The Honorable Tom Harkin
Chairman
Senate Health, Energy, Labor, and Pension Committee
731 Hart Senate Office Building
Washington, DC 20515

The Honorable Michael B. Enzi
Ranking Member
Senate Health, Energy, Labor, and Pension Committee
379 A Russell Senate Office Building
Washington, DC 20515

June 8, 2012

Dear Chairman Harkin and Ranking Member Enzi:

The organizations listed below represent clinicians, hospitals, and patient advocacy groups who are writing in support of your efforts to address the drug shortage crisis within the Food and Drug Safety and Innovation Act of 2012 (S. 3187, H.R. 5651). We thank you for working in a bipartisan manner to pass this critical legislation by overwhelming majorities in both houses of Congress. We look forward to working with you as both versions get merged into a final bill in the coming weeks.

In particular, we strongly support the early notification requirements listed in both versions of the bill and given FDA's track record of success with early notification (195 shortages avoided in 2011), we believe this notification is an essential component to help alleviate shortages. We urge conferees to ensure that drugs and biologics are included within the early notification requirements as well as in the other provisions in the drug shortage title of the PDUFA bill and are broadly defined to cover complex and critical uses such as drugs used in surgery and emergency medicine, drugs used in cancer treatment, as well as drugs and biologics used to treat blood and other disorders. Specifically, we ask that the final bill not exempt human plasma protein therapies and their recombinant analogs from the early notification requirement. Finally, we understand that the intent of this provision is to include pre-1938 drugs, which are unapproved drugs but nonetheless essential for care, within the early notification requirement and we support inclusion of these products as well. During the many in person meetings we have held with both House and Senate offices, it seems clear that Congressional intent is to be inclusive of these products, and we hope the final bill language will reflect that intent.

We understand that civil monetary penalties for failing to notify FDA under the early notification requirements are not included in either version of the bill. We continue to believe that monetary penalties would represent the most effective mechanism to encourage reporting; however, given that this is currently not an option in either bill, we support the approach taken in the House version whereby a failure to report by a manufacturer would trigger an automatic letter by FDA to that company requesting an explanation of why it did not report to FDA. As these letters and responses would be a matter of public record, as are other FDA enforcement actions, manufacturers would be held accountable for justifying failure to report a stoppage in production of a life-saving product that could result in patient harm or death.

Additionally, we support further collaboration between FDA and the Drug Enforcement Administration (DEA), to examine the impact of quotas on controlled drugs and to adjust those quotas if need be to avoid a shortage. Therefore, we support the House language that allows for more flexibility of controlled drug quotas.

The Senate version includes a provision that would require FDA to create a task force charged with developing a strategic plan for preventing and mitigating drug shortages. Under this provision, the task force would consult with external stakeholders such as the groups signed on to this letter, for input on interagency coordination, communication and decision making as it relates to drug shortages. As stakeholders with unique expertise and interest in drug shortages, we support inclusion of this provision in the final bill.

Finally, we are supportive of efforts to allow for repackaging of non-controlled medications in short supply for use within the same health system. While both versions address it in some form, the House language is more prescriptive and would be a better approach to address repackaging of non-controlled drugs for use within a health system. In addition, if there is a willingness among the conferees to enable both hospital and non-hospital providers (such as oncology clinics) within the same health system to have access to repackaged drugs in short supply, we would endorse such a technical correction.

Again, we thank you for your commitment to preventing and alleviating the worst drug shortage in our nation's history and we look forward to working with you to finalize and pass this critical legislation.

Sincerely,

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American Society of Clinical Oncology


ASHP
American Society of
Health-System Pharmacists


AMERICAN SOCIETY OF HEMATOLOGY


ACCC
Association of Community Cancer Centers


CHILDREN'S
HOSPITAL
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