Leavitt Partners (LP) has deep experience bringing stakeholders together to develop consensus resolutions to policy, regulatory, legislative, and business challenges. We help diverse health care and life science organizations develop multi-disciplinary collaborations to resolve complex challenges and accomplish their objectives through policy reform, regulatory reform, legislative action, and development of industry best practices. We leverage our strong regulatory and policy expertise and decades of government and private-sector experience to serve as the conveners and leaders of alliances and to help clients develop, advocate for, and achieve innovative, consensus-based solutions. Our proven process of collaboration provides value through the enhanced influence of a broad unified voice; leverage of shared financial, multi-disciplinary, multi-sector and in-kind resources; and advocacy for shared policy positions without undesired attribution to any single organization.

The Pharmaceutical Distribution Security Alliance (PDSA). The LP-led alliance, PDSA (www.pdsaonline.org), is a prime example of a successful multi-sector, interdisciplinary collaboration resulting in significant legislative reform and effective agency implementation of the resulting statute. Over the course of several years, this broad alliance of drug supply chain stakeholders worked across sectors and with Members of Congress and their staffs to draft and pass legislation (the Drug Supply Chain Security Act) that established a national, uniform traceability system for drug products throughout the supply chain. The collaborative success of the alliance has led to ongoing efforts to streamline implementation of the statute and has made PDSA a recognized thought leader.

The Issue. Stakeholders throughout the drug supply chain long recognized the need for a uniform national approach to traceability (*i.e.*, serialization of pharmaceutical products and the sharing of information necessary to trace those products as they move through the supply chain); however, technical feasibility, operational difficulties, and historical competitive relationships prevented the development of a national approach. Ambitious state-based drug pedigree requirements in California forced industry to recognize the need to come together to propose and enact a more effective alternative.

Collaboration. PDSA brought together individual companies (global, national, regional, and local) and the major trade associations from every sector of the drug supply chain—innovator manufacturers, generic manufacturers, primary wholesale distributors, secondary wholesale distributors, third-party logistics providers, chain pharmacies, and independent pharmacies. The extraordinary breadth of representation in PDSA made clear that the proposals put forth by the group would be viewed as viable solutions to the longstanding traceability challenge. This group of more than 30 organizations had common objectives but often disparate views and operational and technical solutions to achieve those ends. Through extensive collaboration the group developed an achievable, sustainable industry consensus around a technical and operational pathway for product traceability systems and processes, a regulatory structure for enforcement, and full, express federal preemption of any related state requirement.

Process and Results. Leavitt Partners organized the legislative drafting and advocacy work that led to the signing of bipartisan legislation without a single recorded vote in opposition, and the bill was signed into law by President Obama in November of 2013 at a time when most bills were held up in bipartisan

wrangling and legislative inaction. Leavitt Partners organized, managed, and executed on a wide range of activities to support that result, including:

- Analyzing viable standards, technologies, technical and operational systems, and their relationship to a technology and policy migration pathway over the course of the next ten years of product innovation and evolution.
- Developing shared understanding among PDSA members of existing state regulatory landscape, member interests, and member concerns.
- Synthesizing policy positions and managing collaborative negotiations to develop a viable consensus alliance proposal.
- Drafting proposed legislative concepts and text.
- Supporting legislative efforts through technical assistance in the bill's drafting and negotiation stages.
- Coordination of federal lobbying efforts.
- Public education efforts.

California electronic pedigree legislation passed in 2004 created an onerous financial burden on pharmaceutical manufacturers, and industry spent many years prior to the 2015 implementation date, lobbying the California legislature in traditional ways. Industry's lack of success in reforming the California electronic pedigree requirements drove industry to a last-ditch collaborative effort to reform the system through a federal solution. Through a broad, diverse group of industry players, the alliance was able to work with the Congress and the FDA to fashion a consensus solution, demonstrating that, even in polarized environments, progress can be made through a collaborative process.

Implementation. PDSA members recognized the value of PDSA's cross-sector collaborative approach to policy development and execution and have remained actively engaged in the implementation—both regulatory and operational—of the Drug Supply Chain Security Act. Leavitt Partners has proven its ability to develop a comprehensive understanding of members' operational considerations and meld that understanding with regulatory expertise to help members develop efficient and effective approaches to implementation of the statutory requirements. In addition, through its strong relationships at FDA, LP has helped PDSA actively engage in the development of implementing guidance and regulations that result in a more secure drug supply chain for patients without unduly burdening the companies that deliver drugs to those patients.

Thought Leadership. The alliance's ability to collaborate internally to advance proposals supported throughout industry has made PDSA a leading authority on supply chain security. Its ability to speak credibly as the industry voice has significantly enhanced PDSA's influence among legislative drafters and policy makers at the FDA. The proposals put forth by PDSA carry significant weight with industry, regulators, and the public, and the group's expertise has kept PDSA members at the forefront of operational innovation, technological development, and compliance.