



**AMERICAN ACADEMY of
DERMATOLOGY | ASSOCIATION**

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March 20, 2020

The Honorable Scott Peters
U.S. House of Representatives
2338 Rayburn HOB
Washington, D.C. 20515

The Honorable Brett Guthrie
U.S. House of Representatives
2434 Rayburn HOB
Washington, D.C. 20515

The Honorable Elliot Engel
U.S. House of Representatives
2426 Rayburn HOB
Washington, D.C. 20515

The Honorable Michael McCaul
U.S. House of Representatives
2001 Rayburn HOB
Washington, D.C. 20515

The Honorable Anna Eshoo
U.S. House of Representatives
202 Cannon HOB
Washington, D.C. 20515

The Honorable Richard Hudson
U.S. House of Representatives
2112 Rayburn HOB
Washington, D.C. 20515

The Honorable Kurt Schrader
U.S. House of Representatives
2431 Rayburn HOB
Washington, D.C. 20515

The Honorable Gus Bilirakis
U.S. House of Representatives
2227 Rayburn HOB
Washington, D.C. 20515

Dear Reps. Peters, Engel, Chairwoman Eshoo, and Reps. Schrader, Guthrie, McCaul, Hudson and Bilirakis:

The American Academy of Dermatology Association (Academy), which represents more than 13,800 dermatologists nationwide, is pleased to offer its support for H.R. 6080, the “Preventing Drug Shortages Act,” which is intended to address drug shortages by providing additional authority to the Food and Drug Administration (FDA) to ensure a stable supply of medications. 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; supporting and enhancing patient care to reduce the burden of disease. One in four Americans suffers from a skin disease. Dermatologists diagnose and treat more than 3,000 diseases, including skin cancer, psoriasis, immunologic disease and many genetic disorders. *This bill is particularly timely during our current national health crisis. It is crucial that we strengthen the drug supply chain during public health emergencies, such as the COVID-19 pandemic.*

The Academy appreciates that H.R. 6080 would improve reporting requirements for drug makers and establish new requirements for makers of active pharmaceutical ingredients (APIs), including notifying the FDA of API shortages as well as the cause, source and expected duration of the shortage; address vulnerabilities in the drug supply chain by conducting periodic risk assessments that identify vulnerabilities and develop plans to mitigate these risks associated with any identified vulnerabilities. H.R. 6080 would also direct the Government Accountability Office (GAO) to issue a report evaluating the FDA’s efforts to prioritize

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applications and inspections for drug shortages as well as assess and improve the FDA's interagency ability to coordinate in response to drug shortages and risk for shortages.

As dermatologists, we are advocating for our patients to have access to medically necessary treatments including sterile injectable medications. We as well as other medical specialties are concerned about the ongoing national shortages of lidocaine with epinephrine, lidocaine, and other local anesthetics. Patients and physician practices are significantly impacted by physicians' difficulty obtaining needed local anesthetics due to critical shortages. Manufacturers and suppliers are filling backorders at an unpredictable and slow pace. Physicians are running out of their stocks before they can obtain replacements.

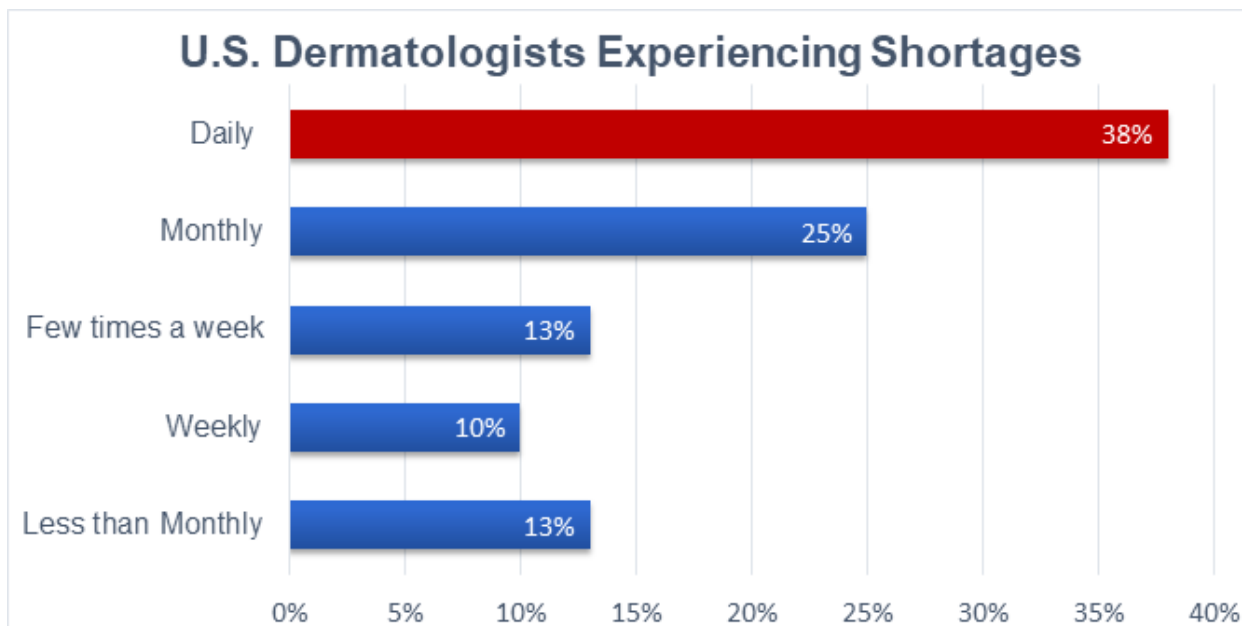
Another sterile injectable medication that continues to be on shortage is sodium bicarbonate, which is added to lidocaine with or without epinephrine using aseptic technique to neutralize the pH of the preparation. This process is called "buffering." The buffering of lidocaine significantly decreases the subjective pain of the injection and increases the onset of the local anesthesia for the patient.¹ According to the American Academy of Dermatology's "Guidelines for the use of local anesthesia in office-based dermatologic surgery: "The addition of sodium bicarbonate to local anesthetic, particularly lidocaine with epinephrine, is recommended to decrease the pain of delivery by subcutaneous or intradermal infiltration."² The strength of this recommendation was given an "A in this guideline meaning that the "[r]ecommendation [is] based on consistent and good quality patient-oriented evidence." Reduced pain from buffered injected anesthetics is important for all patients but is critically important for pediatric patients, adult patients, and patients on blood thinners undergoing large or prolonged procedures (e.g., Mohs micrographic surgical procedures).

In response to the FDA's Drug Shortages Task Force's request for data on the root causes and adverse consequences to patients and health care providers, the AADA surveyed its membership in 2018 regarding ongoing drug shortages. The results show the following:

- 9 in 10 dermatologists believe that drug shortages have negatively impacted patient outcomes- even directly causing patient harm
- 8 in 10 dermatologists have taken time away from patient care to determine alternate treatments due to shortages
- 73% reported that they have had their practice costs increase due to both shortages and resulting substitutions needed
- 4 in 10 dermatologists experience drug shortages daily and 9 in 10 experience it at least monthly

¹ Afolabi O, Murphy A, Chung B, Lalonde DH. The effect of buffering on pain and duration of local anesthetic in the face: A double-blind, randomized controlled trial. *Can J Plast Surg*. 2013 Winter;21(4); 209-212

² Kouba DJ, LoPiccolo MC, Alam M, Bordeaux JS, Cohen B, Hanke CW, et al. Guidelines for the use of local anesthesia in office-based dermatologic surgery. *J Am Acad Dermatol*. 2016 Feb 27. pii: S0190-9622(16)00074.



In the survey, dermatologists also reported that due to shortages, they sometimes had to refer patients to an ambulatory surgery or hospital setting where they could use general anesthesia. In these cases, it was reported that patients were generally pediatric or had a large skin cancer removal on the face or digits. If the dermatologists could have performed the procedure in the office with the appropriate drugs, it would have lowered costs for the patient and healthcare system and decreased the risk to the patient. Additionally, some dermatologists, who specialize in Mohs surgery, reported almost having to close their offices as they cannot perform surgery without lidocaine with epinephrine.

Dermatologists also reported having to delay biopsies of suspicious lesions that confirm the diagnosis of skin cancer. Treating skin cancer effectively early costs less than \$2,000. If not treated early and the cancer becomes metastatic, then treatment can cost up to \$150,000 per year.³ Access to this medication and other treatments for these conditions is not only medically necessary, it is life-changing.

Last January, the AADA communicated its concern to the FDA regarding drug shortages and asked that the FDA and we communicate these asks to you in hopes that you will help us achieve these goals:

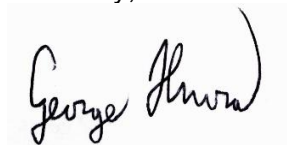
- Create incentives that will encourage manufacturers to produce lidocaine with epinephrine and other local anesthetics during a shortage;
- Allow temporary importation of lidocaine with epinephrine due to the severe backlog of orders;
- Issue a formal response to address the shortages of critical drugs such as in this case to inform stakeholders of the current status and forthcoming developments;
- Have a main point of contact for national shortages of specific drugs for physicians seeking drugs on shortage;
- Provide regular updates to the physicians and the public regarding the status of a national shortage;

³ Lim, Henry W. et al. The burden of skin disease in the United States. *Journal of the American Academy of Dermatology*, Volume 76, Issue 5, 958-972

- Require manufacturers to have plans in place to address and mitigate production issues or delays; and
- Monitor the prices of generic drugs during and after a shortage by both manufacturers and suppliers and work quickly to help mitigate price increases by creating innovative incentives for manufacturers to contain prices.

The Academy has made patients' access to affordable treatments and transparency in drug pricing a top priority. We appreciate your continued leadership in championing patient access issues. Please feel free to contact Christine O'Connor, the Academy's Associate Director, Congressional Policy at coconnor@aad.org or (202) 609-6330 if you have any questions or if we can provide additional information.

Sincerely,

A handwritten signature in black ink that reads "George Hruza". The signature is written in a cursive style with a large initial "G" and "H".

George J. Hruza, MD, MBA, FAAD
President, American Academy of Dermatology Association