AMA
AMERICAN MEDICAL ASSOCIATION

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The Honorable Tom Harkin
Chairman
Health, Education, Labor and
Pensions Committee
731 Senate Hart Office Building
Washington, DC 20510

The Honorable Mike Enzi
Ranking Member
Health, Education, Labor and
Pensions Committee
379 Senate Russell Office Building
Washington, DC 20510

Dear Chairman Harkin and Ranking Member Enzi:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments on provisions of the Senate Health, Education, Labor and Pensions (HELP) Committee second legislative draft concerning drug shortages and next generation antibiotics. The AMA applauds your efforts to address the troubling rise in drug shortages as well as the market dynamics and regulatory barriers that hinder development of next generation antibiotics. We have highlighted key areas we strongly support below, as well as provisions that we urge the HELP Committee to strengthen in order to avert or mitigate prescription drug shortages that divert scarce health care resources and lead to poor patient outcomes.

Antibiotics

The AMA supports Title VIII of the draft that would provide incentives to manufacturers of next generation antibiotics. The proposed incentives and the increased regulatory transparency are urgently needed in order to promote the development and market availability of new antibiotics. The AMA is alarmed that the number of manufacturers engaged in research and development (R&D) for the next generation of antibiotics has plummeted. The current regulatory approval pathway for new antibiotics is resource intensive, uncertain, and lengthy. For manufacturers of other drugs and biologics, market approval and the subsequent exclusivity period allow for a return on R&D and regulatory approval costs. For antibiotics, however, best practices often dictate that the newest antibiotics serve as the treatment of last resort. This means the value of the market exclusivity afforded to antibiotic innovators under the current regulatory approval process is greatly diminished by physician patterns of use designed to combat antibiotic resistance. Manufacturers are now reluctant to invest in developing new antibiotics because of this lack of return on investment. Therefore, we strongly support the incentives for antibiotic manufacturers contained in this draft. Furthermore, the AMA appreciates revisions made by the Committee to the original language that was widely interpreted as limiting the diagnostic test that can be used with an antimicrobial product. Physicians and patients should continue to have access to the entire range of available diagnostic tools.

Drug Shortages

The AMA acknowledges the significant improvements made to the draft concerning drug shortages. It is evident that the HELP Committee has taken to heart the comments and recommendations made by the physician community, which is on the front lines of this crisis and is responsible for averting serious harm to patients. The AMA welcomes the current approach and it is clear that significant progress had been made. We strongly support the following:

- The revisions to the timing of advanced notifications under the proposed Section 506C(b). We strongly support the decision to strike all exceptions to the advance notice requirement contained in the last draft. As noted in our prior comments, it is essential that all covered manufacturers should provide notice at least six months in advance or as soon as practicable if such advance notice was impossible. Based on current experience, the advance notice requirement is key to averting shortages or providing adequate time for mitigation.

- The revisions to the charge and responsibilities of the Task Force under the proposed Section 506(d). We applaud the requirement that the Task Force develop a strategic plan to address drug shortages and submit recommendations to Congress. Consistent with our prior comments, we strongly support requiring the Food and Drug Administration (FDA) to develop effective communication with outside stakeholders, including physicians, that will not compromise mitigation efforts.

- The revision to the definition of "meaningful disruption" from "highly likely to lead to a reduction in the supply of a drug" to "reasonably likely to lead to a reduction in the supply of drug" in the proposed 506C(f)(3). The prior definition did not adequately reflect the need to ensure that notice was provided with sufficient time to avert or mitigate harm. The AMA strongly supports this improvement.

- The addition of a new subsection, proposed Section 506C(d)(4), that directs the agency to identify or establish a mechanism by which healthcare providers, among others, may report evidence of a drug shortage. As discussed below, we remain concerned that the current draft does not provide the FDA with any meaningful tools to enforce the advance notice requirement. As a result, this new provision, essential since the first alarm, unfortunately, may be raised by those who are in crisis management mode—physicians. While we applaud the addition of the new provision, as we discuss below, we continue to urge the Committee to confer the FDA with tools to compel compliance.

The foregoing revisions represent significant and important improvements that will assist physicians with the essential tools they need to improve patient outcomes—prescription medicines. While we strongly support these changes, the AMA continues to urge the HELP Committee to require manufacturers of products subject to 21 U.S.C. section 503(b)(1) to provide advance notice of a shortage. By designating all prescription drugs as reportable products, the FDA's ability to dedicate its limited resources to mitigate or avert shortages is maximized. The AMA acknowledges that the HELP Committee has expanded the drugs covered by this provision from life-supporting, life sustaining, or intended for use in the prevention of a debilitating disease or condition, to now include sterile injectable products as well as prescription drugs used in emergency medical care or surgery.

We remain concerned that even though a prescription drug may not appear to meet the proposed criteria, patients with co-morbidities and their physicians who have established a unique and specific balance in the patient's medication regimen may reach a different conclusion whether a medication should be covered by the criteria. The negative impact on patient outcomes of a drug shortage must be managed by physicians, not manufacturers. As a result, physicians must have adequate notice and time to mitigate the drug shortage's damage. We continue to urge the HELP Committee to adopt a bright line approach that ensures manufacturers clearly understand they have an obligation to provide advance notice.

Further, we remain concerned that manufacturers may not report because consequences for failing to report are lacking. To ensure compliance, we urge the working group to provide the FDA with the discretion to impose civil monetary penalties where there is evidence that a manufacturer knowingly and willfully fails to provide advance notice; otherwise an alternative enforcement mechanism to ensure compliance should be provided.

Finally, we continue to urge the HELP Committee to coordinate with the Senate Judiciary Committee in order to address the lack of authorizing language that allows the FDA and the Drug Enforcement Agency to work collaboratively and provide flexibility where needed in quota development for manufacturers producing controlled drugs.

Conclusion

The AMA appreciates the efforts of Congress to identify the underlying causes of prescription drug shortages and the HELP Committee's efforts to mitigate or avert such shortages and provide incentives for the development of next generation antibiotics. The second draft legislative proposals released by the HELP Committee represent significant progress. We believe, however, that until the underlying causes of shortages are resolved, the FDA needs as much time and advance notice as possible to expedite solutions that avert or mitigate shortages. When a shortage is unavoidable, physicians and patients also need adequate forewarning to implement alternative treatment plans. The AMA welcomes the opportunity to continue working with the HELP Committee and Congress to address these issues that have a direct and real impact on patient health outcomes and often drive up health care costs.

Sincerely,

James L. Madara, MD