitive outcomes.[47]

The Commission has never done a retrospective of a consummated pharma merger. To the extent the FTC studied these remedies it found they were entirely successful. As we noted earlier that was because the FTC asked the wrong question – the FTC asked whether IP assets were successfully transferred, not whether competition was fully restored.

We strongly suggest that the FTC conduct formal retrospectives of pharma mergers especially those which raised controversial issues. The Commission should use outside academic experts for these studies to assure independence. The studies should address a full range of issues and not just price effects. These remedy retrospectives can aid future enforcement actions, as the hospital merger example demonstrates.

B. The FTC Needs to Increase its Scrutiny of Divestiture Buyers

Finding a suitable buyer in pharmaceutical drug markets is a daunting task. Under the law, a remedy is permissible only where it fully restores competition and "restoring competition requires replacing the competitive intensity lost as a result of a merger…" rather than just maintaining premerger levels.[48] This essentially means that the divestiture buyer must have very similar capabilities as the seller of the divested assets. In the FTC's approval of AbbVie's acquisition of Allergan, the Commission approved product divestitures to Nestle and AstraZeneca and neither met the appropriate standard. First, Nestle is not a pharmaceutical

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[47] Prepared Opening Remarks of Chairman Joseph J. Simons, Hearings on Competition and Consumer Protection in the 21st Century, Merger Retrospectives, April 12, 2019 available at https://www.ftc.gov/system/files/documents/public_statements/1513555/merger_retrospectives_hearing_opening_remarks_chairman.pdf.

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

manufacturer with a portfolio of drugs that comes anywhere close to what Allergan had.[49] Second, AstraZeneca, which is a formidable pharmaceutical manufacturer, was nevertheless not a suitable buyer of the pipeline assets that it was acquiring because it did not have the financial incentive or ability to fully restore competition. Even more troubling was that AstraZeneca acquired the assets for nothing. The Commission's statement noted that "AstraZeneca's incentive to develop brazikumab does not depend on how much AstraZeneca paid for those rights but how much money it can make going forward."[50] That is exactly the point. The fact that AstraZeneca did not pay anything reflected its assessment that the product's commercial success was doubtful. Without any substantial financial investment, it lacks the incentives to bring the product to market. The FTC needs to scrutinize the viability and experience of divestiture buyers and whether the buyers have the financial incentives to compete going forward.

C. For a Divestiture of a Pipeline Drug To Be Effective in the Face of a Firm Engaged in Exclusionary Conduct Such As Rebate Walls, the Commission Should Impose Behavioral Restrictions to Ensure that the Merged Firm Is Prohibited From Engaging in that Conduct in the Future

Again, focusing on the FTC's remedy in AbbVie's acquisition of Allergan, we do not believe that Allergan's transfer of brazikumab pipeline assets to AstraZeneca will restore competition because even if brazikumab finally obtains FDA approval and comes to market, it will likely face AbbVie's rebate wall. In situations like this one, where the Commission knows that certain industry characteristics and practices as well as the merged firm's contracts are likely to stifle the entry and expansion of rivals including the divestiture buyer, the Commission needs to use a hybrid approach to remedies by requiring divestitures along with behavioral restrictions on the seller to enhance the likelihood that the buyer will fully restore competition. The FTC and the Department of Justice have both used hybrid remedies in the past where they have imposed conduct provisions prohibiting the merged firm from using restrictive contracts that increased entry barriers of rivals.[51] Given that the Commission has the authority and flexibility to craft consent orders in ways to ensure that the relevant markets are competitive, we believe that the Commission should adopt a policy that when necessary it will impose non-structural remedies along with a divestiture requirement to improve the chances of success.

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[49] Statement of Commissioner Rohit Chopra, Regarding the Review of the FTC's Pharmaceutical Merger Enforcement Program, May 11, 2021; Dissenting Statement of Commissioner Rohit Chopra, In the Matter of AbbVie/Allergan.

[50] Commission Majority Statement Concerning the Acquisition of Allergan by AbbVie, May 5, 2020 available at https://www.ftc.gov/system/files/documents/public_statements/1574619/abbvie-allergan_majority_statement_5-5-20.pdf.

[51] *In the Matter of Simon Property Group, Inc.*, FTC File No. 101-0061 (Jan. 13, 2011); *In the Matter of CoStar Group, Inc., Lonestar Acquisition Sub, Inc., and LoopNet, Inc*., FTC File No. 111-0172 (Aug. 29, 2012). *See United States v. Anheuser Busch InBev SA/NV*, No. 16-1483 Modified Final Judgment (October 22, 2018).

V. We Strongly Support Commissioner Chopra's Recommendations

We urge the Commission to embrace Commissioner Chopra's recommendations.[52] We agree that the Commission should use a reinvigorated and broader look when evaluating pharmaceutical drug mergers. We also agree that the FTC needs to enhance its capabilities to analyze prospective buyers and remedies. To reverse the trend of failed divestitures, the FTC needs to strengthen its process wherever it can. The Commission must go further and demand more of its divestiture buyer candidates because it is critical that they have the proper infrastructure and incentives to succeed. We also agree that the FTC should work closely with the states in merger investigations because the states have a wealth of information gained from their own investigations. The sharing of information could help FTC lawyers and economists with their review. The states have numerous pharmaceutical enforcement actions and have the unique expertise that comes from being close to the concerns of consumers. Finally, as many current and former Commissioners have observed transparency is essential to effective enforcement. We believe the Commission can provide much greater transparency of its merger reviews as outlined in Commissioner Chopra's statement.[53]

VI. Concluding Thoughts

We appreciate the considerable work of Commission staff in evaluating pharmaceutical mergers, but we believe that it is time for the Commission to change its approach from a narrow review of therapeutic overlaps to a reinvigorated broader look that will identify the full range of concerns posed by pharmaceutical mergers. The Commission needs to carefully investigate the potential for pharmaceutical mergers 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. Challenging mergers that reduce innovation and facilitate anticompetitive conduct is a start, but if the FTC decides to remedy these potential harms, it must make sure that its consent orders fully restore competition and protect consumers. And the Commission should always take steps to prohibit the merged firm from engaging in exclusionary conduct when there is evidence that the transaction increases the merged firm's incentive and ability to foreclose competition. It is also necessary for the Commission to demand divestitures on in-market products over pipeline assets and if it does not, demand behavioral conditions along with divestitures of pipeline products to ensure that its remedy will fully restore competition. Finally, the FTC must litigate to block mega-mergers and mergers of firms that have been engaged in past and ongoing anticompetitive and exclusionary conduct.

[52] Statement of Commissioner Rohit Chopra, Regarding the Review of the FTC's Pharmaceutical Merger Enforcement Program, May 11, 2021.

[53] We note that the Commission failed to provide a meaningful response to the extensive public comments filed by the State of California, unions, consumer groups and patient groups, to the proposed Abbvie-Allergan merger. This was in spite of the substantial concerns raised and is inconsistent with the approach of the Department of Justice under the Tunney Act.

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

Respectfully submitted,

Families USA

Public Interest Research Group

Services Employees International Union

American Federation of State, County and Municipal Employees

Consumer Action

Alliance for Retired Americans

Doctors for America

Social Security Works

Treatment Action Group