AMERICAN ACADEMY of DERMATOLOGY | ASSOCIATION

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September 15, 2017

Scott Gottlieb, MD
Commissioner
Food and Drug Administration
U.S. Department of Health and Human Services
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: [Docket No. FDA-2017-N-3615] Administering the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access; Public Meeting; Request for Comments

Dear Dr. Gottlieb:

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 Food and Drug Administration's (FDA) request for comments on administering the Hatch-Waxman Amendments. 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 FDA's efforts to collect information to maintain a balance between encouraging innovation in drug development, and accelerating the availability of lower cost alternatives to the public.

The AADA appreciates the FDA's efforts to: 1) prioritize review of generic drug applications until there are three approved generics for a given drug product, 2) publish a list of approved drug products which are off patent and off exclusivity and for which the FDA has not approved a new drug application referencing that drug product, and 3) reduce the generic drug application backlog. The recent FDA public meeting served as a valuable venue for collecting ideas to revamp the Hatch-Watchman amendments. The AADA looks forward to further announcements that are a component of the Drug Competition Action Plan.

Dermatology is unique in that it has experienced increasing prices for both generic and specialty medications. For example, dermatologists and their patients experienced doxycycline, an antibiotic, go from $20 for 500 tablets in 2013 to $1,849 a few months later. Similar price increases have also affected clobetasol, a steroid. Rising prices of topical drugs are highlighted in the recent Government Accountability 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 price increases between 2011 and 2012."[1] The findings of the GAO report align with what dermatologists are experiencing in their offices.

[1] Government Accountability Office. *Generic Drugs Under Medicare*. August 2016

Price Spikes
Ongoing drug price fluctuations make it increasingly difficult for dermatologists to prescribe the most cost-effective treatment for patients. 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% or more each year or per course of treatment, and the justification for the price increase. The AADA recommends the FDA examine how price increases, specifically for generics, may be limiting access to necessary medications.

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 Aldara creams are approved to effectively treat widespread actinic keratosis(AKs) and basal cell carcinomas (BCC). If AKs or BCCs are treated early with 5-FU or Aldara, it can help prevent invasive skin cancer. Often times, there are no therapeutic substitutes, so access to these generic drugs is necessary for successful treatment. The vehicle of application is also important to effectively treat a disease. In some cases, a patient may react better to a cream than a gel or have an allergy to an ingredient in a specific formulation. Each patient's circumstances are unique and the recommended course of treatment must be a decision made between a patient and physician.

Competition and Recent FDA Policy Change
The AADA requests minor adjustments to the new FDA public list of approved drug products that show which products are off patent and off exclusivity, and for which the FDA has not approved a new drug application referencing that drug product. It is recommended to split up the list by vehicle of application and drug class. This will help manufacturers better target where there is a need for a generic. A recent study examined commercial prescription claims to determine estimated price changes and levels of competition. The researchers found that of the 1,120 generic drugs identified in the study more than half were in a duopoly and many were in a monopoly. **"**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."[2] This study demonstrates the importance of competition in the generic market. With this information being more easily accessible, the AADA requests that in addition to updating the public list the FDA monitor if they receive more applications for these off-patent drugs.

FTC and FDA Collaboration
The AADA recognizes that the Federal Trade Commission (FTC) is not able to regulate drug prices, but instead monitors for anti-competitive behavior. The public is directed to contact the FTC's Bureau of Competition with concerns regarding anti-trust issues. As studies emerge or physicians become aware of likely anti-competitive behavior, we ask that the FDA recommend the FTC provide a more streamlined method for submitting information to help with their investigations. It is known that the FDA works with the FTC on

[2] Chintan V.Dave, C. et. al. *High Generic Drug Prices and Market Competition, A Retrospective Cohort Study*. Annals of Internal Medical. July 4, 2017.

some of the investigations, but 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.

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 sodium bicarbonate. This continues 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 shortage, 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 call the drug manufacturer.

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, there needs to be a formal response by the FDA to address the issue. First, the AADA recommends that the FDA have a main point of contact for national shortages of specific drugs. Second, the FDA should provide regular updates to the public regarding the status of a national shortage. Provider associations like the AADA frequently become aware of shortages early on, know when it escalates, and can be a resource to the FDA. Overall, there is a need for greater transparency regarding what the FDA is doing to address drug shortages. Lastly, the AADA requests the FDA to 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.

Risk Evaluation and Mitigation Strategies (REMS) Abuses

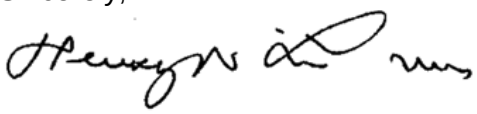
The AADA appreciates the focus the FDA has brought to the issue of abuses of the REMS program. The AADA supports H.R. 2051, the Fair Access for Safe and Timely (FAST) Generics Act" and H.R. 2212 / S. 974, the "Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2017," that are 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 further examining REMS programs to ensure generic drugs are not inappropriately denied access and thus delayed from entering the market. The FDA must address any contract or REMS patent issues that are preventing the sharing of samples as well as bringing more transparency to ongoing REMS discussions between the generic and brand manufacturers and the FDA. Congress intended for REMS to protect against adverse effects; not prevent competition. Lastly, as generics are developed for drugs with REMS programs, we request that they share the same REMS program. If a generic drug were to use a separate REMS program this would place a significant burden on physicians.

Pharmacy Benefit Managers (PBMs) and Pricing Process
The AADA recommends the FDA also explore the role of PBMs. The AADA supports transparency in how PBMs play a role in establishing 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's business practices are having any impact on the use of generics and its prices. If the FDA examines PBM practices, it should also look for additional effects on the generic market.

Future FDA Work
We welcome the opportunity to engage in a dialogue as the FDA looks to future efforts to increase access and promote innovation. Specifically, as the FDA begins to develop guidance on how to show the sameness for complex drugs such as some topical drugs, we are available to serve as a scientific expert resource. Additionally, as more and more biosimilars are approved in the United States the AADA encourages the FDA to reach to provider groups for feedback on education to help with integration into the market. In the future a robust biosimilar market and increasing uptake by physicians will lead to increased competition in the drug market.

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 or (202) 609-6332 if you have any questions or if we can provide additional information.

Sincerely,



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