April 24, 2019

Norman E. Sharpless, M.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Building l, Room 2217
Silver Spring, MD 20993

RE: Promulgation of Required Regulation Pursuant to the Drug Supply Chain Security Act (DSCSA)

Dear Acting Commissioner Sharpless:

As associations representing members of the pharmaceutical supply chain, we are writing to express our serious concerns about the prolonged delay in issuance of certain statutorily mandated regulations implementing the Drug Supply Chain Security Act of 2013 (DSCSA).\(^1\) We would like to take this opportunity to outline the grave and mounting implications of this delay for pharmaceutical supply chain security. We also write in support of the concerns raised by the International Warehouse Logistics Association (IWLA) in its recent letter to your predecessor, Dr. Scott Gottlieb (IWLA letter).\(^2\)

We join the IWLA in respectfully requesting your attention to this urgent matter to assure that these long-overdue regulations are swiftly promulgated.

Our organizations, listed below, represent members of the pharmaceutical supply chain. Collectively, our members are responsible for helping to ensure that critically important pharmaceutical products reach the patients for whom they are intended in a safe, secure manner, whenever and wherever they are needed. Product integrity is paramount, and we are committed to working with FDA and other supply chain members to accomplish these vital public health goals.

Congress enacted the DSCSA to enhance FDA’s ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful. We appreciate Dr. Gottlieb’s recognition in February 2018 at FDA’s DSCSA public meeting that a critical component of the law’s supply chain security protections is “the DSCSA direction to FDA to establish national licensure standards for wholesale distributors and third-party logistics providers” and that “fragmentation of state licensing regimes was one of the security

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\(^1\) The DSCSA is Title II of Public Law No. 113-54, the Drug Quality and Security Act. All citations are to the Federal Food, Drug and Cosmetic (FDC) Act, as amended by the DSCSA.

\(^2\) September 28, 2018 Letter to Scott Gottlieb, M.D., Commissioner, Food and Drug Administration from Steve DeHaan, President and CEO, International Warehouse Logistics Association (IWLA) (attached).
vulnerabilities Congress sought to address in the law.” To that end, we were encouraged by assurances that FDA plans “to release new regulations that... will apply to all state and federal licenses issued to wholesale distributors and 3PLs.” The DSCSA mandated the issuance of these regulations to establish national standards for the licensure of wholesale distributors and 3PLs by November 27, 2015. Unfortunately, it is now well beyond three years since this statutorily mandated deadline and FDA has yet to issue these crucial regulations – even in proposed form.

We have shared our concerns about this delay with Agency staff on numerous occasions and are grateful for their responsiveness and ongoing efforts to meet this regulatory mandate. However, the continuing delay has become gravely disruptive, and there does not appear to be a firm date by which proposed regulations will be issued. The regulations were intended to simultaneously strengthen the supply chain and eliminate the patchwork of different and inconsistent state requirements by establishing national standards for wholesale distributors and 3PLs, bringing much needed uniformity to recordkeeping, personnel qualifications, storage and handling of drugs, and other important matters.

The protracted delay has also had a significant impact in the states. For example, as IWLA describes, long-standing, well-established 3PLs are eager to comply with the DSCSA, but have been unable to obtain appropriate licenses from various states. This inability to obtain licenses appears primarily due to state licensing authorities’ uncertainties about DSCSA licensure requirements. The inability of 3PLs to obtain state licenses harms their own businesses and ripples throughout the supply chain, disrupting longstanding and efficient supply arrangements with wholesale distributors and pharmacies. 3PL customers have had to endure increased costs and burdens to find other means to receive the prescription drugs they need for patient care.

In response to the IWLA letter, Donald Ashley, Director of the FDA Office of Compliance, noted that he understood these concerns. He stated that FDA staff are working to clarify DSCSA requirements with state officials at various meetings. While we recognize and support these efforts, they are not a substitute for the uniform, national licensure standards the DSCSA mandates.

Moreover, in the absence of the FDA-promulgated regulations, we are concerned that the terms of the DSCSA, as well as information being shared with state officials, are being interpreted and

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4 Id.

5 “The Secretary shall, not later than [November 27, 2015], establish by regulation standards for the licensing of [wholesale distributors] under section § 503(e)(1)...” § 583(d)(1). “Not later than [November 27, 2015], the Secretary shall issue regulations regarding the standards for licensing … including the revocation and reissuance of such license, the third-party logistics providers...” § 584(d)(1).

6 § 583(b)-(c), § 585.

7 See December 12, 2018 letter from Donald Ashley to Steve DeHaan, President and CEO, IWLA.
implemented differently by officials in each state, thereby undermining national uniformity in supply chain security. Though the DSCSA was intended to, among other things, assure consistent national standards, the absence of regulations has resulted in multiple instances in which state regulatory authorities have established, or considered establishing, requirements that are inconsistent with the DSCSA.

We believe the absence of the uniform national licensure standards the DSCSA mandates has significantly strained pharmaceutical supply chain organizations as they continue to address conflicts, inconsistencies, and confusion that Congress intended to resolve with the FDA regulations. We collectively feel that their issuance would substantially resolve – if not entirely eliminate – most of these difficulties. Moreover, without the licensure regulation, the DSCSA’s safety and security measures are not reaching their full potential as the pharmaceutical supply chain works towards final implementation of DSCSA requirements for pharmaceutical traceability.⁸

In conclusion, the entire pharmaceutical supply chain recognizes the many challenges faced, and the diligent efforts performed, by FDA’s staff. It is with our full support of both the DSCSA and of the Agency’s efforts to oversee implementation of this landmark legislation that we urge your attention to spur publication of these vitally important, and legally required, regulations as soon as possible.

We thank you for the opportunity to bring this to your attention. We look forward to continuing the dialogue with you and your staff about implementation of this important legislation.

Sincerely,

Thomas E. Menighan, BSPharm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO
American Pharmacists Association (APhA)
https://www.pharmacist.com/

Matthew J. Rowan
President and CEO
Health Industry Distributors Association (HIDA)
http://www.hida.org/

Rebecca P. Snead
Executive Vice President/CEO
National Alliance of State Pharmacy Associations (NASPA)
www.naspa.us

John M. Gray
President and CEO
Healthcare Distribution Alliance (HDA)
www.hda.org

⁸ See, e.g., § 582(g) (by November 27, 2023, the interoperable, electronic tracing of pharmaceutical packages shall go into effect).
Karen L. Moody  
President  
National Coalition of Pharmaceutical Distributors (NCPD)  
Karen.moody@atlanticbiologicals.com

Thomas A. O’Donnell, IOM  
Senior Vice President  
National Association of Chain Drug Stores (NACDS)  
www.nacds.org

CC:
Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research.
Douglas Throckmorton, M.D., Deputy Director Center for Drug Evaluation and Research
Anna K. Abram, Deputy Commissioner for Policy, Planning, Legislation, and Analysis
Donald Ashley, Director, Office of Compliance, CDER
Ilisa B. Bernstein, Deputy Director, Office of Compliance, CDER
Connie Jung, Senior Policy Advisor, ODSIR