BlueCross BlueShield Association

1310 G Street, N.W.
Washington, D.C. 20005
202.626.4800
www.BCBS.com

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Maureen K. Ohlhausen
Acting Chairwoman
Federal Trade Commission
Office of the Secretary
600 Pennsylvania Avenue, NW
Room CC-5610 (Annex A)
Washington, DC 20580

Scott Gottlieb, MD
Commissioner
U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Submitted via Federal Trade Commission Web Portal: https://ftcpublic.commentworks.com/ftc/pharmaworkshop/

RE: Federal Trade Commission Workshop on "Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics"

Dear Acting Chairwoman Ohlhausen and Commissioner Gottlieb:

The Blue Cross Blue Shield Association (BCBSA) – a national federation of 36 independent, community-based and locally operated Blue Cross and Blue Shield companies ("Plans") that collectively provide healthcare coverage for one in three Americans – appreciates the opportunity to respond to the Federal Trade Commission's (FTC) request for comments on the *Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics* workshop held on November 8, 2017.

BCBSA is committed to addressing the underlying regulatory and market challenges that are driving up prescription drug costs for everyone. This fall, we released a policy paper, "Ensuring Patient Access to Safe, Effective and Affordable Prescription Medicines," to educate the public about the causes of escalating drug prices and present policy solutions to make the market for drugs work better for consumers. One of the strategies in the policy paper is to reduce barriers that limit competition and consumer choice, particularly those that limit patient access to new, lower-cost drugs.

The FTC Workshop highlighted several BCBSA concerns with such barriers to generic product entry once patent life and exclusivity expire. We appreciate the collaboration at this workshop between the FTC and the Food and Drug Administration (FDA) to address concerns with generic entry in the drug market. Earlier this year, BCBSA submitted comments to the FDA on its July public meeting, "Administering the

Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access." Our recommendations identified several solutions to imbalances in the drug market.

This response to the FTC's request for comments derives themes from BCBSA's comments to the FDA as well as proposals from our recently published policy paper. Our comments focus on the premise that ***patients need timely access to safe, effective, cutting-edge prescription medicines and their generic equivalents at the most affordable price***. We believe the FTC is positioned to address some of these barriers to generic and biosimilar medicines – barriers that once removed will enable competition, improve consumer choice, and make prescription medicines more affordable. Our recommendations call on the FTC to:

- Build on successes discouraging "pay-for-delay" agreements and work with Congress on a legislative solution;

- Work with the FDA to report to Congress on the scope of the REMS and restricted distribution systems abuses where generic manufacturers are unable to obtain samples of a branded product and advise Congress on a legislative solution (e.g., the CREATES ACT);

- Address anticompetitive strategies and tactics, commonly referred to as "evergreening" and "product hopping," related to reformulated prescription drugs; and

- Collaborate with the FDA to identify when a citizen petition delays the approval of a generic and engage in enforcement actions when antitrust laws have been violated.

In what follows, we offer detailed recommendations in response to the FTC's questions as well as additional topics raised during the workshop.

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BCBSA DETAILED COMMENTS AND RECOMMENDATIONS ON IDENTIFYING BARRIERS THAT PREVENT GENERIC DRUGS FROM ENTERING THE MARKET

Issue:

One of the questions from the FTC workshop request for comments involved generic manufacturers having sufficient incentives to enter markets where the brand drug is off-patent. The FTC has identified "pay-for-delay" arrangements as a disincentive for generic entry and an impediment towards a more competitive prescription drug market.

Recommendation:

The FTC should build on its successes in *Federal Trade Commission v. Actavis, Inc.* and subsequent legal briefs to define patent litigation settlements that are anticompetitive. Also, we recommend the FTC advise Congress on a legislative solution prohibiting such agreements.

Rationale:

Congress and FDA created incentives for generic drug manufacturers to submit applications when a brand drug has no blocking patent or exclusivities. These include: (1) a priority review program that expedites applications for the first generic of a reference drug, and (2) a 180-day exclusivity period for the first applicant to submit a complete application ("first-to-file"). Incentives for generic manufacturers are only effective if generic products are developed, approved by the FDA, and marketed to consumers.

Pay-for-delay agreements circumvent these incentives resulting in delayed generic drug market entry. These agreements involve a brand-name drug manufacturer paying a generic drug manufacturer – or making other financial agreements – to not bring lower-cost alternatives to the market. The FTC estimates these anticompetitive arrangements cost taxpayers and consumers $3.5 billion in higher drug costs every year.[1] A recent FTC staff report demonstrates the effect of the *FTC v. Actavis* (2013) U.S. Supreme Court decision that identified patent settlements including payments to generic firms as potential violations of antitrust law. The Bureau of Competition staff reported the number of potential pay-for-delay agreements in FY 2015 was 14 – two years after *FTC v. Actavis* – down from 21 in FY 2014 and a high of 40 potential pay-for-delay agreements in FY 2012.[2] This is a promising trend to discourage such settlements and encourage manufacturers to use the incentives in place – the priority review program and the 180-day exclusivity period mentioned above – as Congress intended.

The Commission is engaged in a decades-long effort to curb arrangements that block competition from lower cost drugs. We encourage the FTC to continue monitoring private settlements, pursue litigation and file *amicus* briefs when necessary, and advise Congress on a legislative solution prohibiting such agreements.

Issue:

The FTC inquired about reports of "strategies to reduce generic drug competition when the branded drug is off-patent." There are well-documented reports, including comments from the FTC and the FDA, of

[1] Federal Trade Commission. "Pay-for-Delay: When Drug Companies Agree Not to Compete." https://www.ftc.gov/news-events/media-resources/mergers-competition/pay-delay.

[2] Federal Trade Commission. "Agreements Filed With the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in Fiscal Year 2015: A Report By the Bureau of Competition." 1 November 2017. https://www.ftc.gov/news-events/press-releases/2017/11/ftc-staff-issues-fy-2015-report-branded-drug-firms-patent

brand manufacturers restricting access to brand drugs and engaging in other actions that delay generic drug competition.

Recommendation:

The FTC should work with the FDA to report on the scope of the Risk Evaluation and Mitigation Strategies (REMS) and restricted distribution system abuses where generic manufacturers are unable to obtain samples of a branded product and attain FDA approval. We encourage the agencies to present such a report to congressional committees with jurisdiction on this issue and advise Congress on a legislative solution that addresses all aspects of brand manufacturer activity where generic manufacturers are unable to (1) obtain samples of a branded product; and (2) agree upon a shared safety protocol with a brand manufacturer.

Rationale:

It is well-documented that generic drug firms are facing difficulties accessing product samples of branded drugs, which is a necessary step to generic drug development. In congressional testimony, Markus Meier, Acting Director of the FTC's Bureau of Competition, outlined how brand manufacturers are able to delay entry of generic drugs by: (1) refusing to "provide samples so that the generic firm cannot perform the required preclinical and clinical testing required to complete an ANDA for FDA approval;" and (2) "denying the generic firm access to the existing REMS distribution system so that the FDA cannot approve the generic firm's ANDA application and labelling."[3] Brand manufacturers use limited or restricted distribution systems for drugs without a REMS, with an FDA REMS, or with a self-imposed REMS to deny access to their products.

The Center for Drug Evaluation and Research Director, Dr. Janet Woodcock, stated the Agency has received about 150 "inquiries" from generic product developers regarding difficulty accessing samples for bioequivalence testing.[4] FDA Commissioner Gottlieb has indicated that the agency will begin releasing these letters, as stated in the July 2017 FDA public meeting, to "make more widely known the instances where generic drug makers may be having trouble getting access to branded drugs."[5] Publicizing the letters will inform the public debate by bringing transparency to the scope of REMS abuses.

The FTC and FDA should collaborate on a report of these market abuses to date, building in these FDA public letters, the Commission's *amicus* briefs for antitrust cases, and other available information. While

[3] Markus H. Meier, Acting Director, Bureau of Competition, U.S. Federal Trade Commission. Prepared Statement before the House of Representatives Judiciary Committee Subcommittee on Regulatory Reform, Commercial and Antitrust Law on "Antitrust Concerns and the FDA Approval Process." 27 July 2017.
[4] Congressional Research Service. "FDA Risk Evaluation and Mitigation Strategies (REMS): Description and Effect on Generic Drug Development." 11 April 2017.
[5] Scott Gottlieb, M.D., Commissioner of Food and Drug Administration. Opening remarks on the FDA Part 15 Public Meeting, Generic Drug Competition. 18 July 2017.

there is a body of evidence regarding these abuses and Congress has held investigatory hearings, a joint report from the FTC and FDA would provide a convincing argument for congressional action. We urge the FTC and the FDA to present this report to Congress and work with legislators on a solution that provides a safe, efficient and targeted pathway to end these abusive, anticompetitive practices.

BCBSA supports H.R. 2212 / S. 974, the CREATES Act, to produce such a pathway, make brand-name products available to generic manufacturers, and more expeditiously bring lower cost generics to consumers in accordance with the Hatch-Waxman amendments. We call on the FTC and FDA to publicly support this legislation and call for its passage.

Issue:

The FTC inquired about the steps being taken that reduce generic drug competition. Several speakers at the workshop mentioned brand manufacturer product lifecycle management strategies that may be anticompetitive.

Recommendation #1:

The FTC should confront anticompetitive strategies and tactics related to reformulated prescription drugs when market actions have the impact of delaying the availability and / or take-up of generic drugs.

Rationale #1:

The success of the generic market is dependent on the ability to substitute generic products for brand products at the doctor's office and the pharmacy. The brand drug manufacturer practices of "evergreening" and "product hopping" are a direct challenge to the generic market and lead to increased spending on prescription drugs without measureable improvements in quality and outcomes. Prohibiting such anticompetitive tactics will bring generic options and lower costs to consumers more quickly.

Most brand drug reformulations are categorized as improvements to existing therapies and not necessarily timed to infringe on the entry of generic competitors. However, the presumed medical benefit from these reformulated products serves only to prolong patent protections and thwart generic entry for less expensive, clinically comparable therapies. This includes activity when the manufacturer engages in a hard switch (the original product is pulled from the market and replaced by the reformulated product) or a soft switch (both products remain on the market). In addition, there are examples of reformulations where there is little evidence of consumer benefit. These include changing a drug from a tablet to a capsule, altering the chemical structure that yields little or no consumer value, and back-to-back

reformulations (e.g., changing form three pills a day, to two pills a day, then to one pill a day).[6] The application filing and market entry of these reformulated prescription drugs often are timed at the end of the original product's data exclusivity.

We encourage the FTC to monitor activity that may be deemed anticompetitive and bring litigation or otherwise engage the participants if antitrust laws have been violated. Interagency coordination and oversight of reformulation prescription drugs and market activity will help to: (1) identify when the primary intent of a manufacturer is to delay generic entry, and (2) discourage similar activity in the future.

Recommendation #2:

The FTC should collaborate with the FDA to identify when a citizen petition delays the approval of a generic, determine if the sole intent is to delay generic drug market entry, and engage in enforcement actions when antitrust laws have been violated.

Rationale #2:

The citizen petition process is a mechanism for the public to request changes in FDA policy. It also has been a mechanism by which brand drug manufacturers tied up FDA resources with the effect of delaying generic drug market entry. In 2007, Congress enacted a law instructing the FDA to not delay the approval of a generic drug because a citizen petition has been filed with the Agency unless a delay is necessary to protect public health.[7] Last year, the FDA finalized guidance ("Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act") that addressed "505(q)" petitions – petitions that specifically request the FDA to act against a generic drug application.

While a few 505(q) petitions may be raising valid medical or safety objections to a generic application, this process is rife with petitioners seeking action to delay generic competitors that are ultimately rejected by the FDA. One study found that brand manufacturers filed 92 percent of all 505(q) citizen petitions. The FDA denied 92 percent of all petitions, 98 percent of all petitions filed within six months of a brand drug's patent life or exclusivity, and 100 percent of petitions where the FDA settles a petition on the same day it approves a generic.[8] We applaud the FTC's action against Shire ViroPharma, Inc., earlier this year citing abuses of both the citizen petition process and the courts to delay generic competition. We encourage the FTC to continue oversight of brand manufacturers' use of this government process and determine if policy changes are necessary to discourage anticompetitive behavior.

[6] Shadowen, Steve D., et. al. "Anticompetitive Product Changes in the Pharmaceutical Industry." Rutgers Law Journal, Vol. 41, No. 1-2, Fall/Winter 2009.
[7] 21 U.S.C. 355(q) or section 505(q) of the FD&C Act.
[8] Carrier, Michael A. and Carl J. Minniti III. "Citizen Petitions: Long, Late-Filed, and At-Last Denied." *66 American University Law Review*. 305. (2016).

Recommendation #3:

The FTC should urge Congress to investigate practices whereby generic and biosimilar products are delayed entry to the market due to questionable patent management strategies. This includes legal arrangements related to branded drug patents where the intent of the arrangement is to avoid judicial and administrative challenges to patents.

Rationale #3:

Congress passed the Hatch-Waxman Act, and later the Biologics Price Competition and Innovation Act, to provide pathways for pharmaceutical companies to bring generic and biosimilar products to market. After a brand drug's exclusivity period ends, generic manufacturers must challenge the validity of a brand drug's patents before seeking FDA approval of a generic product. Generic manufacturers may challenge the validity of drug patents through litigation and/or through the inter partes review (IPR) process under the U.S. Patent and Trademark Office's Patent Trial and Appeal Board. The latter is an administrative process created by Congress with the intent to streamline the consideration of patent validity, including brand drug product patents.

Unfortunately, manufacturers have engaged in behaviors that result in the unwarranted extension of patent protections and delays in consumer access to generic and biosimilar products. One such recent example involves the manufacturer Allergan and one of its top selling drugs, Restasis. Allergan faced challenges of Restasis' patents via the IPR process, and a decision on those patent challenges was expected later this year. To dispense with these patent challenges, Allergan transferred the patent rights to the St. Regis Mohawk Tribe. In return, the Tribe granted Allergan licensing rights to Restasis and moved to dismiss the IPR patent challenge claiming sovereign immunity. Resulting from this financial arrangement with the St. Regis Mohawk Tribe, it has been largely speculated that Allergan may evade challenges to its patents.

We encourage the FTC and Congress to examine questionable drug manufacturer activities that extend the patent life of brand products such as in the example above. Without inquiries and investigations, these tactics and others will continue to proliferate and consumers will lose timely access to lower-cost generic and biosimilar medicines.

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We appreciate your consideration of our comments and proposals to address issues with generic entry in the prescription drug market. We look forward to working with FTC and the FDA and would be happy to provide additional details on any of the recommendations discussed above. If you have any questions, please contact Paul Eiting, Senior Manager, Value-Based Policy, at 202.626.4832 or paul.eiting@bcbsa.com.

Sincerely,

Kris Haltmeyer
Vice President, Legislative and Regulatory Policy
Office of Policy and Representation