April 6, 2012

Dear Chairman Harkin and Ranking Member Enzi:

The organizations listed below are pleased to provide comments to the Senate bipartisan working group's discussion draft that addresses drug shortages. Our organizations represent patients, clinicians, and hospitals, all of whom have been impacted by the worst shortages of generic drugs in our nation's history. Given that patient harm has already occurred, we applaud your efforts to address the problem in a swift yet thoughtful manner. We believe this is a tremendous 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 improved to ensure that the true goal of eliminating generic drug shortages can be accomplished.

In General

Within the early notification section, we support notification based upon broad parameters of drugs that are life-supporting, life-sustaining or intended for use in prevention of a debilitating disease or condition. Earlier drafts based this upon a list of critical drugs in short supply. It has been widely noted that basing the reporting upon a list is difficult as it must be constantly updated and may create some confusion among manufacturers about when they must report. We thank the working group for taking the approach of using criteria over a list, however, we urge the working group to ensure that emergency medicine drugs, anesthetics, and drugs used in the management of a debilitating disease are included as well.

We are strong supporters of the early notification requirement and note that it has a track record of successfully avoiding drug shortages as evidenced by the 195 shortages avoided in 2011, as reported by the Food and Drug Administration (FDA). We thank the working group for including this requirement in the draft. However, one concern we have is whether this reporting is mandatory. Without any redress such as civil monetary penalties, how is the FDA going to enforce this requirement? Typical Agency enforcement actions available for current use include injunctions or halting production, however, 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 isn't 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 consider including 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 FDA that good cause exists. We are pleased to see that any exceptions would be at the discretion of FDA; however, we would ask that the working group receive input from the Agency on the potential that this would add another layer of bureaucracy. Many of the groups signed on to this letter have noted the added burden drug shortages has 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. Our concern here is 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 (D), economic hardship, would be troublesome if it were a sole source manufacturer of a life-saving 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 (E) notes the exception for a bankruptcy filing.

Coordination

(1) Task Force

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 would simply ask that consideration be given to either 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, as their participation and input would be extremely valuable.

Recordkeeping and Reporting

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

Definitions

Under (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:

> 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.

We believe this definition provides a better framework for manufacturers to report and is based upon average historic demand, rather than highly subjective terms such as "highly likely" and "negligible." These 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. Furthermore, 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's 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.

Items Not Included in the Draft

While we realize the boundaries of the HELP committee's jurisdiction regarding DEA issues, we do believe that this policy option should be explored jointly with the committee 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. All of us hear not only from our constituencies but also from patients who are struggling to find medications that in some cases, are essential to their survival. As you well know, this problem has become a national crisis and we must take steps to address

it now. 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.

American Academy of Emergency Medicine Resident and Students Association


Continuum
Health Partners


HOPA
Hematology/Oncology
Pharmacy Association


ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES


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MEDICINE


MUSC
Children's Hospital


NCPA
NATIONAL COMMUNITY
PHARMACISTS ASSOCIATION


NYU Langone
MEDICAL CENTER


Society of
Critical Care Medicine
The Intensive Care Professionals


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