



November 25, 2014

BY ELECTRONIC MAIL

DrugTrackandTrace@fda.hhs.gov

Ilisa B.G. Bernstein, Pharm.D., J.D.
Acting Director
Deputy Director, Program Operations
Office of Compliance
Food and Drug Administration
Room 5266, White Oak Office Building 51
10903 New Hampshire Avenue
Silver Spring, MD 20993
ilisa.bernstein@fda.hhs.gov

Connie T. Jung, RPh, PhD
Associate Director for
Policy and Communication
Office of Compliance
Food and Drug Administration
Room 2242, White Oak Office Building 51
10903 New Hampshire Avenue
Silver Spring, MD 20993
connie.jung@fda.hhs.gov

Re: Industry Readiness for January 1, 2015 Implementation of the Drug Supply Chain Security Act (DSCSA)

Dear Dr. Bernstein and Dr. Jung:

On behalf of the Healthcare Distribution Management Association (HDMA) and our primary distributor members, I am writing to bring to your attention concerns about the pharmaceutical supply chain's ability to comprehensively meet the January 1, 2015 implementation deadline for key product tracing provisions of Title II of Public Law No. 113-54, the Drug Supply Chain Security Act (DSCSA).

As you know, HDMA has been a long-time champion of the DSCSA as it represents the best solution for enhancing supply chain security, creating uniformity across the country and ensuring the safety of our nation's drug supply. To that end, HDMA and our member companies have been working diligently toward successful implementation since enactment of this groundbreaking law in November 2013.

HDMA members are committed to this effort and expect that implementation work will continue at full speed up and through the January 1 deadline. In our experience, this is one of the most widespread and cooperative efforts the pharmaceutical distribution chain has ever engaged in and we commend our colleagues across the supply chain for their level of commitment to the implementation of the DSCSA. This is, however, a learning experience for all involved and at this time, we expect continued development through at least the first quarter of 2015, particularly as distributors expand their focus to also include on-boarding dispenser customers.

However, HDMA is concerned that the complexities of implementing a law of this magnitude across the entire chain could impair the timely flow of product on January 1, absent additional guidance or enforcement discretion from the Food and Drug Administration (FDA) related to handling of product transactions that are non-compliant. From our industry's vantage point at the center of the supply chain, primary distributors are acutely aware that implementation readiness is not measured by the work of one sector or component, but by the collaborative and coordinated efforts of manufacturers, distributors and dispensers.

While we believe most trading partners will be ready, there is concern among HDMA member distributors that the supply chain will not be 100 percent compliant with the DSCSA requirements on January 1, due to some legitimate products entering the supply chain without adequate transaction data. To forestall potential disruptions to the pharmaceutical supply chain, we urge the agency to ensure that the overarching priority in implementing this law is that patients continue to receive the products they need. Factors contributing to this concern include, at a minimum:

- Lack of communication or responsiveness by a portion of supply chain stakeholders;
- Concerns about vendor resources and ability to on-board all trading partners;
- Uncertainties related to the inability to adequately test data exchange by a significant number of stakeholders in advance of the implementation date; and
- Questions about the reliability of untested data exchange.

In order to prevent potential drug shortages and disruptions in patient access, we urge the agency to be mindful of the status of the supply chain as a whole and exercise discretion in enforcement activities where necessary to ensure patient access to medicines.

HDMA thanks FDA for its consideration of this matter and looks forward to continuing our work together to meet this important milestone. If you have any questions, please contact Liz Gallenagh at 703-885-0234 or Anita Ducca at 703-885-0240.

Sincerely,

A handwritten signature in black ink, appearing to read 'Jm Gray', with a stylized flourish at the end.

John M. Gray
President and CEO

HDMA is the national association representing primary healthcare distributors, the vital link between the nation's pharmaceutical manufacturers and healthcare providers. Each business day, HDMA member companies ensure that 15 million prescription medicines and healthcare products are delivered safely and efficiently to more than 200,000 pharmacies, hospitals, long-term care facilities, clinics and others nationwide. HDMA and its members work daily to provide value and achieve cost savings, an estimated \$42 billion each year to our nation's healthcare system. For more information, visit www.HealthcareDistribution.org.