PDSA
Pharmaceutical Distribution Security Alliance

February 23, 2015

Dr. Ilisa Bernstein
Deputy Director, Office of Compliance
Food and Drug Administration
10903 New Hampshire Avenue
Bldg. 51, Rm 5271
Silver Spring, MD 20993-0002

Re: Drug Supply Chain Security Act Preemption

Dear Dr. Bernstein:

As you know, the Pharmaceutical Distribution Security Alliance (PDSA) is a coalition of companies and organizations dedicated to the safety and integrity of the pharmaceutical distribution supply chain. On December 4, 2014, PDSA submitted comments to the public docket regarding the Agency's Draft Guidance on the Effect of Uniform National Policy on Drug Product Tracing and Wholesale Drug Distributor and Third-Party Logistics Provider Standards. Despite publication of that draft guidance, some States continue to pursue regulatory policies that indicate significant, and problematic, differences in State approaches to implementation of the Drug Supply Chain Security Act (DSCSA).

Consistent State adherence to the uniform national requirements of the DSCSA is critical to the successful implementation of the statute. PDSA is concerned that the lack of uniformity among State approaches will undermine the DSCSA's clear objective of establishing national product tracing and licensure requirements. On November 27, 2013, the DSCSA preempted all State requirements related to the tracing of products, as defined in the statute. Similarly, with regard to licensure of wholesale distributors and third-party logistics providers (3PLs), the DSCSA preempted State licensing requirements covered by or directly related to the national standards set out in the DSCSA. While the DSCSA reserved important licensing functions for the States, it is critical that the States perform those functions in a manner that is consistent with the statutory authority granted under the DSCSA. Today, a handful of states are moving forward with product tracing and licensure legislation and we expect that as states conduct their legislative sessions, more will continue to do so. We have seen a lack of uniformity in the approaches that states are taking and we have heard many expressing a desire to understand the scope of the federal preemption more fully.

The following are a few examples of the State activity that lead us to believe that stronger education and outreach to states on the scope of DSCSA preemption would alleviate many of the legislative concerns:

North Dakota Senate Bill 2086. Senate Bill 2086[1] under consideration in North Dakota seeks to establish a licensure requirement for 3PLs that does not distinguish 3PLs from wholesale distributors as mandated by Section 585(b)(2) of the DSCSA.[2] Of note, the Bill would add 3PLs to the state definition of an "authorized distributor of record" and expressly require 3PLs to comply with North Dakota's "pedigree requirements."[3] However, the DSCSA preempted all State pedigree requirements, including North Dakota's, on November 27, 2013. Furthermore, the DSCSA also makes clear that traceability requirements are inapplicable to 3PLs.

Nevada Proposed Modification to NAC 639.6305. This proposal amends current state law to require out-of-state third-party logistics providers to obtain a state license. However, Section 584 of the DSCSA establishes national standards for 3PL licensure and says a State cannot require an out of state 3PL to obtain a license if it is licensed by the Secretary. Moreover, Section 582(a)(7) says that until "the effective date of the third-party logistics provider licensing regulations under section 584, a third-party logistics provider shall be considered 'licensed' under [the DSCSA] unless the Secretary has made a finding that the third-party logistics provider does not utilize good handling and distribution practices and publishes notice thereof."

Taken together, under the DSCSA, a 3PL can conduct activities in a State without an out-of-State license from that State, because that 3PL is deemed licensed by the Secretary (unless the Secretary has made a finding that the 3PL does not utilize good handling and distribution practices), and the state is prohibited from requiring state licensure pursuant to 584(1)(B).

California Board of Pharmacy Comments on Draft Preemption Guidance. In its comments submitted to FDA regarding the Draft Guidance on the Preemptive Effect of the DSCSA, the California Board of Pharmacy[4] stated:

> We also concur with your conclusion that section 503(e)(1)(A) (as amended) requires that a wholesale distributor "be licensed by the State from which the drug is distributed or else by the Secretary of Health and Human Services if the

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[1] *Available at* http://www.legis.nd.gov/assembly/64-2015/documents/15-8029-01000.pdf?20150125103846.

[2] Similar concerns exist with regard to proposed revisions to sections 639.6282 and 639.6305 or the Nevada Administrative Code. In fact, challenges related to definitions exist in many states. The DSCSA carefully defines five types of trading partners—manufacturers, wholesale distributors, 3PLs, dispensers, and repackagers. The statute imposes specific traceability and licensure requirements based upon those definitions. Misalignment of definitions among the states creates significant confusion in the marketplace on this issue, particularly with regard to licensure requirements as those apply only to entities defined in the DSCSA as a wholesale distributor or 3PL. For example, an entity that is a manufacturer under the DSCSA may have historically been considered a wholesale distributor by a state and been required to be licensed as such. For reasons such as this, it is important to clarify that the DSCSA definitions preempt state definitions with regard to related requirements.

[3] *See* Section 5 of the bill.

[4] *Available at* http://www.regulations.gov/contentStreamer?objectId=0900006481930a0c&disposition=attachment&contentType=pdf.

> distributing wholesale drug distributor's State chooses not to have a licensing program" and, "[i]n addition, . . . by the State into which the drug is distributed (if required by that State)." We presume the effect of identical language in section 584, as to third party logistics providers, is the same (licensure may be required by both states). It may be helpful to also have that specified in the final version of the Guidance document.
> (Emphasis added.)

The text in section 584(a)(2) is not "identical" to section 503(e)(1)(A), and therefore we do not believe that section 584(a)(2) can be presumed to have the same effect. Indeed, unlike the language applicable to wholesale distributors, section 584(a)(2) plainly states that a non-resident 3PL is only required to be licensed if the non-resident 3PL "is not licensed by the Secretary."

Florida Declaratory Statement. The Florida Department of Business and Professional Regulation recently issued a Declaratory Statement. The Declaratory Statement concludes that traceability requirements[5] related to "products" that are excluded from the DSCSA definition of "transaction" are not preempted by Section 585 of the DSCSA and may continue to be enforced by the States. However, the plain language of Section 585(a) preempts all state "requirements for tracing *products*" through the distribution chain. The term "product" is carefully defined in the DSCSA and includes products that are excluded from the definition of a "transaction", such as intravenous products intended for replenishment of fluids and electrolytes.

In light of these examples and the other states moving forward with inconsistent approaches to product tracing and licensure legislation, we urge the Agency to engage in focused efforts to ensure uniform state understanding of DSCSA implementation and federal preemption. An FDA-led education and outreach effort could uniquely highlight DSCSA obligations for states in an authoritative and public way, and could prevent much of the apparent confusion and disunity surrounding federal preemption.

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PDSA appreciates the FDA's continued efforts in implementation of the DSCSA. We welcome the opportunity to discuss this important topic or provide any other assistance that would be valuable to the Agency.

Sincerely,

Vince Ventimiglia
President, Leavitt Partners Collaborative Advocates and Advisor to PDSA
1050 K Street NW, Suite 310
Washington, D.C. 20001-4448
vince@leavittpartners.com

[5] Specifically, the tracing requirements in Fla. Stat. § 499.0121(6)(a)1.-5 are referenced.