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CALIFORNIA HEALTHCARE INSTITUTE

CHI Supports Uniform National Standard Provision In Pharmaceutical Supply Chain Integrity Legislation

National Drug Tracing Standards Will Strengthen Patient Protections

California Healthcare Institute (CHI), the public policy association representing California's statewide life sciences sector – including biotechnology, pharmaceutical, medical device and diagnostics companies, universities and private research institutions, and venture capital firms – applauds federal efforts to improve the integrity of our nation's drug and biologic products supply to better protect patients against the dangers of counterfeit, subpotent, stolen, misbranded or otherwise altered medicines.

California was the first state to enact legislation outlining an electronic tracing system for our nation's pharmaceutical supply chain, and our state should be applauded for laying the groundwork for these important reforms that will help ensure the safety of our nation's medicines. Since the California law was passed, several other states have taken similar steps to set up electronic tracing systems – the unfortunate result, however, is an emerging patchwork of individual state laws that are proving to be exceedingly difficult for manufacturers and other stakeholders in the drug supply ecosystem to manage.

The creation and implementation of new standards and capacities to track the distribution of pharmaceutical products is a tremendous undertaking for manufacturers, wholesalers, and dispensers alike – in one state alone, such efforts will likely cost hundreds of millions of dollars. These changes in business practice will have profound consequences for the highly complex operations of manufacturing facilities, packaging lines, distribution centers, and the operations of third-party partners and logistics providers. Rather than being distracted by implementing incompatible state standards, and squandering limited human and capital resources on developing new systems for state provisions that may be ultimately discontinued, CHI believes it is important to focus attention and resources on implementing a uniform, federal traceability standard.

To this end, CHI recommends federal legislation contain the following elements:

- **Uniform National Standard**: The potential for up to 50 separate and potentially inconsistent statutory pedigree and traceability schemes would introduce significant inefficiencies into the national drug distribution system, erect barriers to interstate commerce, and create confusion which counterfeiters and bad actors may seize upon. Congress must establish appropriate, uniform national drug serialization and tracing standards, rather than rely on the emerging patchwork of individual state mandates.

- **Immediate Preemption of Existing State Laws:** So that all supply chain stakeholders will have the confidence necessary to immediately begin investing in new national capacities for tracking prescription drugs that will benefit patients and help to further combat criminal counterfeiting in all 50 states, immediate preemption of existing state laws should be enacted.

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It is important to note that the existing California law is self-preempting and explicitly states*: "Upon the effective date of federal legislation or adoption of a federal regulation addressing pedigree or serialization measures for dangerous drugs, [the California law][1] shall become inoperative."*[2] Unless the underlying California law itself is amended, any federal legislation will serve to preempt the California law regardless of how the federal preemption is structured. While California should be proud to have led the way on this issue, it is also to be credited with including this forward-looking provision.

- **Unit-Level Traceability**: Federal legislation should include a process for moving toward a national unit-level traceability system informed by appropriate pilots and studies. Unit-level tracing, which is also favored by FDA and drug safety advocates, would maximize the effectiveness of an electronic tracing system and bring the greatest protection to patients.

CHI is strongly supportive of federal legislative efforts to more efficiently and effectively protect American patients and consumers through a single, uniform and national pharmaceutical distribution supply chain solution. **We therefore support Congressional passage of S. 959, the *Pharmaceutical Quality, Security, and Accountability Act*, as an important step toward fulfilling this goal.**

[1] California Business and Professional Code, Sections 4034, 4163, 4163.1, 4163.2, 4163.4, and 4163.5

[2] California Business and Professional Code 4034.1, http://www.leginfo.ca.gov/cgi-bin/displaycode?section=bpc&group=04001-05000&file=4015-4045