PDSA
Pharmaceutical Distribution Security Alliance

December 4, 2014

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Federal Register Notice Requesting Comments on Draft Guidance for Industry on the Effect of Uniform National Policy on Drug Product Tracing and Wholesale Drug Distributor and Third-Party Logistics Provider Standards: Questions and Answers
Docket No. FDA-2014-D-1411-0001

Dear Sir/Madam:

On behalf of the Pharmaceutical Distribution Security Alliance (PDSA), I am pleased to submit these comments regarding the Food and Drug Administration's (FDA or Agency) October 8, 2014 Federal Register notice seeking comments on its Draft Guidance for Industry on The Effect of Uniform National Policy on Drug Product Tracing and Wholesale Drug Distributor and Third-Party Logistics Provider Standards: Questions and Answers (the Guidance).[1]

PDSA is a multi-stakeholder coalition with membership that spans the entire spectrum of the U.S. pharmaceutical distribution system, including manufacturers, repackagers, wholesale distributors, third-party logistics providers, and pharmacies. More than 30 companies are formal members of PDSA, while many other external stakeholders provide additional policy and technical support through industry trade associations. Our primary goal is ensuring patients have uninterrupted access to safe, authentic, FDA-approved medicine.

PDSA appreciates the opportunity to provide input on the Guidance, which is critical to successful implementation of the Drug Supply Chain Security Act (DSCSA).[2] Our comments represent the operational expertise of individuals throughout industry and reflect the knowledge of those at the front lines of implementing the DSCSA. PDSA hopes to remain engaged throughout the development and finalization of the Guidance as well as the implementation of other portions of the DSCSA. To the extent it is useful to the Agency, we offer our experience and expertise as a resource and welcome the opportunity for further discussion about this important topic.

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[1] 70 Fed. Reg. 60853 (Oct. 8, 2014).
[2] Title II of the Drug Quality and Security Act, Pub. L. No. 113-54, 127 Stat. 587 (2013).

The DSCSA establishes a national system for the traceability of certain prescription pharmaceutical products through the distribution chain and provides for uniform national standards for licensure of pharmaceutical wholesale distributors and third-party logistics providers (3PLs). The national uniformity of the DSCSA is achieved through preemption of certain state[3] requirements, as set out in Section 585 of the Food, Drug, and Cosmetic Act (FDCA). We appreciate the Agency's efforts to bring greater clarity to the preemptive effect of Section 585, particularly at this time when a number of states seem to lack clear understanding of that preemptive effect. While the Agency's efforts are greatly appreciated, we are deeply concerned by its characterization of the scope of the DSCSA's preemptive effect on wholesale distributor and 3PL licensing standards. These concerns are explained below, along with other suggestions that we believe will make the Guidance more useful for industry, the states, and other stakeholders. We respectfully ask that the Agency address the comments below in its final guidance.

1. The Guidance should clarify that Section 585 preempts state requirements and related definitions.

Section 585(a) of the FDCA preempts all state traceability requirements that are inconsistent with, more stringent than, or in addition to any requirement in Section 503(e) or Subchapter H. Subchapter H contains both the definitions set out in Section 581 and the traceability requirements set out in Section 582. Therefore, the preemptive effect of Section 585(a) extends to any state requirements related to product tracing as well as the definitions that underlay any such requirements.

The definitions in Section 581 are a critical part of the requirements in Section 582. For example, different requirements under Section 582 apply to manufacturers, repackagers, wholesale distributors, 3PLs, and dispensers. Each of those terms is specifically defined in Section 581. If a state were permitted to adopt different definitions of those terms, the state would effectively be able to alter the requirements under Section 582 and create significant confusion in the marketplace. Similarly, the scope of the requirements under Section 582 is largely determined by the definition of a "product" under Section 581(13)—a definition carefully crafted by Congress. Any state definition that were to narrow or expand the DSCSA definition of "product" would significantly alter the traceability requirements established by the DSCSA and clearly run contrary to the statute's intent.

Similarly, the definition of "wholesale distribution" in Section 503(e)(4) and "third-party logistics provider" in Section 581(22) are critical to the licensure requirements in Sections 503, 583, and 584. In particular, the definition of "wholesale distribution" expressly excludes "the distribution of a drug by the manufacturer of such drug."[4] Accordingly, a manufacturer is not a wholesale distributor when distributing its own products, and a state cannot require a manufacturer to be licensed as a wholesale distributor. Such state requirements for manufacturers are inconsistent with and directly related to the federal licensure requirement for wholesale distributors and therefore are preempted under Section 585(b)(1).

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[3] Like the Guidance, we use the term "state" to refer to states and political subdivisions of states.
[4] FDCA § 503(e)(4)(H).

We ask that the Agency clarify that the preemptive effect of Section 585 extends to both the requirements of the DSCSA and the definitions set out in it.

2. Additional examples of the types of state requirements related to traceability which are preempted would be valuable.

Lines 96–100 of the Guidance identify types of state requirements that are considered "requirements for tracing products through the distribution system." The list of such requirements included in the Guidance mirrors the list included in Section 585(a) and therefore adds little clarity to the traceability preemption. We believe it will be useful if the final guidance includes additional examples of requirements the Agency believes are related to tracing product through the distribution system.

3. The Guidance mischaracterizes the preemptive scope of Section 585(b).

Section 585(b) establishes uniform licensure requirements for wholesale distributors and 3PLs by preempting state licensure requirements that do not utilize the federal standards to be developed by the Agency. Section 585(b) was intended to preempt state requirements that exceed the federal standards, yet the Guidance inaccurately characterizes the federal standards as only minimum standards for licensure. We ask the Agency to clarify that states must not exceed or otherwise deviate from the federal standards that will be developed.

The clear and primary intent of the DSCSA was to establish uniformity among states. In fact, with regard to licensure, the statute itself expressly states its intent to establish uniformity. Section 583(b) provides that the licensing standards established by the DSCSA are "[f]or the purpose of ensuring ***uniformity*** with respect to [the federal licensing] standards."[5] That section goes on to explain that "the standards established [by the Agency] shall apply to all State and Federal licenses . . . ." Uniformity[6] simply does not exist unless all states are required to utilize identical standards.

Congress emphasized its desire for uniformity in its consideration and passage of the DSCSA. In passing the DSCSA, Representative Latta explained the DSCSA was intended to "replac[e] the current patchwork of multiple State laws with a ***uniform*** national standard, [thereby] improving safety, eliminating duplicative regulations, and creating certainty for all members of the pharmaceutical supply chain."[7] The intent to create certainty and predictability with regard to wholesale distributor and 3PL licensure was echoed in the Senate where it was explained that the licensing provisions of the DSCSA are intended to "ensur[e] that national distributors and third-party logistics providers do not face the burden of dealing with a confusing and inconsistent patchwork of State-by-State rules."[8]

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[5] FDCA § 583(b) (emphasis added).
[6] Black's Law Dictionary defines "uniform" as "Characterized by a lack of variation; identical or consistent."
[7] H.R. 3204, 113th Cong., 159 Cong. Reg. 131, at 5962 (statement of Rep. Latta) (2013) (emphasis added).
[8] Drug Quality and Security Act, 113th Cong., 159 Cong. Rec. 164, at 58071 (statement of Sen. Isakson) (2013).

Despite the clear intent of the statute, the Guidance mischaracterizes Section 585(b) as establishing only minimum standards and implying that states can establish standards different from the federal standards so long as the state standards are more onerous than the federal standards. Six times throughout the Guidance, the Agency notes that states are prohibited from establishing licensure standards that "fall below the minimum standards established by Federal law."[9] This standard expressed by the Agency is inconsistent with the statute and runs directly contrary to the legislative intent of the DSCSA. If states could establish higher standards, wholesale distributors and 3PLs could be left having to comply with 50 different sets of rules, which, as explained by Representative Matheson, "doesn't make sense."[10] A patchwork of licensing standards is precisely the regulatory burden the DSCSA was intended to eliminate.

Permitting states to establish standards that go beyond the standards established by the Agency pursuant to Sections 583 and 584 is also poor public policy. Many wholesale distributors and 3PLs operate, and are subject to licensure in, multiple states. Tracking and complying with different standards for different facilities is time consuming and adds unnecessary costs to the distribution chain. Furthermore, such variations are not necessary to protect patient health as the DSCSA was specifically designed to raise the standards for wholesale distributor and 3PL licensing.[11]

At first blush, one may be tempted to conclude that the difference in statutory language in Sections 585(a) and 585(b) suggests that the federal licensing standards are minimum standards only. That, however, is not an accurate representation of legislative intent. The difference in statutory language was intended to signal that traceability preemption under Section 585(a) is *broad* (*i.e.*, any requirement directly or indirectly related to product tracing) and complete (*i.e.*, any state requirement not identical to the federal standard), whereas licensure preemption under Section 585(b) is *narrow* (*i.e.*, strictly limited to licensing standards) and complete. This distinction is important.

The difference in statutory language in 585(a) and 585(b) was not intended to suggest that either is not complete preemption (*i.e.*, preemption of any state requirement not identical to the federal requirement), but rather to indicate a difference in breadth. With regard to product tracing, Congress sought to preempt any state requirement related, even indirectly, to product tracing. With regard to licensing standards, however, Congress sought to preempt only those state requirements that are *directly* related to[12] licensing standards. Specifically, Congress did not want to tread into other areas of regulation related only indirectly to licensing standards. For example, Congress wanted to ensure that Section 585(b) did not prevent states from continuing to collect fees for prescription drug monitoring programs, which are important tools for addressing prescription drug abuse and misuse. Similarly, Congress did not want Section 585(b) to prevent states from enforcing tangentially related, generally applicable regulatory requirements, such environmental registration or permit requirements applicable to all types of businesses.

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[9] *See* lines 136, 144, 148-149, 170, 183, and 201 of the Guidance.
[10] H.R. 3204, 113th Cong., 159 Cong. Reg. 131, at 5964 (statement of Rep. Matheson) (2013)
[11] *See* H.R. 3204, 113th Cong., 159 Cong. Reg. 131, at 5961 (statement of Rep. Pallone) (2013).
[12] FDCA § 585(b).

The preemptive effect of Section 585(b) applies to all state requirements that are "inconsistent with, less stringent than, directly related to, ***or*** covered by" the federal standards. Meaning and effect must be given to each and every one of the four standards included in Section 585(b). Take, for example, the wholesale distributor licensing standard regarding surety bonds. The statute provides that a non-governmental wholesale distributor must submit a surety bond of $100,000. Under the Agency's interpretation of Section 585(b) in the Guidance, a state would be permitted to require a surety bond of $150,000. It is impossible to see how a $150,000 bond requirement is not a state standard which is "directly related to" or "covered by" the federal standard for surety bonds.

We strongly urge the Agency to clarify that the federal licensing standards for wholesale distributors and 3PLs will not be merely minimum standards, but rather, will be the single set of standards from which states must not deviate.

4. The DSCSA anticipates that states will not establish licensure requirements for 3PLs until the federal licensing standards for 3PLs are published by the Agency.

We are concerned that subsection C.2. of the Guidance will encourage states to establish conflicting licensure requirements for 3PLs prior to the Agency's adoption of federal standards for 3PL licensure. As explained above, the DSCSA was intended to eliminate the existing patchwork of licensing standards and establish a single, uniform set of licensing standards. The development of state licensing requirements for 3PLs prior to the Agency's publication of federal licensing standards will only increase the patchwork of regulatory requirements 3PLs must navigate. Furthermore, given the preemptive effect of Section 585(b), any licensing requirements established prior to release of the federal standards will almost certainly have to be revised when those federal standards go into effect. This burdens state regulators and 3PLs alike.

The development of state licensure requirements prior to release of the federal standards also has the potential to create significant confusion. For example, assume a 3PL is licensed by a state prior to release of the federal standards and the license does not expire until after the effective date of the federal standards. If the initial state licensing standards do not comply with the federal standards (which they almost certainly will not prior to development of the federal standards), there will be significant confusion surrounding the 3PL's licensure obligations as of the effective date of the federal standards.

The DSCSA statutory text itself also clearly contemplates that states will not establish 3PL licensure requirements until federal standards are developed and released. Specifically, Section 582(a)(7) provides that, until states properly establish 3PL licensure requirements, a 3PL is deemed to be licensed for purposes of the DSCSA. Furthermore, until the federal standards are effective, Section 582(a)(7) grants the Agency adequate authority to protect the supply chain from unqualified and unscrupulous 3PLs by revoking their deemed licensed status. This clearly suggests that Congress expected states would refrain from establishing 3PL licensure requirements that would conflict with the federal standards once they are released.

In recognition of the practical challenges that would be created by divergent state licensure requirements in advance of the federal standards, rather than encourage states to establish such requirements, we encourage the Agency to assure states that it will exercise its authority to revoke the deemed-licensed status of unscrupulous 3PLs. This assurance will provide states protection of the supply chain without establishing inconsistent licensure requirements. Specifically, we urge the Agency to replace subsection C.2. of the Guidance with the following:

> *FDA recognizes the logistical challenges associated with licensing 3PLs before the new Federal regulations for 3PL standards and licensing go into effect. Due to the preemptive effect of sections 585(b)(1) and 585(b)(2) of the FD&C Act, any licensing requirements established by a state before the new Federal regulations for 3PL standards and licensing go into effect will likely have to be amended to conform to those new Federal regulations.*
>
> *Prior to the effective date of the federal 3PL licensing standards, section 582(a)(7) of the FD&C Act provides that a 3PL is considered licensed for purposes of the DSCSA unless the Secretary makes a finding that the 3PL does not utilize good handling and distribution practices and publishes notice thereof. Recognizing the challenges associated with 3PL license requirements before the Federal regulations go into effect, the Agency will utilize its authority under Section 582(a)(7) to revoke the licensed status of any 3PL that does not utilize good handling and distribution practices in order to maintain a secure supply chain in states that do not establish 3PL licensure requirements prior to release of the federal standards.*

5. The Agency should clarify that the preemptive effect of Section 585(b)(2) applies to wholesale distributor licenses currently held by 3PLs.

We appreciate the Agency's recognition[13] that states are prohibited from regulating 3PLs as wholesale distributors. Recognition of the practical operational differences between wholesale distributors and 3PLs is critical. To this end, we ask that the Agency further clarify that the immediate preemption of wholesale distributor licensure requirements, as applied to 3PLs, extends to wholesale distributor licenses currently held by 3PLs.

Many 3PLs were required to be licensed as wholesale distributors at the time the DSCSA was enacted. Many of those wholesale distributor licenses are now beginning to, or will soon, expire. Consistent with its recognition that states cannot require 3PLs to be licensed as wholesale distributors, the Agency should clarify that 3PLs are not required to maintain such wholesale distributor licenses.

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We appreciate the opportunity to provide these comments on this important topic, and we thank the Agency for its consideration of these comments. As useful to the Agency, we welcome the opportunity for further discussion on the Guidance and related topics.

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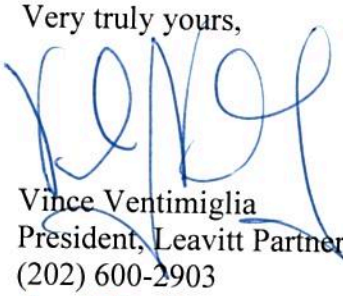
[13] *See* section C.4. of the Guidance.

Very truly yours,



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