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April 9, 2012

The Honorable Tom Harkin
Chairman
Health, Education, Labor and Pensions Committee
U.S. Senate
Washington, DC 20510

The Honorable Michael Enzi
Ranking Member
Health, Education, Labor and Pensions Committee
U.S. Senate
Washington, DC 20510

Dear Chairman Harkin and Ranking Member Enzi:

Thank you for your work and thoughtful draft on additions to the Prescription Drug User Fee Act of 2012 that will address the current drug shortage crisis. The Cancer Support Community, a non-profit organization **directly** providing support, education and hope to people affected by cancer is far too familiar with the impact of drug shortages on our constituents, as the availability of important cancer treatment options has wavered significantly over the past two years. We welcome and appreciate this opportunity to work with you, and respectfully submit the following comments.

We are concerned that the draft definition of eligible drugs, “life-supporting, life-sustaining or intended for use in the prevention of a debilitating disease or condition” would not necessarily cover chemotherapeutic agents. We suggest that the definition be changed to “life-supporting, life-sustaining or intended for use in the prevention **or management** of a debilitating disease or condition.”

We support the creation of a task force to study the issue and root causes of the drug shortage issue. We also support the requirement of a report to the Secretary and the general public. We respectfully request the language to specify that the work of this task force be directed at second generation, solution oriented guidance and that the task force include the input of outside stakeholders, including patient advocacy organizations, cancer centers, suppliers and other organizations that are affected by or have insight regarding drug shortages.

We support the creation of early reporting as a way to trigger an expedited review. We also support efforts to ensure that the FDA has adequate resources to meet the demands on the system resulting from such reporting.

We are concerned about the implementation of the Secretary having a final decision about action or communication toward manufacturers particularly as it relates to the time it might take to secure action and the potential impact to patient safety. We propose the addition of clearer language to specify expected turnaround time for decision-making and clarification on specific situations that would allow immediate action (e.g. viral or bacterial contamination, particulate matter, etc). As always, we believe patient safety should drive all action.

The proposed amendment has neither incentives for compliance nor penalties for noncompliance. We propose the task force create early solutions around this.

We know you share our opinion that the drug shortage issue remains a very complex situation. We look forward to working as your partner toward both short and long-term solutions that involve multiple stakeholders and broad system change. We will be making Hill visits on May 8th and would appreciate the opportunity to meet with you to share our insights and experience. We will follow up with your staff shortly regarding this meeting request. Thank you again for your commitment to innovation, patient safety and ensuring timely access to important therapies. We appreciate the opportunity to share our comments and look forward to working with you.

Sincerely,

A handwritten signature in black ink, appearing to read "K. Thiboldeaux". The signature is fluid and cursive, with a large initial "K" and a long, sweeping tail.

Kim Thiboldeaux
President & CEO
Cancer Support Community