



December 7, 2017

Maureen K. Ohlhausen  
Acting Chairman  
Federal Trade Commission  
600 Pennsylvania Avenue, NW  
Washington, DC 20580

Submitted via <https://ftcpublic.commentworks.com/ftc/pharmaworkshop/>

RE: "Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics"; Public Meeting; Request for Comments

Dear Ms. Ohlhausen:

On behalf of the more than 13,500 U.S. members of the American Academy of Dermatology Association (AADA), I appreciate the opportunity to respond to the Federal Trade Commission's (FTC) request for comments on competition in prescription drug markets. The Academy is committed to excellence in medical and surgical treatment of skin disease; advocating high standards in clinical practice, education, and research in dermatology and dermatopathology; and supporting and enhancing patient care to reduce the burden of disease. Access to effective and affordable treatments is a priority for the AADA and we support the FTC's efforts to collect information on potential regulatory changes, specifically inquiring about: (1) incentives and disincentives generic manufacturers consider when deciding whether to enter the market, whether policymakers should alter these incentives and if so, how; (2) strategies being used to deter generic competition; (3) the role of intermediaries such as group purchasing organizations (GPOs) and pharmacy benefit managers (PBMs), including their benefits and costs; and (4) how stakeholders should evaluate proposals to reduce drug prices and improve consumer access.

The AADA appreciates the FTC and the Food and Drug Administration's (FDA) commitment to working together to promote competition in the prescription drug market. The recent FTC workshop served as a valuable venue for collecting ideas regarding potential regulatory changes. The AADA looks forward to further announcements that are components of this work.

### Price Spikes

Dermatology has been affected particularly in that it has experienced increasing prices for both very common generic and specialty medications. For example, dermatologists and their patients experienced doxycycline, an antibiotic, increase from \$20 for 500 tablets in 2013 to \$1,849 a few months later. Similar price increases have also affected clobetasol, a topical steroid. Rising prices of topical drugs are highlighted in the recent Government Accountability Office (GAO) Report titled, *Generic Drugs Under Medicare: Part D Generic Drug Prices Declined Overall, but Some Had Extraordinary Price Increases*. Specifically the analysis led the GAO to highlight that, "topical drugs, such as creams and ointments...represented 46 percent of all extraordinary

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price increases between 2011 and 2012.”<sup>1</sup> The findings of the GAO report align with what dermatologists are experiencing in their offices.

Ongoing drug price fluctuations make it increasingly difficult for dermatologists to prescribe the most cost-effective treatment for patients and for patients to access medically necessary treatments. Dermatologists are often first notified of price increases of commonly used dermatologic generic drugs when their patient discovers the price change at the pharmacy. To protect against large price spikes, the AADA supports requiring pharmaceutical manufacturers to provide public notice before increasing the price of any drug (generic, brand or specialty) by 10 percent or more each year or per course of treatment, and to also provide the justification for the price increase. The AADA recommends that the FTC examine how price increases, specifically for generics, may be limiting access to necessary medications. Additionally, the FTC should work with the FDA to help manufacturers enter the market safely and quickly when prices increase for critical drugs.

### **Importance of Generic Topicals**

Preserving access to affordable and effective dermatologic generic drugs is important to the practice of dermatology. Generic topicals are the first line of defense to prevent a recurrence of a disease or a flare-up, and can often be used to avoid costly surgeries. For example, 5-fluorouracil (5-FU) and imiquimod creams are approved to effectively treat actinic keratosis (AKs) and basal cell carcinomas (BCCs), both of which are common. If AKs or BCCs are treated early with 5-FU or imiquimod creams, this treatment can help prevent invasive skin cancer. Oftentimes there are no therapeutic substitutes, so access to these generic drugs is necessary for successful treatment. A medication’s vehicle and formulation are important in treatment. Creams, ointments, gels and lotions are not all the same and their formulations affect drug bioavailability, treatment effectiveness, and can also contain ingredients to which patients are allergic. Each patient’s circumstances are unique and the recommended course of treatment must be a decision made between a patient and physician.

### **Overview of Current Generic Market and Barriers to Entry**

Today there are several generic manufacturers that operate in a monopoly or duopoly market. A recent study, *High Generic Drug Prices and Market Competition: A Retrospective Cohort Study*, examined “1.08 billion Prescription claims from commercial health plans” between 2008 and 2013. Using the claims, the researchers found 1,120 generic drugs they could study during this time period. The results showed that almost half of the generic drugs were in a duopoly, with many others also operating in a monopoly. When examining price, the researchers concluded that “drugs in the low-competition group exhibited the largest increase in average price (63.8%), followed by the medium-competition (43.8%) and high-competition (9.7%) groups.” When a lower-than-average cost drug was in a market with minimal competition, it experienced higher price increases compared to a higher-than-average cost drug in the same market. The study also found that drugs that served a small patient population often also increased disproportionately.

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<sup>1</sup> Government Accountability Office. *Generic Drugs Under Medicare*. August 2016

Lastly, the authors cite how manufacturers of drugs without many therapeutic alternatives may have more latitude in increasing the price of a drug in a market with minimal competition.<sup>2</sup>

### **Strategies that Reduce Drug Competition for Branded, Off-Patent Drugs**

#### *Risk Evaluation and Mitigation Strategies (REMS) Abuses*

The AADA appreciates the focus the FTC and FDA has brought to the issue of abuses of the REMS program. The AADA supports H.R. 2051, the “Fair Access for Safe and Timely (FAST) Generics Act” and H.R. 2212 / S. 974, the “Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2017,” that are intended to close a loophole in the REMS program that some branded pharmaceutical companies have used to avoid sharing samples of drugs with generic manufacturers that are looking to produce a generic version of the drug. The AADA supports the FDA’s efforts to further examine the REMS program to ensure generic drugs are not inappropriately denied access and thus be delayed from entering the market. The FDA and FTC must address any contract or REMS patent issues that are preventing the sharing of samples, and bring more transparency to ongoing REMS discussions between the generic and brand manufacturers and the FDA. Congress intended for REMS to protect against adverse effects for patients; not prevent competition between manufacturers.

### **Pharmacy Benefit Managers (PBMs) and Pricing Process**

The AADA recommends the FTC also explore the role of PBMs. The AADA supports transparency in how PBMs play a role in setting drug prices for patients. The consolidation of the industry and current financial arrangements must be monitored to avoid a conflict of interest when developing formularies and/or tiers. The AADA believes PBMs must disclose how much of the rebates and discounts are passed onto the patient. Further investigation is necessary to determine the extent to which PBM negotiations and arranged rebates affect formularies, tiers, and drug prices. Lastly, it is unknown whether PBM business practices are having any impact on the use of generics and prices. If the FTC examines PBM practices, it should also look for additional effects on the generic market.

### **The Role of the FTC in Reducing Drug Prices and Increasing Consumer Access**

The FTC can play a large role to play in reducing prices. Financial relationships in the drug market are continually evolving and must be evaluated, along with the impact of these relationships on consumers. Specifically, the AADA recommends that the FTC:

- Evaluate mergers and acquisitions and the potential effects on the supply chain. We continue to experience an increasing number of businesses conducting vertical integration.
- Conduct local visits to stakeholders of the supply chain. The FTC expressed interest in understanding the supply chain, and therefore we encourage the agency to go on site with different stakeholders in the supply chain, including physicians and patients, to better understand the downstream effects of top-level business or regulatory decisions.

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<sup>2</sup> Dave et. al, High Generic Drug Prices and Market Competition: A Retrospective Cohort Study, *Annals of Internal Medicine*. 2017 Aug 1;167(3):145-151. DOI: 10.7326/M16-1432.

- Explore the impact of new entrants into the pharmaceutical supply chain, including the impact this has on the market.
- Monitor potential instances of pay-for-delay and evergreening.
- Investigate the financial relationships in value-based contracts for drugs as the models are developed. A one-size-fits-all approach for these contracts may not be appropriate as more and more consolidation in the market occurs.
- Analyze current reimbursement processes and rebate/coupon structure.
- Examine biosimilars and their effect on competition as they enter the drug supply chain. Currently, there is a slower uptake of biosimilars in the United States. Oftentimes, the biosimilars may not be covered by health plans.

### **Drug Shortages**

Dermatologists have been greatly affected by national shortages of drugs important to their treatment of patients. Currently, there is a national shortage of lidocaine hydrochloride injection with epinephrine, as well as a shortage of sodium bicarbonate, medications used daily and essential to ordinary dermatologic practice. These shortages continue to plague physicians and their patients as many patients, including pediatric patients, are forced to endure painful lidocaine injections without buffering sodium bicarbonate, and/or lidocaine injections without epinephrine. Additionally, because of the shortages, physicians are having to use these drugs sparingly, are facing disrupted workflows, and are delaying surgeries. The only ways to obtain any information regarding the matter is to check the FDA drug shortage website or contact the drug manufacturer directly

The AADA recognizes that shortages can happen for a variety of reasons such as difficulty accessing raw materials or increased demand. The AADA supported language included in the recently passed FDA Reauthorization Act of 2017 which would accelerate the approval of generic drug applications when there is a shortage. With a multifactorial issue such as drug shortages, there is still more that can be done. For example, when there is a national shortage of an important drug, similar to what dermatology is currently experiencing, a formal response by the FDA or FTC should address the issue. First, the AADA recommends that the FTC have a main point of contact for national drug shortages. Provider associations like the AADA frequently become aware of shortages early on, know when they escalate, and can be resources to the FTC. Overall, the AADA requests that the FTC monitor the prices of generic drugs during and after a shortage. Currently, dermatologists are concerned that once the drug is back in stock it will only be available at a much higher price. The AADA also recommends that the FTC analyze whether there are any market trends leading to an increase in drug shortages. The FTC can look to see whether the increase in mergers and acquisitions led to an increase in drug shortages, or if there are other factors impacting the market

### **FTC and FDA Collaboration**

The AADA recognizes that the FTC is not able to regulate drug prices, but that it instead monitors for anti-competitive behavior, with the public being directed to contact the FTC's Bureau of Competition with concerns regarding anti-trust issues. As studies emerge or physicians become aware of potentially anti-competitive behavior, we ask that FTC provide a more streamlined method for submitting information to help with their investigations. Though the FDA works with the FTC on some of the investigations, the AADA recommends

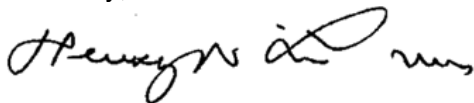
that a more formal information sharing agreement is formed due to the complexity of these situations. This may help better target anti-competitive behavior when it arises.

**Future FTC Work**

We welcome the opportunity to engage in a dialogue as the FTC looks to future efforts to increase access and promote innovation. Specifically, as the FTC implements new policies, we ask that the agency put mechanisms in place that monitor the impacts of the policy changes.

We appreciate your efforts to prioritize this issue. Please feel free to contact Ashley John, Senior Specialist in Advocacy and Policy at [ajohn@aad.org](mailto:ajohn@aad.org) or (202) 609-6332 if you have any questions or if we can provide additional information.

Sincerely,



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