

April 24, 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. We continue to work with the Health, Education, Labor and Pensions Committee in a bipartisan manner to provide additional input and feedback. We are extremely pleased with the progress that has been made and remain optimistic that the final Prescription Drug User Fee Act (PDUFA) bill will include efforts to address drug shortages. It is encouraging to see the Committee work in a bipartisan manner to help address a crisis that has resulted in undue patient suffering.

Specifically, the recent draft of the PDUFA reauthorization includes a section that would require drug manufacturers to report to the Food and Drug Administration (FDA) when they experience a production interruption or discontinue making a drug. 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. Furthermore, we are supportive of the proposed generic user fee program as a way to help speed FDA approvals for manufacturers seeking to produce generic drugs.

We remain hopeful that we can continue to work with the Committee to address the lingering issues of Drug Enforcement Administration quotas, effective enforcement of the early notification requirement, and ensuring FDA has the resources it needs to maintain the supply of safe, effective medications that our patients rely on.

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

Sincerely,



**American Academy of Emergency Medicine
Resident and Students Association**





American Society of Clinical Oncology

