

CANCER LEADERSHIP COUNCIL

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

April 26, 2013

The Honorable Tom Harkin
135 Hart Senate Office Building
United States Senate
Washington, D.C. 20510

The Honorable Richard Burr
217 Russell Senate Office Building
United States Senate
Washington, D.C. 20510

The Honorable Lamar Alexander
455 Dirksen Senate Office Building
United States Senate
Washington, D.C. 20510

The Honorable Michael Bennet
458 Russell Senate Office Building
United States Senate
Washington, D.C. 20510

Re: HELP Committee Draft Proposal to Improve Drug Distribution Security

Dear Chairman Harkin, Ranking Member Alexander, Senator Bennet, and Senator Burr:

The undersigned organizations representing cancer patients, physicians, and researchers appreciate the opportunity to provide comments on the Senate Committee on Health, Education, Labor, and Pensions (HELP) draft proposal to improve the safety of the pharmaceutical distribution system.

All of us depend on a cancer research and development system and a pharmaceutical distribution system that provide access to safe and effective medicines for cancer treatment, symptom management, and treatment of the late and long-term effects of cancer and cancer therapies. Counterfeit drugs may put cancer patients at grave risk of adverse effects. Of equal concern is the possibility that patients will be unknowingly administered counterfeit drugs that are ineffective. In this circumstance, patients waste precious time receiving treatments that do not provide benefit.

We support the Committee's effort to establish a system that will ensure the participation of all supply chain stakeholders and that will support verification and traceability. We urge modification of the draft proposal to support the establishment of a system that permits traceability and ensures the authenticity of patients' medicines.

Timelines

The discussion draft establishes an initial lot-level traceability system, followed by a full unit-level traceability system to be implemented in 10 years. This timeline is a responsible one for implementation of an electronic unit-level traceability system, and we recommend against the extension of the current timeline.

Preemption

The discussion draft provides that preemption of state laws will be effective upon enactment. We urge instead that preemption be triggered by the effective date (270 days after enactment) of transaction history requirements. This modification of the draft will better protect the pharmaceutical supply chain by leaving in place state pedigree laws until transaction history requirements are effective. We agree that a uniform standard is crucial to protecting patients from adulterated products, but until the transaction history requirements are in effect, we urge that state laws remain in effect.

Full participation of all pharmaceutical supply chain partners

The discussion draft requires the Food and Drug Administration (FDA) to commission a study on pharmacy financial impact and feasibility and creates a subsequent waiver process for small businesses based on its findings. Pharmacy participation is critical to ensuring patient protection as well as maintaining the integrity of the pharmaceutical supply chain, and a unit-level traceability system must include all participants. We recommend that the FDA be given the ability to ensure meaningful participation of all supply chain participants in a unit-level electronic traceability system.

Meaningful verification

The current discussion draft requires supply chain stakeholders to check a drug's serial number only when investigating "suspect products" or during the returns process. We recommend a system that protects patients by providing the FDA with the scope to advance verification expectations beyond "suspect scenarios" and return scenarios. Verification of drug serial numbers by supply chain partners is an effective way to ensure illegitimate products do not enter the distribution system and reach patients. In addition to preventing drug diversion, this process of reviewing serial numbers can also identify and detect stolen and counterfeit drugs that criminals may attempt to introduce or sell as legitimate pharmaceutical products.

Enhanced traceability

In addition to verifying a serial number, another key to improved security of drug distribution is establishing a drug's distribution history, which means understanding who handles the drugs as they move from manufacturer, through a succession of wholesalers, to the pharmacy or hospital and to the patient. A critical success of this draft is the establishment of an electronic traceability system by a date certain at the *unit*-level. Such a system is a significant improvement over a system that tracks drugs only by the lot number, which would in many scenarios fail to catch unsafe medicines. A lot can contain numerous cases of many thousands of individual bottles. Each may be sold separately, and lot-level tracing does not allow industry or regulators to know who bought and sold a given drug during distribution.

However, this draft only provides regulators with the ability to request the distribution history. In order to have a system that appropriately protects patients, pharmaceutical supply chain participants and trading partners – and not just regulators – must be able to use the system to ensure the legitimacy of the distribution history. We recommend that all trading partners in the supply chain be able to use the system to ensure that a drug's distribution history is legitimate.

We commend your commitment to protecting the safety of the nation's drug supply and the collaborative process you have employed for development of strong legislation to achieve this goal. We appreciate the opportunity to comment on the draft legislation you have developed.

Sincerely,

Cancer Leadership Council

American Society of Clinical Oncology
Bladder Cancer Advocacy Network
The Children's Cause for Cancer Advocacy
Coalition of Cancer Cooperative Groups
Fight Colorectal Cancer
International Myeloma Foundation
Kidney Cancer Association
Lymphoma Research Foundation
National Coalition for Cancer Survivorship
National Lung Cancer Partnership
Ovarian Cancer National Alliance
Prevent Cancer Foundation
Susan G. Komen for the Cure Advocacy Alliance