United States Senate

WASHINGTON, DC 20510

September 17, 2019

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

Dear Chairman Simons:

In light of ongoing consolidation in the pharmaceutical sector, we write to urge the Federal Trade Commission (FTC) to closely scrutinize pharmaceutical mergers that raise competition issues, including AbbVie Inc.'s (AbbVie) $63 billion bid for Allergan plc (Allergan) and Bristol-Myers Squibb Company's (Bristol-Myers) proposed $74 billion acquisition of Celgene Corporation (Celgene).

The past several years have seen a steady increase in mergers and acquisitions across our economy, and the pharmaceutical sector is no exception. In just the first half of 2019, we have seen multi-billion dollar acquisitions announced by Pfizer and Roche in addition to the proposed AbbVie and Bristol-Myers deals. And reports indicate that pharmaceutical mergers and acquisitions are expected to increase.[1] This industry consolidation is occurring against a backdrop of ever rising prescription drug spending and reports that one in four people taking prescription drugs have difficulty affording their medication.[2] It is more important than ever that the FTC take appropriate action to protect consumers from acquisitions that may threaten competition in drug markets, raise drug prices, or reduce patient access to essential medications.

The proposed AbbVie/Allergan and Bristol-Myers/Celgene transactions raise significant antitrust issues. In fact, it has been widely reported that the parties involved in both acquisitions are already preparing to divest certain drug products to resolve potential competition concerns. Allergan announced that it would divest an experimental inflammatory bowel disease therapy, brazikumab, and its marketed pancreatic treatment, Zenpep.[3] Bristol-Myers has already arranged to sell its psoriasis and psoriatic arthritis drug, Otezla,[4] and Celgene has relinquished its rights to an experimental cancer drug, tislelizumab, to its Chinese development partner.[5] While we understand that analyzing and addressing potential antitrust concerns in individual drug markets is part of the FTC's review of pharmaceutical mergers, there are other potential issues that also merit investigation and serious consideration.

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[1] *See* Jack O'Brien, "Pharma M&A Activity Expected to Rise," HealthLeaders (June 13, 2019), at https://www.healthleadersmedia.com/finance/pharma-ma-activity-expected-rise.

[2] *See* "The Pew Charitable Trust, Fact Sheet: A Look at Drug Spending in the U.S." (Updated Aug. 28, 2018), at https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2018/02/a-look-at-drug-spending-in-the-us; Rabah Kamal et al., "Health System Tracker: What are the recent and forecasted trends in prescription drug spending?," Kaiser Family Foundation (Feb. 20, 2019), at https://www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending.

[3] Phil Taylor, "Allergan says it will shed two drugs as AbbVie takeover looms," Pharmaphorum (Aug. 7, 2019), at https://pharmaphorum.com/news/allergan-says-it-will-shed-two-drugs-as-abbvie-takeover-looms.

[4] Alex Keown, "BMS and Celgene Merger Moves Forward with $13.4 Billion Sale of Otezla," BioSpace (Aug. 26, 2019), at https://www.biospace.com/article/amgen-snaps-up-otezla-for-13-4-billion-as-bms-and-celgene-continue-merger-plans.

[5] Alaric Dearment, "BeiGene regains global rights to checkpoint inhibitor from Celgene," MedCityNews (June 18, 2019), at https://medcitynews.com/2019/06/beigene-regains-global-rights-to-checkpoint-inhibitor-from-celgene.

First, we have concerns about the potential impact of these proposed transactions on pharmaceutical innovation. The development of new drugs is essential to fostering competition, reducing drug prices, and ensuring that patients have access to new treatment options. Research has shown that pharmaceutical mergers may have a negative effect on innovation by reducing the competition to discover new therapies.[6] More specifically, reports indicate that AbbVie is planning $1 billion in research and development budget cuts to pay off debt after the merger closes,[7] which does not bode well for innovation at the combined company going forward. If these mergers reduce innovation, competition and patients will suffer.

In addition, combining the drug portfolios of the merging companies may give them increased negotiating leverage to force buyers to provide them with more favorable terms across multiple product categories. The AbbVie/Allergan merger would give the combined company control over AbbVie's anti-inflammatory medication, Humira, the world's top selling drug with U.S. sales of more than $10 billion, as well as Allergan's dry eye drug, Restatis, and Botox. The combined Bristol-Myers/Celgene would control Bristol-Myers's cancer drug, Opdivo, and the anticoagulant, Eliquis, in addition to Celgene's multiple myeloma drug, Revlimid. Post-merger, the combined firms 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.[8]

Finally, if the competitive issues raised by these proposed mergers are resolved by consent decree, we urge the FTC to take all necessary steps to ensure that any settlements are effective in addressing any threats to competition. If divestitures are included as part of a package of negotiated remedies, it is essential that the FTC ensure that those divested products are able to compete effectively in the market. Comments last year by the Director of the Bureau of Competition indicated that the FTC may no longer allow the merging parties to keep a product that is on the market and divest a product still in development because of a history of problems with such divestitures.[9] Yet news reports suggest that Bristol-Myers/Celgene will be allowed to retain Bristol-Myers's marketed cancer drug, Opdivo, and divest Celgene's development-stage cancer drug, tislelizumab.[10] It also appears that AbbVie/Allergan intends to divest Allergan's development-stage brazikumab to treat Crohn's disease and ulcerative colitis, but retain AbbVie's Skyrizi, which is in late stage development for the same conditions and approved for another use.[11] We urge the FTC to ensure that the divested products in any settlements are

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[6] *See* Justus Haucap & Joel Stiebale, "Research: Innovation Suffers When Drug Companies Merge," Harvard Business Review (Aug. 3, 2016), at https://hbr.org/2016/08/research-innovation-suffers-when-drug-companies-merge; Katy Milani, "Pharmaceutical mergers and megamergers stifle innovation," STAT (July 10, 2019), at https://www.statnews.com/2019/07/10/pharmaceutical-mergers-stifle-innovation.

[7] Stephanie Goldberg, "Huge hurdles ahead for AbbVie-Allergan combo," Crains Chicago Business (June 28, 2019), at https://www.chicagobusiness.com/health-care/huge-hurdles-ahead-abbvie-allergan-combo.

[8] *See* Jay Hancock & Sydney Lupkin, "Secretive 'Rebate Trap' Keeps Generic Drugs For Diabetes And Other Ills Out Of Reach," Kaiser Health News (Jan. 18, 2019), at https://khn.org/news/secretive-rebate-trap-keeps-generic-drugs-for-diabetes-and-other-ills-out-of-reach.

[9] *See* Jenna Ebersole, "Bristol-Myers Squibb, Celgene likely to face longer US antitrust probe," MLex US (Mar. 13, 2019), at https://www.mlexwatch.com/articles/4501.

[10] *See* Alaric Dearment, "BeiGene regains global rights to checkpoint inhibitor from Celgene," MedCityNews (June 18, 2019), at https://medcitynews.com/2019/06/beigene-regains-global-rights-to-checkpoint-inhibitor-from-celgene.

[11] *See* Phil Taylor, "Allergan says it will shed two drugs as AbbVie takeover looms," Pharmaphorum (Aug. 7, 2019), at https://pharmaphorum.com/news/allergan-says-it-will-shed-two-drugs-as-abbvie-takeover-looms.

capable of replacing the market competition that would be eliminated by the merger, even if it means compelling the merging parties to divest the more viable product. As always, if the FTC's competitive concerns cannot be resolved by negotiated settlement, we urge the Commission to take appropriate action in district court to protect competition.

The Federal Trade Commission must carefully consider whether the proposed transactions may lessen competition, stifle innovation, or harm consumers. Thank you for your attention to this matter.

Sincerely,

Amy Klobuchar
United States Senator

Richard Blumenthal
United States Senator

Cory Booker
United States Senator

Mazie Hirono
United States Senator

Kamala D. Harris
United States Senator

Elizabeth Warren
United States Senator

Tammy Baldwin
United States Senator

Tina Smith
United States Senator

Bernard Sanders
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Copy to: Commissioner Noah Joshua Phillips, Federal Trade Commission
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