

The Honorable Fred Upton
Chairman
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Henry Waxman
Ranking Member
House Energy and Commerce Committee
2322A Rayburn House Office Building
Washington, DC 20515

May 7, 2012

Dear Chairman Upton and Ranking Member Waxman:

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. The recent draft of the Prescription Drug User Fee Act (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, and we would particularly like to applaud the Energy and Commerce Committee's legislation for inclusion of improved Drug Enforcement Administration quota language.

While we continue to work with the Energy and Commerce 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 PDUFA bill will include efforts to address drug shortages. In what has become one of the most contentious and partisan Congressional sessions in recent memory, it is encouraging to see the Committee work in a bipartisan manner to help address a crisis that has resulted in undue patient suffering.

We remain hopeful that we can continue to work with the Committee to address the lingering issues of effective enforcement of the early notification requirement such as civil monetary penalties, 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 in our nation's history and we look forward to working with to finalize and pass this critical legislation.

Sincerely,

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American Academy of Emergency Medicine
Resident and Students Association



American Hospital
Association



American Society of Clinical Oncology



American Society of
Health-System Pharmacists®



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Pharmacy Association

