



**American Hospital
Association**

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April 10, 2012

The Honorable Tom Harkin
United States Senate
428 Dirksen Senate Office Building
Washington, DC 20515

The Honorable Michael Enzi
United States Senate
835 Hart Senate Office Building
Washington, DC 20515

Dear Senator Harkin and Senator Enzi:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 42,000 individual members, the American Hospital Association (AHA) is pleased to provide comments on the Senate bipartisan working group's discussion draft addressing drug shortages.

The number of drugs in critically short supply is increasing at an alarming rate and threatens quality of care in hospitals nationwide. Many of these drugs play a critical role in life-saving treatments, including cancer therapies, widely used anesthetics, antimicrobials, nutritional supplements and pain medications. In many cases, therapeutic alternatives are not available or carry increased risk of side effects and drug-to-drug interactions. The potential harm to patient safety is of paramount concern.

We believe this draft is a significant first step toward ensuring that patients have access to the medications they need while not compromising the safety and quality of those medications. However, we also believe the draft can be further improved to ensure that the true goal of eliminating generic drug shortages is accomplished.

PENALTY FOR NON-COMPLIANCE

The AHA supports the early notification requirement, which has a strong track record of successfully avoiding drug shortages, as evidenced by the 195 shortages avoided in 2011. We thank the working group for including this requirement in the draft; however, we believe such reporting should be mandatory. Without any redress such as civil monetary penalties, it is unclear how the agency will enforce this requirement. Typical agency enforcement actions available for current use include injunctions or halting production; these types of enforcement actions would have no impact on drug shortages, and in fact could make them worse. We are concerned that a requirement lacking enforcement is not really a requirement. Simply listing the names of manufacturers who fail to comply in an annual report to Congress will not serve as an effective enforcement mechanism. We ask the working group to include civil monetary penalties or some other type of enforcement mechanism to ensure compliance with this section.



REDUCTION IN THE NOTIFICATION PERIOD

The draft outlines a number of exceptions to the early notification system based upon a manufacturer certifying to the Food and Drug Administration (FDA) that good cause exists. We are pleased to see that any exceptions would be at the discretion of FDA; however, we ask that the working group seek input from the agency on the potential for this requirement to add another layer of bureaucracy. Many of our members have noted the added burden drug shortages have created by taking time away from clinicians caring for patients in order to track down medications. In other words, time spent tracking medications is time not spent caring for patients. We are concerned that, by creating more bureaucracy, it would limit FDA's ability to address drug shortages. Again, we would defer to agency input on whether this section would create significant paperwork burdens on the agency due to increased requests for exceptions to the notification requirements.

Furthermore, the exception listed under section (D), economic hardship, would be troublesome if it were a sole source manufacturer of a lifesaving product that did not have to report to FDA under the guise of "economic hardship." We do not believe that the economic hardship suffered by a manufacturer outweighs the hardship of an untimely death due to a medication in short supply. We ask that the working group reconsider this exception, especially since section (E) notes the exception for a bankruptcy filing.

COORDINATION

In general, we are pleased to see the creation of a task force to promote both inter- and intra-agency coordination, communication, planning and decision making. We ask that consideration be given to either stakeholder inclusion in the task force, or a requirement that stakeholders regularly participate in task force meetings or communications. We believe it is essential for FDA and other agencies to regularly hear from clinicians, patients and supply chain members.

RECORDKEEPING AND REPORTING

We are pleased that, within the recordkeeping and reporting section, FDA would be required to collect the names of manufacturers who did not comply with the early notification requirement. However, in the absence of civil monetary penalties, this provision should require that a list of non-compliant manufacturers be made publicly available. Congress could help ensure compliance with early notification by specifying that, upon receipt of the list, the leaders of the committees of jurisdiction will request justification from those manufacturers who fail to report.

DEFINITIONS

Under section (3), meaningful disruption, we urge the working group to consider the following alternative to this definition. Within H.R. 2245, the term “interruption” is defined as:

The term ‘interruption’ means a change that--

‘(A) may result in the total supply of a drug manufactured by the individual manufacturer not meeting average historic demand; and

‘(B) consists of--

‘(i) a change in the supply of one or more raw materials, including active pharmaceutical ingredients;

‘(ii) an unplanned interruption in ability to produce the drug;

‘(iii) a business decision affecting the manufacture of the drug, such as a merger or a change in production output; or

‘(iv) any other type change that could have the result described in subparagraph (A), as determined by the Secretary.

This definition provides a better framework and is based upon average historic demand, rather than highly subjective terms such as “highly likely” and “negligible.” These terms may be subject to interpretation. It may be worth noting that the above definition was developed with significant input from a manufacturer.

DISTRIBUTION

We strongly urge the working group to amend this section by replacing “may” with “shall.” We believe that public notification is essential so that caregivers can adequately plan for potential disruptions in patient care caused by a drug shortage. We ask that the group consider adding some additional criteria in the distribution; for example, the name of the drug in shortage, the name of each manufacturer, reason for the shortage, and anticipated duration of the shortage as determined by the secretary. These criteria are listed in the “Distribution” section of the discussion draft developed by the House Energy and Commerce Committee (pages 195 and 196). We realize that all of this information may not be available to distribute but, to the extent that it is practicable, we ask that it be included.

INCLUSION OF BIOLOGICAL PRODUCTS

We strongly support the inclusion of both biologics and biosimilar products within the discussion draft. This will become increasingly critical in the future as the development and approval of biosimilar products for use in the United States become more prevalent. We commend the working group’s efforts to include biological products.

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Page 4 of 4

ITEMS NOT INCLUDED IN THE DRAFT

While we understand the boundaries of the HELP committee's jurisdiction regarding Drug Enforcement Agency (DEA) issues, we believe that additional policy options should be added by other committees of jurisdiction. Given the severity and scope of drug shortages, it is difficult to fathom that significant opposition from members of another committee would be a barrier to at least requiring FDA and DEA to work collaboratively and provide flexibility, where needed, in the development of quotas for manufacturers producing controlled drugs. We ask that consideration be given to addressing this issue.

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 agency. We fully understand that you, as authorizers, are not appropriators and are not in a position to direct additional resources to FDA, but we ask that consideration be given to include language that expresses the sense of the Congress that additional resources be allocated to FDA to address drug shortages.

CONCLUSION

Thank you for hard work and commitment to this issue. This problem has become a national crisis and we must take steps to address it as quickly as possible. Your hard work and dedication is making this possible. Again, we appreciate your efforts and look forward to working with you to address this problem.

Sincerely,

Rick Pollack
Executive Vice President