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## **Nonprofit Governance Body Launched to Achieve Interoperable Drug Tracing**

**Washington, D.C., December 16, 2019** --- Dozens of leading health care and pharmaceutical companies have joined together to establish the Partnership for DSCSA Governance, Inc. (PDG). PDG, an independent nonprofit organization, will serve as an independent, balanced, sector-neutral pharmaceutical industry governance body to support the interoperable electronic tracing of pharmaceuticals, as required by the Drug Supply Chain Security Act (DSCSA).

This launch marks a major milestone on the pathway to interoperability, establishing a critical mechanism by which the pharmaceutical supply industry will collaborate to develop a comprehensive shared vision for interoperable drug tracing. General membership in PDG includes pharmacies, distributors, third party logistics providers, manufacturers, industry trade associations and technology providers committed to developing an implementation plan that builds toward a shared vision for interoperability.

“I am encouraged by the broad multi-sector engagement in this effort and commend my fellow founding members for their commitment to interoperability governance. For PDG to be as effective as it can be, it’s critical that we expand membership to include the broadest base of pharmaceutical supply representatives as possible. Participating in the governance body will allow members the opportunity to advance the compliance and flexibility that their organization’s need. It is particularly important that small businesses and non-traditional businesses engage in order to make their voices heard,” said Max Peoples R.Ph., Chairman of the PDG Board and owner of Uptown Pharmacy.

The DSCSA mandates the development and implementation of systems and processes for the “interoperable, electronic tracing of [pharmaceutical] product at the package level” no later than November 27, 2023. In order to reach that milestone efficiently and effectively, the organizations in PDG are committed to advancing a technical vision for the achievement of interoperability. PDG will govern interoperable verification and tracing (as required by DSCSA) as well as the practices and processes that impact the integrity and reliability of interoperable verification and tracing.

“While DSCSA specifies what needs to be accomplished, it does not explicitly state how. This provides pharmaceutical trading partners—of all sizes and from all sectors—a unique challenge and opportunity to

have a voice and hand in figuring out how interoperable tracing will be achieved. It is exciting to now have PDG to serve as the forum for this undertaking,” said Matt Price, Vice Chairman of the PDG Board and Senior Director of Government & Regulatory Affairs at Medline Industries, Inc.

In addition to starting work on the development of a shared vision for interoperability, one of the first tasks of PDG will be to work with the Food and Drug Administration (FDA) through the FDA Pilot Program to execute on the pilot previously approved by the Agency. This pilot activity will provide early validation of PDG’s value through the development of shared expectations for how the authorized status of trading partners is assured in electronic communications, an issue that has already proven significantly challenging for industry in the absence of a recognized governing body. PDG looks forward to collaborating with the Agency in this way to support this activity and the industry’s development of a clear pathway to interoperability.

“Regulators define the requirements of the DSCSA, so our regular engagement with FDA is essential to the success of interoperable tracing and of governance. Regulator engagement with the governance body will provide valuable feedback on governance activities and help provide confidence that our activities and plans are consistent with FDA’s expectations,” says Matt Sample, a PDG Board member and Vice President of Manufacturer Operations at AmerisourceBergen.

“Industry has recognized through various industry and FDA meetings over multiple years that a balanced, sector-neutral industry governance mechanism will be essential to achieving interoperable traceability, as required by the DSCSA. We are very pleased to have completed the work needed to establish that body, but there is a tremendous amount of work yet to be done to achieve interoperability. PDG looks forward to beginning its work to establish a technical vision for interoperable drug tracing in earnest in January and to producing a blueprint for DSCSA interoperability in 2020. Development of a successful blueprint will require input from stakeholders across the industry, and we look forward to expanding the PDG membership to ensure all voices are heard,” said Eric Marshall, Executive Director of PDG.

Membership in PDG is open to all trading partners and their associations. Solutions providers and technical experts are also invited to formally engage and lend their expertise. For more information about how to join PDG, contact Eric Marshall, Executive Director at [Eric.Marshall@LeavittPartners.com](mailto:Eric.Marshall@LeavittPartners.com).