AMERICAN ACADEMY of DERMATOLOGY | ASSOCIATION

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January 11, 2019

Commissioner Scott Gottlieb, MD
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: [Docket No. FDA-2018-N-3272] Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions

Dear Commissioner Gottlieb,

On behalf of the more than 13,800 U.S. members of the American Academy of Dermatology Association (AADA), I am writing you in response to the request for comments on *Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions* published by the Food and Drug Administration (FDA) on September 10, 2018. 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 our 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. Our dermatologist members of anecdotally reported price increases of drugs currently or previously on shortage.

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 "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

[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.

[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).

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 ask that the FDA:

- 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 shortage 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;
- 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.

We would also like to thank the FDA drug shortages staff, especially CAPT Valerie Jensen, RPh, Associate Director for taking the time to speak with AADA and other medical specialty staff to communicate concerns to manufacturers and provide updates on specific drugs in shortage. 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,

Suzanne Olbricht, MD, FAAD
President
American Academy of Dermatology Association

cc: Elaine Weiss, JD, Executive Director and CEO
Barbara Greenan, Senior Director, Advocacy and Policy
Leslie Stein Lloyd, JD, CAE, Director, Regulatory and Payment Policy