



May 20, 2019

Keagan Lenihan
Associate Commissioner for Strategic Initiatives
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Placement of lidocaine with epinephrine, lidocaine and sodium bicarbonate on the proposed essential drugs list

Dear Associate Commissioner Lenihan,

On behalf of the more than 13,800 U.S. members of the American Academy of Dermatology Association (AADA), **I am writing you to express our concern about the ongoing national shortages of lidocaine with epinephrine, lidocaine, other local anesthetics, and sodium bicarbonate along with our support for including these critical drugs on the proposed essential drugs list.** The AADA is committed to excellence in medical and surgical treatment of skin disease; advocating high standards in clinical practice, education, and research in dermatology; and 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 diseases, and many genetic disorders.

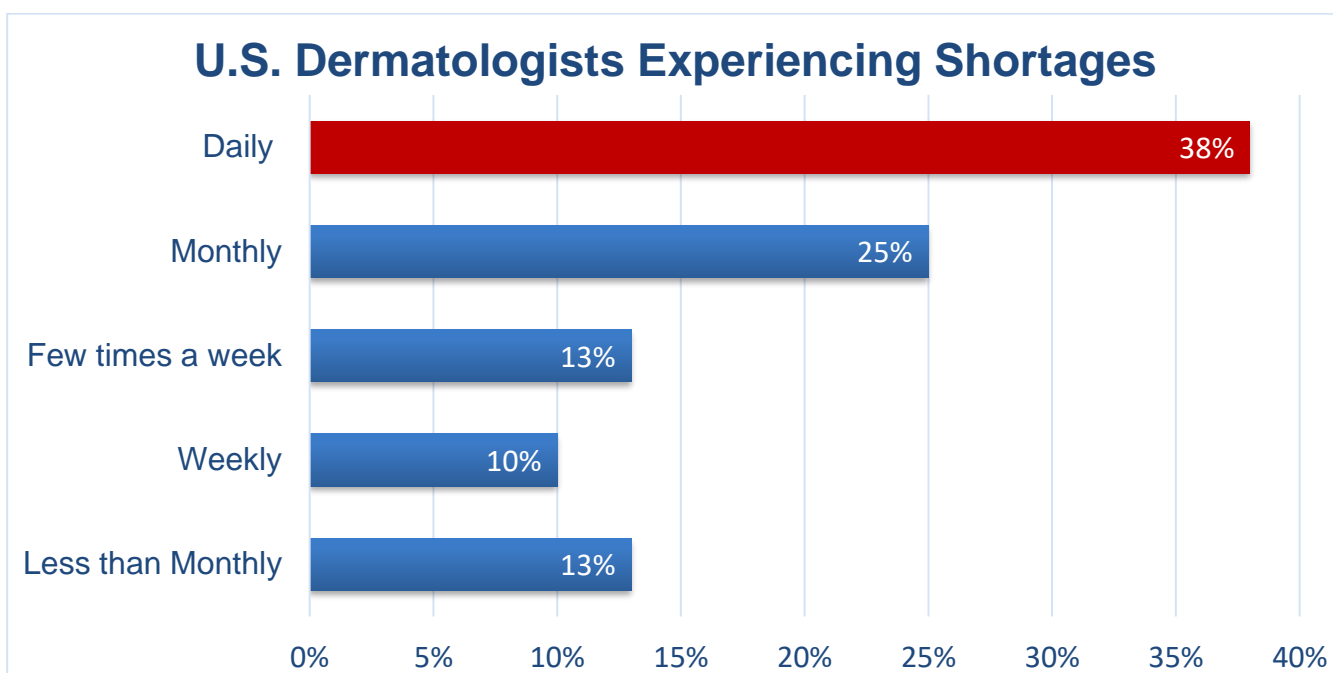
As dermatologists on the front lines fighting skin cancer and treating numerous skin diseases, we are advocating for patients to have access to medically necessary treatments including sterile injectable medications. We write to express our concern regarding the ongoing national shortages of lidocaine 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. Sodium bicarbonate 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 pain of the injection and accelerates the onset of the local anesthesia for the patient.¹ 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).

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.

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



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.² Access to this medication and other treatments for these conditions is not only medically necessary, it is life-changing.

As the task force considers several proposals to address drug shortages, we recommend that sterile injectables such as lidocaine with epinephrine, lidocaine and sodium bicarbonate be added to the proposed essential drugs list. Access to these medications is crucial for the treatment of skin cancer and many other skin diseases. In times, such as now when there is a shortage, more action is needed to ensure the long term sustainability of the supply of these drugs. The creation of an essential drug lists with these drugs on it will allow for the FDA to take further action to mitigate the ongoing shortages.

With a multifactorial issue such as drug shortages, there is still more to be done and we appreciate that the Drug Shortages Task Force is engaging stakeholders. We welcome the opportunity to meet to discuss the survey data in further detail.

Please contact Natasha Pattanshetti, JD, MPH, manager, regulatory policy at (202) 712-2618 or npattanshetti@aad.org if you have any questions or if we can provide additional information.

Sincerely,



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

cc: Irv Bomberger, Interim Executive Director
Barbara Greenan, Chief Advocacy & Policy Officer
Leslie Stein Lloyd, JD, CAE, Director, Regulatory and Payment Policy

² 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.