CANCER LEADERSHIP COUNCIL

A PATIENT-CENTERED FORUM OF NATIONAL ADVOCACY ORGANIZATIONS ADDRESSING PUBLIC POLICY ISSUES IN CANCER

November 7, 2012

The Honorable Tom Harkin
Chairman
HELP Committee
United States Senate

The Honorable Fred Upton
Chairman
Energy and Commerce Committee
United States House of Representatives

The Honorable Michael B. Enzi
Ranking Member
HELP Committee
United States Senate

The Honorable Henry A. Waxman
Ranking Member
Energy and Commerce Committee
United States House of Representatives

Dear Senator Harkin, Senator Enzi, Representative Upton, and Representative Waxman:

The undersigned cancer patient, provider, and research organizations are writing to express their appreciation for your hard work to develop legislation to protect the pharmaceutical distribution supply chain and to offer comments and recommendations regarding the draft bill.

Cancer patients depend on safe and effective pharmaceutical products as critical elements of their diagnosis and treatment. The care that cancer patients receive may be seriously compromised if drugs are counterfeit or if they have been adulterated at any step in the distribution process. The cancer community recently experienced a situation where a counterfeit version of a drug for treatment of several different cancers was introduced into the distribution system and may have reached medical practices. This incident has underscored for the cancer community the necessity to move steadily and as rapidly as possible toward a distribution that is secure and reliable.

We appreciate the challenges associated with implementing a nationwide system that incorporates unit-level tracking requirements, but the final version of the distribution system must include such tracking if it is to protect cancer patients and all other Americans who depend on safe and effective pharmaceutical products. In addition, implementation of distribution systems in certain states and debate in other states about such systems make federal action necessary to ensure a predictable system rather than a patchwork of state systems.

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We offer the following comments and recommendations regarding the draft bill:

- We support the definition of a lot-level tracking system that is included in Section 2 of the draft bill as a first step toward enhanced pharmaceutical distribution security. This section of the bill includes solid policies to ensure the identification and investigation of suspect products in the supply chain and an effective alert system for the industry and the Food and Drug Administration (FDA). The shorter timeframes for implementation of Section 2 of the bill should be retained in the final draft. We would like to emphasize the importance of progressing to the unit-level tracking system as established in Section 3 of the draft.
- In the interim, strong verification requirements should be included in the lot-level tracking system. Returned products and suspect products should be verified; a requirement of this sort is necessary to protect patients.
- We urge that Section 3 of the current draft, Enhanced Drug Distribution Security, be retained in the final version of the bill. This section of the draft bill defines a unit-level tracking and authentication system for drugs, necessary for the protection of cancer patients and others and also critical to ensure a national, rather than state-by-state, unit-level tracking.
- Timelines must be as short as possible. Even the shortest timelines proposed in the discussion draft will result in delays of up to a decade before a comprehensive system is in place to protect patients. We recommend instead that the HHS Secretary be required to write proposed regulations to implement Section 3 within 5 years and that these regulations should include all elements identified in the draft bill, including requirement to establish unit-level tracking and routine, proactive verification.
- The policy should include all participants in the U.S. pharmaceutical system in order to proactively authenticate medicines at the unit level. The distribution security of the pharmaceutical supply cannot be assured without the participation of all members of the distribution chain.
- Public meetings and pilot programs can provide insights and models for distribution security systems. However, there is the potential that design and implementation of a nationwide distribution security system could be hindered by the requirement that guidance documents be prepared after each public meeting or by a requirement that pilots be completed and evaluated before implementation of a national tracking system is initiated. We urge that the final bill protect against those possibilities.

We appreciate the opportunity to comment on the drug distribution security draft bill and look forward to working with you as this legislation is introduced and considered by Congress.

Sincerely,

Cancer Leadership Council

American Society for Radiation Oncology
Cancer Support Community
Children's Cause for Cancer Advocacy
Fight Colorectal Cancer
International Myeloma Foundation
Kidney Cancer Association
The Leukemia & Lymphoma Society
National Coalition for Cancer Survivorship
National Lung Cancer Partnership
Ovarian Cancer National Alliance
Pancreatic Cancer Action Network
Prevent Cancer Foundation
Sarcoma Foundation of America
Susan G. Komen for the Cure Advocacy Alliance
Us TOO International Prostate Cancer Education and Support Network

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