Resolution: 3
(I-22)

Introduced by: Anirudh Gautam, MD

Subject: Medication Wastage

Referred to: Reference Committee

Whereas, Over 200 drugs have been short each year from 2010 to 2018; and

Whereas, Our AMA and AMA-RFS has policy which acknowledge national drug shortages to be an urgent public health crisis (H-100.956; 80.002R), including to advocate that the FDA take action to alleviate current national shortages of lidocaine, normal saline preparations, and iodinated contrast media (D-120.925); and

Whereas, The Statement from the ACR Committee on Drugs and Contrast media on the intravenous Iodinated Contrast Media Shortage includes recommendations on individual and institutional strategies to reduce waste; and

Whereas, Our AMA has policy encouraging the avoidance of waste in the use of contrast media (H-455.983); and

Whereas, Considerable amounts of anesthetic drug wastage have been observed including 20.6% end of day cost loss of lidocaine; and

Whereas, Drug wastage accounts for a large financial cost in the treatment of malignancies; and

Whereas, The significant source of pharmaceuticals in the environment is household disposal of expired/leftover/unused pharmaceuticals; and

Whereas, Iodinated contrast usage can be safely reduced by up to 83% by using strategies to target utilization such as weight-based dosing, reducing tube voltage, and utilizing noncontrast CT when it will minimally affect diagnostic accuracy; therefore be it

RESOLVED, That our AMA-RFS acknowledge the role of reducing medical wastage in addressing drug shortages; and be it further

RESOLVED, That our AMA support the development and implementation of policies and procedures at a societal and institutional level to reduce the impact of wastage, including by optimizing utilization, while minimizing clinical impact; and be it further

RESOLVED, That our AMA commend ongoing efforts by societies across disciplines in advocating to reduce medical wastage.

Fiscal Note: Minimal
References:


Relevant RFS Position Statements:

80.002R Prescription Drug Shortages, A National Emergency
That our AMA-RFS acknowledge the critical issue of medicine shortages in the United States and support legislative efforts to address these issues. (Resolution 2, I-11)

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 and pharmacy benefit managers 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), pharmacy benefit managers, 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.

D-120.925 National Shortages of Lidocaine, Saline Preparation, and Iodinated Contrast Media

Our AMA will work with national specialty societies and other relevant stakeholders to advocate that the FDA take direct and prompt actions to alleviate current national shortages of lidocaine, normal saline preparations, and iodinated contrast media.

Citation: Res. 223, A-22

H-455.983 Radiographic Contrast Media

(1) Third party payers should provide full reimbursement for the use of the contrast media which is deemed medically necessary by the physician.

(2) Avoidance of waste in the use of contrast media should be encouraged.

(3) The development and implementation by hospitals of procedures and policies to help ensure that contrast media are used when medically appropriate should be supported.

Citation: Joint CMS/CSA Rep., I-90; Reaffirmed: Sunset Report, I-00; Modified: CSAPH Rep. 1, A-10; Modified: CSAPH Rep. 01, A-20