AMA
AMERICAN MEDICAL ASSOCIATION

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The Honorable Fred Upton
Chairman
Energy and Commerce Committee
U.S. House of Representatives
2183 Rayburn House Office Building
Washington, DC 20515

The Honorable Henry Waxman
Ranking Member
Energy and Commerce
U.S. House of Representatives
2204 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton and Ranking Member Waxman:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments on the U.S. House of Representatives Energy and Commerce Committee draft legislation that would address, among other things, the drug shortage crisis. The AMA applauds your leadership and efforts to address the alarming increase in drug shortages. While the draft represents a significant step forward, we strongly urge the Committee to consider the concerns we have highlighted and adopt the recommendations offered below.

Background

A growing number of physicians from across medical specialties and geographic regions in the country and their patients have struggled to ameliorate the adverse outcomes that result when patients are unable to access needed medication and treatment. Shortages not only impact the well-being of patients, but they increase health care costs and divert scarce resources needed to improve quality and patient outcomes. In some cases, previously stabilized patients have not responded well to alternative medication or experienced adverse side effects of varying degrees. Also, some patients have been forced to delay treatment as their condition worsens, while physicians and other members of the patient's health care team have struggled to find viable alternatives. As we grapple with policies, programs, strategies, and formulas to improve patient outcomes, widespread concern exists among physicians that the basic tools for providing effective medical care—prescription medicines—are increasingly in short supply. The resources needed to avert or ameliorate the harm are increased when physicians and patients have little to no warning of a shortage.

Early Notification

The AMA supports legislation that would require all manufacturers of Food and Drug Administration (FDA) approved drugs to give the agency advance notice of anticipated voluntary or involuntary, permanent or temporary, discontinuance of manufacture or marketing of such a product. We appreciate the Committee's effort to reach a consensus. However, we urge the Committee to adopt a bright line rule that clearly delineates which manufacturers are required to provide notice to the FDA. Accordingly, we strongly urge the Committee to require manufacturers of products subject to 21 U.S.C. section 503(b)(1) to provide advance notice. By requiring all manufacturers of drugs covered by section 503(b)(1) to report, the potential for ambiguity or confusion is removed. It also maximizes the ability of the FDA to dedicate its limited resources to mitigate or avert shortages that are of greatest concern. Furthermore, it ensures that physicians and patients are not left at a disadvantage if a drug necessary for the patient's care is not covered by the current draft language. Even though drugs may not appear to meet the proposed criteria and are not included on a critical drug list, patients with co-morbidities and their physicians who have established a unique and specific balance in the patient's medication regimen, may reach a very different conclusion about whether a medication should be covered by the criteria.

We strongly support the early notification requirement because it has proven effective in mitigating and averting shortages. The FDA reports that 195 shortages were avoided because of early notification in 2011. We thank the Committee for including this in the draft. Nonetheless, we remain concerned that manufacturers may not report because consequences for failing to report are lacking. To ensure compliance, we urge the Committee to provide the FDA with the discretion to impose civil monetary penalties (CMPs) where there is evidence that a manufacturer knowingly and willfully fails to report or otherwise provide for an alternative enforcement mechanism to ensure compliance.

Inclusion of Biological Products

We strongly support and encourage the Committee to include both biologics and biosimilar products within the reporting requirement and encourage the Committee to expand the reporting requirement accordingly. This will become increasingly critical as the development and approval of biosimilar products for use in the United States become more prevalent.

Congressional Reporting

We urge the Committee to require the FDA to identify the manufacturers that do not comply with the early notification requirement. If CMPs are not included in the final legislation, we recommend the list of non-compliant manufacturers to be publicly available. Furthermore, we encourage Congress to consider language specifying that upon receipt of the list, committees of jurisdiction will receive justification from those non-compliant manufacturers.

Public Notification

We strongly support and appreciate the Committee's decision to require the FDA to provide public notice of shortages. Public notification is essential for a physician's advance planning in patient care caused by a drug shortage.

Drug Enforcement Administration (DEA) and FDA Coordination

In light of the severity and scope of drug shortages, we support the Committee's inclusion of provisions that would require the FDA and the DEA to collaborate to avert or ameliorate drugs shortages where the manufacturers of shortage drugs are limited by a DEA quota. FDA and DEA flexibility is needed in the development of quotas for manufacturers producing controlled drugs.

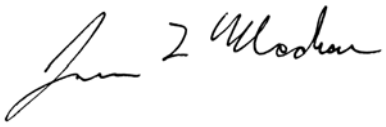
Resources

Finally, given the additional authority and requirements of FDA to promulgate rules, develop guidance, strategic planning and convene a task force, we ask that consideration be given to the resource constraints of the FDA. We request that the Committee include language that expresses the sense of the U.S. House of Representatives that additional resources be allocated to FDA to address drug shortages.

Conclusion

We appreciate the efforts of Congress to mitigate or avert such prescription drug shortages. We look forward to working with Congress to ensure physicians and patients have access to all prescription medication.

Sincerely,



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