

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 223
(A-22)

Introduced by: American Academy of Dermatology, American Society for Dermatologic Surgery Association, American Society of Dermatopathology, American College of Mohs Surgery, Society for Investigative Dermatology, American Society of Ophthalmic Plastic and Reconstructive Surgery, Louisiana, South Carolina, Missouri, Arizona, International Society of Hair Restoration Surgery, Iowa, Texas, Florida, Mississippi, Kansas, American Academy of Otolaryngology- Head and Neck Surgery, American Association of Neurological Surgeons, Congress of Neurological Surgeons, American College of Rheumatology

Subject: National Drug Shortages of Lidocaine and Saline Preparations

Referred to: Reference Committee B

1 Whereas, Despite repeated legislative attempts to alleviate national drug shortages, critical drug
2 shortages for many medications, including lidocaine, lidocaine with epinephrine, and saline
3 preparations remain; and
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5 Whereas, There is need for greater transparency regarding what actions the Food and Drug
6 Administration (FDA) has taken or plans to take to help alleviate current drug shortages; and
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8 Whereas, Small and independent physician practices have minimal if any bargaining power with
9 drug distributors and wholesalers, and thus are often disproportionately affected by drug
10 shortages. Additionally, products in short supply are frequently allocated based on previous
11 order history, which unfairly discriminates against new or growing medical practices; and
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13 Whereas, National drug shortages negatively impact patients with the potential for delays in
14 care and patient harm; therefore be it
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16 RESOLVED, That our American Medical Association work with national specialty societies and
17 other relevant stakeholders to draft a letter to the FDA calling for direct and prompt actions to
18 alleviate current national shortages of lidocaine and normal saline preparations (Directive to
19 Take Action); and be it further
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21 RESOLVED, That our AMA amend existing HOD policy H-100.956 on National Drug Shortages
22 by addition and deletion to read as follows:
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24 "8. Our AMA supports the view that wholesalers should routinely institute a transparent
25 allocation-based system for distribution of drugs in short supply that does not
26 discriminate against small, independent or new medical practices or those with less
27 purchasing power that attempts to fairly distribute drugs in short supply based on
28 remaining inventory and considering the customer's purchase history." (Modify Current
29 HOD Policy)

Fiscal Note: Not yet determined
Received: 05/11/22

Reference:

US FDA: Current and Resolved Drug Shortages and Discontinuations Reported to the FDA,

<https://www.accessdata.fda.gov/scripts/drugshortages/>

Institute for Safe Medication Practices: Management of Drug Shortages with 0.9% Sodium Chloride, Sterile Water for Injection, and EPINEPHrine, <https://www.ismp.org/resources/management-drug-shortages-09-sodium-chloride-sterile-water-injection-and-epinephrine>

RELEVANT AMA POLICY**National Drug Shortages H-100.956**

1. Our AMA considers drug shortages to be an urgent public health crisis, and recent shortages have had a dramatic and negative impact on the delivery and safety of appropriate health care to patients.
2. Our AMA supports recommendations that have been developed by multiple stakeholders to improve manufacturing quality systems, identify efficiencies in regulatory review that can mitigate drug shortages, and explore measures designed to drive greater investment in production capacity for products that are in short supply, and will work in a collaborative fashion with these and other stakeholders to implement these recommendations in an urgent fashion.
3. Our AMA supports authorizing the Secretary of the U.S. Department of Health and Human Services (DHHS) to expedite facility inspections and the review of manufacturing changes, drug applications and supplements that would help mitigate or prevent a drug shortage.
4. Our AMA will advocate that the US Food and Drug Administration (FDA) and/or Congress require drug manufacturers to establish a plan for continuity of supply of vital and life-sustaining medications and vaccines to avoid production shortages whenever possible. This plan should include establishing the necessary resiliency and redundancy in manufacturing capability to minimize disruptions of supplies in foreseeable circumstances including the possibility of a disaster affecting a plant.
5. The Council on Science and Public Health shall continue to evaluate the drug shortage issue, including the impact of group purchasing organizations on drug shortages, and report back at least annually to the House of Delegates on progress made in addressing drug shortages.
6. Our AMA urges continued analysis of the root causes of drug shortages that includes consideration of federal actions, evaluation of manufacturer, Group Purchasing Organization (GPO), and distributor practices, contracting practices by market participants on competition, access to drugs, pricing, and analysis of economic drivers.
7. Our AMA urges regulatory relief designed to improve the availability of prescription drugs by ensuring that such products are not removed from the market due to compliance issues unless such removal is clearly required for significant and obvious safety reasons.
8. Our AMA supports the view that wholesalers should routinely institute an allocation system that attempts to fairly distribute drugs in short supply based on remaining inventory and considering the customer's purchase history.
9. Our AMA will collaborate with medical specialty society partners and other stakeholders in identifying and supporting legislative remedies to allow for more reasonable and sustainable payment rates for prescription drugs.
10. Our AMA urges that during the evaluation of potential mergers and acquisitions involving pharmaceutical manufacturers, the Federal Trade Commission consult with the FDA to determine whether such an activity has the potential to worsen drug shortages.
11. Our AMA urges the FDA to require manufacturers to provide greater transparency regarding the pharmaceutical product supply chain, including production locations of drugs, and provide more detailed information regarding the causes and anticipated duration of drug shortages.
12. Our AMA supports the collection and standardization of pharmaceutical supply chain data in order to determine the data indicators to identify potential supply chain issues, such as drug shortages.
13. Our AMA encourages global implementation of guidelines related to pharmaceutical product supply chains, quality systems, and management of product lifecycles, as well as expansion of

global reporting requirements for indicators of drug shortages.

14. Our AMA urges drug manufacturers to accelerate the adoption of advanced manufacturing technologies such as continuous pharmaceutical manufacturing.

15. Our AMA supports the concept of creating a rating system to provide information about the quality management maturity, resiliency and redundancy, and shortage mitigation plans, of pharmaceutical manufacturing facilities to increase visibility and transparency and provide incentive to manufacturers. Additionally, our AMA encourages GPOs and purchasers to contractually require manufacturers to disclose their quality rating, when available, on product labeling.

16. Our AMA encourages electronic health records (EHR) vendors to make changes to their systems to ease the burden of making drug product changes.

17. Our AMA urges the FDA to evaluate and provide current information regarding the quality of outsourcer compounding facilities.

18. Our AMA urges DHHS and the U.S. Department of Homeland Security (DHS) to examine and consider drug shortages as a national security initiative and include vital drug production sites in the critical infrastructure plan.

Citation: CSAPH Rep. 2, I-11; Modified: CSAPH Rep. 7, A-12; Modified: CSAPH Rep. 2, I-12; Modified: CSAPH Rep. 8, A-13; Modified in lieu of Res. 912, I-13; Modified: CSAPH Rep. 3, A-14; Modified: CSAPH Rep. 2, I-15; Appended: CSAPH Rep. 04, I-17; Modified: CSAPH Rep. 02, A-18; Reaffirmed: CMS Rep. 08, A-19; Reaffirmed: Res. 105, A-19; Modified: CSAPH Rep. 1, I-20