Healthcare Distribution Alliance

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Dear Doctors Throckmorton, Verbois, and Jung:

The Healthcare Distribution Alliance (HDA) thanks the Food and Drug Administration (FDA) for this opportunity to provide you with our proposed *Phased Approach To Achieving Interoperable Electronic Exchange Of Product Identifiers In Transaction Information* (*Phased Approach*). As we have discussed with each of you, this Phased Approach sets out our recommendations for achieving the prescription drug product traceability and security goals of the Drug Supply Chain Security Act (DSCSA) while also minimizing the potential for supply disruptions and interruptions to patient care.

About HDA And The DSCSA

HDA represents primary pharmaceutical distributors – the vital link between the nation's pharmaceutical manufacturers and more than 200,000 pharmacies, hospitals, long-term care facilities, clinics, and others nationwide. This essential function is provided with little public recognition or visibility, and at great savings to the healthcare system. HDA members serve as the central link in a sophisticated national supply chain. HDA members take this mission very seriously, and we support manufacturers, healthcare providers, and the government in ongoing efforts to ensure the U.S. medicine supply remains secure, efficient, and highly regulated.

HDA and its wholesale distributor members have long supported the DSCSA. We collaborated with FDA and industry stakeholders to achieve passage of the DSCSA in 2013. Since that time, HDA's pharmaceutical wholesale distributor members have invested years of work and millions of dollars to reach the DSCSA's final requirements on November 27, 2023.

The Problem

Congress mandated in the DSCSA that ten years after the law's enactment, by November 27, 2023, prescription drug manufacturers, wholesale distributors, and dispensers must begin interoperably and electronically exchanging data with each other that identifies each prescription drug package purchased and sold. This data exchange will make it possible to trace prescription drugs forward and back in the supply chain at the individual, package level. This very complex capability does not exist today. Rather, today, prescription drugs can only be traced at the lot level, not the individual package level.

The package-level data exchange Congress envisioned is both interdependent and becomes effective for all trading partners at the same time. This means that the ability of wholesale distributors and dispensers to purchase and resell needed medicines from manufacturers is dependent upon a manufacturer's provision of this package-level data. Though this requirement has been known since 2013, given the complexity of developing necessary systems, many, if not most, manufacturers will not be ready by November 27 to send package-level data to their customers. Or, if they are ready, much of the data will not be accurate.

This lack of readiness creates serious risks to pharmaceutical supply. If manufacturers cannot interoperably exchange accurate package-level data, the DSCSA would prohibit wholesale distributors and dispensers from lawfully purchasing the prescription drugs needed for patient care. In other words, this lack of readiness by most manufacturers means their downstream trading partners cannot lawfully purchase the medicines dispensers and other healthcare providers administer and dispense to patients and could result in a significant disruption in patient care.

HDA's Recommended Solution

Given the lack of manufacturer readiness and the DSCSA's single compliance date for all trading partners, HDA recommends that FDA reach the DSCSA's final requirements in phases to build capacity and stabilize these complex processes. As we describe in the attached document, this *Phased Approach* would include an FDA grant of enforcement discretion limited to certain DSCSA requirements and trading partners, with full implementation phased in over a period of 2 years. Trading partners would continue current business practices needed to move medicines to patients safely and securely while also continuing the push toward the package-level tracing and enhanced supply chain security Congress envisioned.

Urgent Action Needed

We are now less than 6 months from final DSCSA implementation. HDA's wholesale distributor members are facing real business consequences right now as they prepare for the November 27 deadline. Our members report they must hire and train hundreds of new employees to implement DSCSA requirements. Many other trading partners are facing similar challenges, decisions, and required investments. We ask that the agency move very swiftly to address these concerns. We feel the recommended *Phased Approach* would be a workable solution that would forestall a potentially significant disruption to the nation's pharmaceutical supply chain.

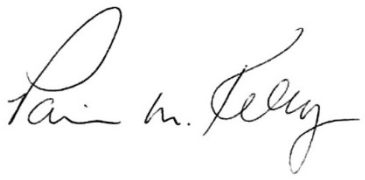
If the agency intends to grant enforcement discretion, it must do so quickly. As we explain, we oppose a blanket delay of the DSCSA 2023 requirements for all trading partners and urge this more nuanced approach. Though it preserves the status quo as trading partners ramp up interoperable data exchange, the *Phased Approach* will take time to understand and implement.

Further Engagement

We welcome the opportunity to meet with you to discuss our proposed *Phased Approach* and how we believe it will mitigate patient impacts while still achieving the important pharmaceutical tracing goals and will of Congress. We are in the process of sharing our *Phased Approach* with other pharmaceutical supply chain stakeholders who have expressed interest in our recommendations. We expect other entities will support our *Phased Approach*.

Please contact me or Elizabeth Gallenagh (egallenagh@hda.org) if you have any questions.

Sincerely,



Patrick Kelly
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