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Title: Impact of Natural Disasters on Pharmaceutical Supply and Public Health
Introduced by: James Szocik, MD, for the Washtenaw County Delegation
Original Author: James Szocik, MD
Referred to: Reference Committee D
House Action: **APPROVED AS AMENDED**

Whereas, in 2017, multiple hurricanes impacted islands in the Caribbean, resulting in direct and indirect damages through destruction of property and loss of municipal power, and

Whereas, recovery in those impacted areas has been slow, with several still without power today, and

Whereas, there is a concentration of pharmaceutical manufacturing in the Caribbean, notably on the island of Puerto Rico, from which the United States receives a significant amount of intravenous fluids and other medications, and

Whereas, hospitals and pharmacies in the United States have seen a shortage of these products, with many shortages expected to continue to worsen further before they improve; therefore be it

RESOLVED: That the Michigan Delegation to the American Medical Association (AMA) ask our AMA to study the impact of natural disasters on the pharmaceutical supply chain and downstream effects on patient care, as well as the adequacy of our governmental response to mitigating these recent natural disasters. And be it further;

RESOLVED: That the Michigan Delegation to the American Medical Association (AMA) asks the AMA to consider the impact of group purchasing organizations on drug shortages.

WAYS AND MEANS COMMITTEE FISCAL NOTE: NONE

CONFLICT OF INTEREST STATEMENT

I have the following conflict of interest to disclose:
Doctor Szocik is employed by Michigan Medicine, which receives federal funding from Medicaid, Medicare; and for resident training; as well multiple private insurance agencies. Doctor Szocik has consulted in the past with MPRO, a peer-review organization.

Relevant AMA Policy:

National Drug Shortages H-100.956

1. 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 experience drug shortages, and will work in a collaborative fashion with these and other stakeholders to implement these recommendations in an urgent fashion.

2. Our AMA supports authorizing the Secretary of Health and Human Services to expedite facility inspections and the review of manufacturing changes, drug applications and supplements that would help mitigate or prevent a drug shortage.
3. 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.
4. The Council on Science and Public Health shall continue to evaluate the drug shortage issue and report back at least annually to the House of Delegates on progress made in addressing drug shortages.
5. Our AMA urges the development of a comprehensive independent report on the root causes of drug shortages. Such an analysis should consider federal actions, the number of manufacturers, economic factors including federal reimbursement practices, as well as contracting practices by market participants on competition, access to drugs, and pricing. In particular, further transparent analysis of economic drivers is warranted. The Centers for Medicare & Medicaid Services should review and evaluate its 2003 Medicare reimbursement formula of average sales price plus 6% for unintended consequences including serving as a root cause of drug shortages.
6. 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.
7. 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.
8. Our AMA will collaborate with medical specialty partners in identifying and supporting legislative remedies to allow for more reasonable and sustainable payment rates for prescription drugs.
9. 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.