PDSA
Pharmaceutical Distribution Security Alliance

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February 9, 2015

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Re: Federal Register Notice Requesting Comments on Draft Guidance for Industry on Drug Supply Chain Security Act Implementation: Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers
Docket No. FDA-2014-D-2083

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the Food and Drug Administration's (FDA or Agency) December 9, 2014 Federal Register notice seeking comments on its Draft Guidance for Industry on Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers (the Guidance).[1]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] 79 Fed. Reg. 73,083 (Dec. 9, 2014).
[2] Title II of the Drug Quality and Security Act, Pub. L. No. 113-54, 127 Stat. 587 (2013).

The DSCSA establishes national standards for the licensure of wholesale distributors and third-party logistics providers (3PLs). As part of that licensure scheme, wholesale distributors and 3PLs are required to annually report to the FDA certain licensure information. The DSCSA carefully describes those reporting requirements, and it is critical that the Agency—both in the Guidance and in practice—adheres to those statutory provisions. To that end, we respectfully ask that the Agency address the comments below in its final guidance.

1. Regulatory creep with regard to reported information and public databases may upset the statutory balance between public health and regulatory burden.

The reporting requirements in Section 503(e)(2) and 584(b) were carefully drafted to establish the parameters for reporting. As with all parts of the DSCSA, it is critical that the statutory requirements be implemented in accordance with the statutory text and not unduly expanded. For example, the differences between the reporting requirements for wholesale distributors and 3PLs were intentional. Expansion of the DSCSA requirements through regulation and guidance runs the significant risk of upsetting the delicate balance struck by the statute between public health and regulatory burden.

The DSCSA sets forth the specific types of information that must be reported by wholesale distributors and 3PLs. For example, the statute requires wholesale distributors to report significant disciplinary actions, but no parallel obligation is included with regard to 3PLs.[3] As we will explain further below, the statute also does not require submission of a facility identifier, yet the Guidance calls for a facility identifier, and wholesale distributors and 3PLs have found that licensure submissions cannot be completed via the FDA portal without including a D-U-N-S number. It is important that the Agency respect these and other differences in statutory text because, absent additional public health interest, the expansion of the reporting obligation to include additional types of information adds unnecessary burden to the supply chain.

It is also important that the Agency not expand the amount or types of information included in the public database of licensed wholesale distributors beyond that which is directed by the statute. Expanding the scope of information available in the public database beyond that information expressly directed by the statute could in fact undermine the goals of the DSCSA. Cargo theft, warehouse theft, and resulting diversions are a serious concern, and the statutory reporting requirements in the DSCSA (*e.g.*, name and contact information, but not facility addresses) represent Congress' appreciation of this concern and their attempt to balance the real need for current licensure information with the availability of information that may enable such thefts. It is important that information that could be used to identify the location of a facility, such as an address or telephone number, not be made publicly available.

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[3] 3PLs are not required to submit disciplinary actions by statute and therefore should not be required to do so by guidance. If disciplinary reporting were required for 3PLs despite the statutory exclusion of such a requirement, it would be critical to ensure that the reporting requirement does not include disciplinary actions taken against the trading partners on behalf of whom a 3PL is acting. For example, if a disciplinary action were taken against a manufacturer to whom a 3PL provides services, the 3PL must not be required to report such action against the manufacturer.

Similarly, the statute clearly and intentionally calls on the Agency to establish a public database only for wholesale distributors. While we recognize the Agency's desire to maximize the usability of reported licensure information, it is important that the Agency's final guidance aligns with, and remain within, the requirements of the statute. Accordingly, we urge the Agency to limit all reporting requirements for wholesale distributors and 3PLs to those set out in Section 503(e)(2) and 584(b).

2. The Agency should clarify that the reporting obligations apply only to wholesale distributors and 3PLs as defined in the DSCSA.

The DSCSA carefully defines five types of trading partners—manufacturers, wholesale distributors, 3PLs, dispensers, and repackagers. The licensure provisions, including the reporting obligations in Sections 503(e)(2) and 584(b), apply only to wholesale distributors and third-party logistics providers. The Agency should clarify that the reporting obligations only apply to those entities that meet the DSCSA definition of a wholesale distributor or 3PL. DSCSA reporting obligations do not extend to manufacturers, repackagers, or dispensers.[4]

Misalignment of definitions among the states has created significant confusion in the marketplace on this issue. 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. Similarly, an entity that is a dispenser under the DSCSA may have historically been considered a wholesale distributor by a state and been required to be licensed as such. The DSCSA sought to eliminate this patchwork confusion.[5] It is important that the Agency clarify that the reporting requirements under Section 503(e)(2) and 584(b) do not apply to any entity that does not meet the DSCSA definition of either a wholesale distributor or a 3PL, regardless of whether a state historically considered such entity to be a wholesale distributor or 3PL.

3. We support the timeframes for initial reporting and reporting disciplinary actions, subject to clarification.

Lines 238–240 of the Guidance require newly licensed wholesale distributor and 3PL facilities to be reported within 30 days of obtaining a license. It is not uncommon for a state to issue a wholesale distributor or 3PL license that is retroactively effective multiple months (*e.g.*, retroactive to the date of application). Therefore, we ask the Agency to clarify that reporting is required within 30 days of the date the wholesale distributor or 3PL actually receives the relevant state or federal license, not the effective date of the license.

Lines 252–253 require wholesale distributors and 3PLs to report significant disciplinary actions within 30 days of final action. As explained above, the DSCSA does not require 3PLs to report disciplinary actions. Aside from that concern, we support the 30-day time frame for reporting

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[4] As PDSA has expressed in that past, the structure of the DSCSA also makes clear that a manufacturer, repackager, or dispenser cannot also be a wholesale distributor or 3PL with regard to a product—a given entity is one, and only one, type of trading partner with regard to a given product. For example, an affiliate of an NDA holder that provides logistics services to the NDA holder is part of the manufacturer, not a 3PL.

[5] This point is also discussed in Section 1 of PDSA's December 4, 2014 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.

and, in particular, support the Agency's explanation that the reporting obligation is initiated by a "final action."

4. We encourage FDA to reconsider the requirement that a D-U-N-S number be reported.

PDSA does not agree with the requirement to include a facility identifier, particularly the D-U-N-S number, and urges FDA to reconsider its inclusion. The DSCSA does not require a D-U-N-S number to be reported. Consistent with this fact, the Guidance states that the D-U-N-S number is a "preferred" facility identifier, but we note that there is not an option in the portal for using any other identifier, effectively mandating a D-U-N-S number even before FDA has received public comments and without a statutory requirement.

Although we believe the best course of action is to eliminate the D-U-N-S requirement, if FDA retains that requirement, it should be noted that PDSA members who have initiated efforts to enter data into the portal have encountered several operational limitations associated with reporting D-U-N-S numbers. Specifically, the following considerations should be addressed in the Guidance:

- If a wholesale distributor and 3PL are co-located in a single facility, a single D-U-N-S number is often issued for that facility, and the same number would therefore apply to the wholesale distributor and the 3PL.
- Many 3PLs obtain a single D-U-N-S number for multiple facilities. Other 3PLs obtain separate D-U-N-S numbers for each facility. The reporting system should accept and recognize either approach.
- A significant amount of time and effort is required to obtain new D-U-N-S and to collect D-U-N-S numbers from existing facilities. Timing requirements and technological capacities of the reporting system should account for this.
- The D-U-N-S number is relatively easy to use to locate a facility's address. Thus, it should not be publicly available on the website in order to avoid disclosing any information that may compromise facility security.

To the extent these considerations have already been reflected in development of, or updates to, the reporting portal, we appreciate the Agency's doing so.

5. A single contact person can be for used for multiple facilities.

Lines 105–107 require the submission of contact information for an individual contact person. In many instances, the same contact person, such as a corporate employee responsible for licensing, will be identified for multiple facilities. We encourage the Agency to clarify that the use of a single contact person for multiple facilities is acceptable.

6. We agree with the Agency's characterization of the licensure requirement for 3PLs.

Lines 189–193 and 201–205 of the Guidance accurately describe a 3PL's obligation to be licensed pursuant to the DSCSA. The licensure requirement for 3PLs has generated significant confusion among the states. We appreciate the Agency's attention to the detail of this

requirement and support the characterization of the licensure requirement in lines 189–193 and 201–205.

7. We encourage outreach by the Agency to improve the usability of the reporting website.

Early reports from industry indicate opportunity for improvement in the usability of the licensure reporting website. To enhance the usability of the website, we encourage the Agency to consider the following:

- The electronic format should allow multiple records to be uploaded through an Excel document or other means. For example, when a 3PL opens operations for a customer, it often must be licensed to provide those services in several, or even dozens of, states. The burden of reporting would be significantly reduced if multiple licenses could be reported in a single file.
- It should be easy to edit uploaded records. Currently if an error in the data is made or a license is forgotten, there is no ability to edit the information once submitted. Similarly, a record for an expiring licensing cannot be updated to reflect that it has been renewed.
- The individuals most often tasked with reporting are not technology experts, but rather licensing or regulatory professionals.
- Some users report that the optional additional information the Agency has asked be submitted (*e.g.*, unique identifier, expiration date of license) is actually required in the submission form.

We strongly suggest the Agency host a webinar to educate wholesale distributors and 3PLs on using the database.

8. The burden of reporting is underestimated.

The Paperwork Reduction Act estimates in the Federal Register notice significantly underestimate the burden of licensure reporting. We encourage the Agency to engage with wholesale distributors and 3PLs—particularly those with multiple facilities—to better understand the true burden of this reporting obligation.

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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.

Very truly yours,

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