December 15, 2014

The Honorable Margaret A. Hamburg, M.D.
Commissioner
U.S. Food and Drug Administration
White Oak Building 1, Room 2217
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg:

For many years, the Healthcare Distribution Management Association (HDMA) has been a leading advocate for the enhanced security, safety and nationwide uniformity principles that are the foundation of Title II of Public Law No. 113-54, the Drug Supply Chain Security Act (DSCSA). HDMA is among the strongest supporters of the DSCSA's comprehensive approach to these goals; however, it is incumbent upon me to bring to your attention a serious concern regarding the supply chain's ability to meet a key statutory deadline and its potential impact on the availability of pharmaceutical products to patients who need them.

As of today, we believe that the majority of primary distributors and their supply chain partners will be ready to exchange the required data, for the majority of transactions, by the January 1 implementation deadline. However, despite extensive and productive efforts to establish methods for data exchange, it is anticipated that some trading partners will encounter challenges beyond their control, which may result in disruptions in the supply chain.

Compliance with the DSCSA requirements typically involves painstaking development of complex information technology (IT) processes, as well as operations and logistics changes. While HDMA and its members have been working diligently since enactment, from our vantage point at the center of the supply chain, we are aware of several factors which may cause disruptions to product flow. These factors include substantial variability in technical expertise from trading partner to trading partner; complexities related to the IT systems that are attempting to connect with one another; and throughout the supply chain, an uneven and incomplete understanding of the DSCSA and its requirements. Because of these and other challenges, we expect continued development of systems and processes through at least the first quarter of 2015, particularly as distributors expand their focus to include on-boarding dispenser customers.

Significantly, without the successful transmission and receipt of complete transaction data, the DSCSA does not permit a supply chain partner to take ownership of or subsequently sell the associated product. Consequently, based on current information about supply chain readiness, there is very real potential for some product transactions to lack appropriate data, contain errors in data or resort to paper-based systems – all of which could result in disruptions to the provision of prescription drug products to patients who need them.

In order to forestall potential disruptions in the pharmaceutical supply chain, we respectfully request that the FDA issue a written statement of intention to use enforcement discretion when evaluating supply chain members' compliance with the DSCSA's data transmission/receipt requirements that become effective on January 1, 2015.

We estimate that a minimum of three months beyond January 1 is needed to reach full compliance across the supply chain with the transaction data exchange requirements. If FDA does not issue a statement

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announcing enforcement discretion, then we request that the agency consider alternatives to ensure timely availability of medicines such as granting a temporary exemption from the data transmission and receipt requirements or providing direction to supply chain partners who receive product without the appropriate transaction data.

Additionally, given that nationwide uniformity was an important Congressional goal in enacting the DSCSA, we also urge FDA to recognize that state regulatory authorities, still working to understand their responsibilities under the DSCSA, would benefit from FDA's leadership in determining appropriate enforcement practices. **Should FDA agree to our request for temporary enforcement flexibility, we urge FDA to inform such state authorities and encourage them to support the goal of uniformity by exercising restraint while the supply chain labors to bring all transactions into full compliance.**

HDMA's members fully intend to continue intense, concerted efforts toward full compliance, but by exercising its authority as described above, FDA would allow progress to continue while minimizing the risk of product shortages or disrupting patient access.

HDMA greatly appreciates your staff's dedication and continuous efforts to oversee DSCSA implementation. HDMA stands ready to meet with you or FDA staff to further discuss this request and provide any assistance we can to ensure implementation proceeds with minimal disruptions to the pharmaceutical supply chain.

Thank you for your leadership and consideration of this request. If you have any questions, please do not hesitate to contact me.

Sincerely,

John M. Gray
President and CEO

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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.