HDA
Healthcare Distribution Alliance
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Healthcare Distribution Alliance (HDA) Testimony
The Honorable Senator Bob D. Hackett
Chair, Senate Health and Medicaid Sub-Committee
Testimony
HB49

Good Afternoon, Chairman Hackett and Members of the Senate Health and Medicaid Subcommittee, thank you for the opportunity to participate in today's hearing. My name is Bryan Lowe, and I am the Director of State Government Affairs for the Healthcare Distribution Alliance (HDA). I am here today to respectfully request a series of amendments to HB49. HDA would like to emphasize the fact that these amendments have been previously discussed with the Ohio Board of Pharmacy and were agreed upon during those conversations. They do not alter the intent of the proposed legislation but instead, simply align the language with the federal Drug Supply Chain Security Act (DSCSA) standard.

HDA is the national trade association representing primary pharmaceutical wholesale distributors. Every day, HDA distributor members deliver approximately 15 million life-saving medications to pharmacy settings nationwide. Working closely with manufacturers, pharmacies, and regulators, HDA members help ensure the efficiency, safety and security of the pharmaceutical supply chain. I appreciate the opportunity to testify today welcome the opportunity to work collaboratively with the Ohio state legislature as HB49 progresses through the legislative process.

The DSCSA was signed into law in 2013 and established a national, uniform solution to ensure a safer and more secure pharmaceutical supply chain phased in over the next ten years.[i] HDA was at the forefront of this legislative effort, and continues to be a nationally recognized resource regarding the proper implementation of DSCSA requirements at the federal and state levels. HDA is currently assisting several states as they progress through both the legislative and regulatory processes required to comply with DSCSA. Both licensure and drug product traceability standards were included with DSCSA. This law also included several standard definitions that provide clarity and uniformity to the supply chain regarding wholesale distributor licensure standards.

HDA has coordinated with the Ohio Board of Pharmacy and has discussed the following recommendations which offer the simplest approach to ensure compliance with federal standards and prevent downstream conflict with federal preemption.

First, HDA requests an amendment to the proposed definition(s) for "Manufacturer." Specifically, we have offered the DSCSA definition of the term which reads,

"The term 'manufacturer' means, with respect to a product –

- *(A) a person that holds an application approved under section 505 or a license issued under section 351 of the Public Health Service Act for such product, or if such product is not the subject of an approved application or license, the person who manufactured the product;*
- *(B) a co-licensed partner of the person described in subparagraph (A) that obtains the product indirectly from a person described in this subparagraph or subparagraph (A) or (C); or*
- *(C) an affiliate of a person described in subparagraph (A) or (B) that receives the product directly form a person described in this subparagraph of subparagraph (A) or (B)."*

Secondly, HDA recommends replacing the definition for *"Sale"* or *"Sell"* with the DSCSA definition of "Transaction", which reads,

"Transaction" means the transfer of product between persons in which a change of ownership occurs.

Finally, HDA recommends replacing the definition of "package" to the DSCSA definition of "package" to exclude shipping units such as cases or totes from the definition. If such exemption remains absent from the final provisions, this language will conflict with federal law as Wholesale distributors are currently not permitted to place the name of a controlled substance on the exterior of shipping containers. We strongly advise against any requirement that would require wholesale distributors to indicate the presence of controlled substances on shipping containers due to the security risk this labeling would pose during shipment and increase risk of diversion.

In summary, HDA requests the above-mentioned amendments to be included within the final version of HB49 to bring the law into compliance with federal law and existing pharmaceutical supply chain industry practices. HDA provides these recommendations and sincerely thanks the State Board of Pharmacy for working with HDA.

Thank you for your time, and I am happy to answer any questions.

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[i] H.R. 3204, The Drug Quality and Security Act (DQSA) was signed by the President on November 27, 2013 (becoming Public Law 113-54)