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# The Long-Term Power of Alliances:

## Supply Chain Collaboration for Patient Safety

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**Case Study →**

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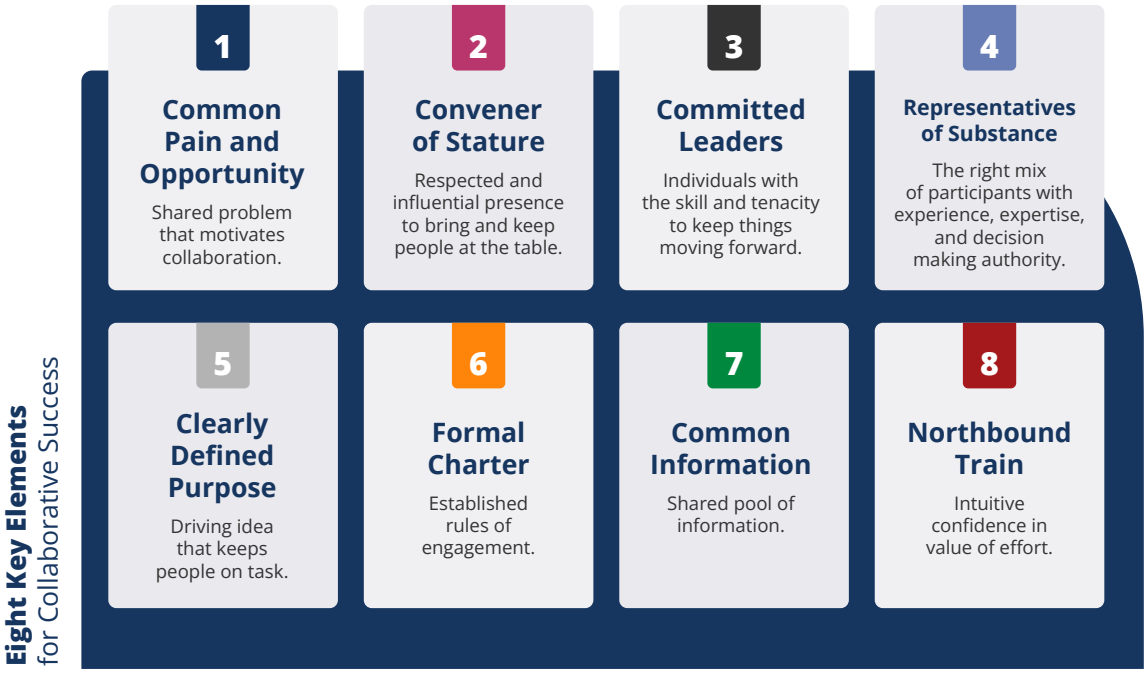
## Introduction

Each alliance is unique—if you've seen one alliance, then you've only seen one alliance. There is a certain logic to this uniqueness given that each alliance's objective is distinct, and that each human member of each alliance is unique. Moreover, each alliance involves distinct alignments of "elements" and "principles" upon which rests each alliance's success. Nevertheless, each successful alliance fits within our overall framework and can be described by at least one "type," just as every person can be classified at the very least of the species of homo sapiens.

We began laying out our alliance framework in our book ***Finding Allies, Building Alliances***, and rely on that thinking in the text that follows. Our forthcoming book, ***Pathways Through Polarization by Finding Allies and Building Alliances***, elaborates on that first text, with insights drawn from almost 15 years in following the Finding Allies framework.

The case study highlights the importance of collaboration among various stakeholders, including manufacturers, distributors, and regulators, to ensure the safety and security of the drug supply chain. It also emphasizes the role of alliances in developing and implementing effective policies and regulations, as well as the ongoing need for cooperation and consensus-building to achieve long-term success.



# The Long-Term Power of Alliances:

Supply Chain Collaboration for Patient Safety

## Background

The Pharmaceutical Distribution Security Alliance (PDSA) and its subsequent counterpart, the Partnership for DSCSA Governance (PDG), are early Leavitt Partners alliances that illustrate two developments in the Leavitt Partners "alliance science."

First, PDSA and PDG reflect the earliest significant efforts to take the eight elements laid out in ***Finding Allies, Building Alliances*** and put them into intentional and comprehensive practice. Indeed, the long-term dedication of the PDSA-PDG leadership team, particularly Eric Marshall, to the alliances led to many of the elaborations on the eight elements and advancements in "alliance science" in our forthcoming book.

Second, is an understanding of evolution. Though PDSA was initially a policy-focused alliance, it continued to work through the implementation of its key legislative success, and assisted in the development of implementing regulations, policies, and practices. It then became important to develop a sister governance alliance—the role that PDG plays—dedicated to forming and governing the environment in which supply chain participants could confidently and assertively comply with all aspects of the law.

In short, PDSA and PDG present excellent perspective not just on the eight elements and the many elaborations on those elements that arose from our practical alliance experience, but on the potential extended life cycle alliances can take when they work beyond innovation.

## The Purpose of Coming Together

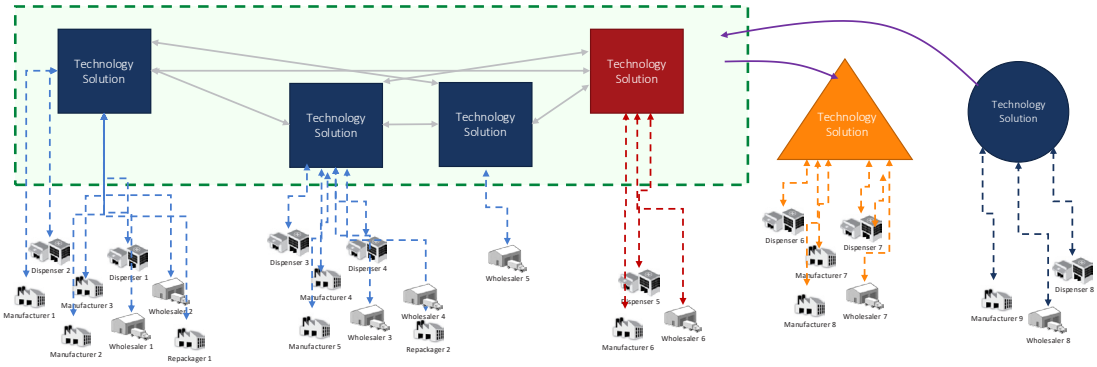
When Leavitt Partners founded the Pharmaceutical Distribution Security Alliance (PDSA) in 2011, its purpose was to address a problem that had been present since the September 11, 2001, attacks on the World Trade Center, the Pentagon, and other targets. After the attacks, criminal activity rose sharply and, as a result, world governments and the financial sector increased their vigilance with the aim of countering organized terror groups. The increase in oversight meant that many organizations, including criminal enterprises, nations that sponsored terror, and extremist groups, lost access to traditional methods of financing their operations. In turn, these bad actors increased their use of non-traditional methods, such as the counterfeiting or theft of high-dollar, high-margin consumer goods, including pharmaceuticals, which could be transported relatively easily and sold at prices that generated significant revenue for the terror, criminal, or extremist organizations and their activities.

While controls were in place to prevent counterfeiting and theft in the pharmaceutical supply chain, a series of well-publicized events,[1,2] and a host of less-than-public intelligence reports circulating among government officials, suggested that more should be done to ensure that the drug supply chain would be safe for consumers, and secured against diversion for illicit profit-taking.

States such as Florida and California, which already had a particular awareness of the elevated risk of counterfeiting and diversion due to their coastal locations, soon moved to implement state-wide regulatory regimes that required supply chain members to be able to track and trace pharmaceuticals through the supply chain.

But how best to track and trace product through a vast set of drug supply chain players? A bottle of pills is generally produced by a manufacturer, shipped by a third-party logistics carrier or wholesale distributor (or several!), and ultimately moved on to a pharmacy, hospital, provider, or grocery store. With 5 billion prescription packages distributed by hundreds of manufacturers and distributors to tens of thousands of care settings every year, the complexity balloons dramatically (see **Figure 1**).

**Figure 1.**
Draft Vision for How Traceability Data Might Flow Through the Supply Chain




Additionally, there are a number of ways that pharmaceuticals are packaged to be shipped. Drugs may be shipped in single-dose packages, in large containers that a pharmacist then breaks down for individual patients, in syringes or infusion bags for delivery by a nurse or doctor, or in multi-dose vials for administration in a public health clinic. How might a patient know that the pill, bottle, syringe, vial, or bag is authentic product, transported safely from a legitimate and even licensed entity? How might the government confirm that same information before the drug is used for a patient? How might the system be triggered to respond in the case of suspicious product, unlawful conduct, or a product recall?

## Common Pain and Multi-Sector Participation

A host of mildly- or wildly-impractical solutions began to surface as regulators rushed to prevent harm to people living in the United States, as stories of foreign threats increased—ideas such as "Implant radio frequency identification tags" in each bottle, box, or syringe, "Just as with Russian dolls, have every bottle carry the paper or digital information from any person who touched the bottle as it moves along," and "Give every pill or bottle a unique barcode or number." One solution went so far as to propose adding microscopic diamond particles into pharmaceutical formulations so as to give each pill a unique spectral signature.

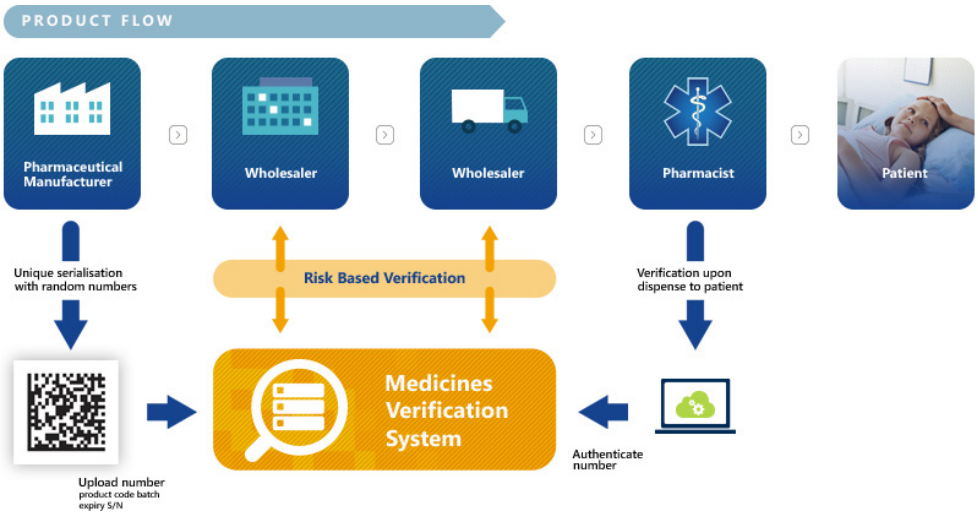
Of course, no one state in our federalist American political system wanted to use another state's solution, making interstate transportation of a bottle of pills unsustainably expensive, if not impossible. Additionally, no one manufacturer was ready to use another manufacturer's system, no one sector wanted to pay for the entire system on its own, and no one company wanted other stakeholders to have to have access to its data.

Over the course of the eight years leading to 2011, if not before, stakeholders started to seek, struggled through attempts at, and eventually stopped pursuing solutions together. Then came an action-forcing deadline—California decreed that companies serialize and track all pharmaceuticals distributed in the state by 2014. It was one of those events that helps push people to the table, drives them to set aside individual interests, and recognize the greater benefits of collaboration.

As with many things in the realm of health care regulation and protection, the State of California acted first, and imposed a deadline of 2014, which required companies to serialize and track all pharmaceuticals distributed in California. But that requirement predated the emergence of technologies capable of the task, imposed rapid deadlines that were infeasible, and established an expectation of data perfection that was unrealistic. This raised the possibility that other states—and countries around the world—might line up with similar requirements. Perhaps even worse, given the inherent interstate and international nature of pharmaceutical manufacture and distribution, was the possibility that other states and nations would impose anything short of identical requirements.

The European Union did have its own international system of requirements. However, most stakeholders sought to avoid replicating the European serialization system (see **Figure 2**[3]), which was just getting off the ground and would aggregate all serialization data—and associated visibility—in one centralized repository built and funded off the backs of drug manufacturers.[4]

**Figure 2.**
The European System




The risk to corporate integrity and brand, and patient health and well-being, not to mention national security, was clear. The problems and potential solutions combined to define common pain across the sectors in unusually stark and compelling ways.

## Solutions, Options, and a Forum for Action

It was the hard regulatory deadline in California that pushed the supply chain to come together and find consensus. Absent that action-forcing deadline, it is possible each sector would have continued to press forward each advocating their preferred solutions. But with a deadline issued, each recognized that the greater risk of not meeting that deadline outweighed the nuanced policy positions each may have to forfeit to achieve a national solution.

When various sectors of the supply chain and manufacturing industries approached Leavitt Partners to help broker a solution, it was with two warnings. First, that stakeholders had been at this for eight years but had been unable to make progress, and, second, which was stated with equal parts earnestness and irony, that Leavitt Partners was not likely to succeed and may never let supply chain representatives darken our door again, given how painful the assignment was anticipated to be.

**The path forward was a bit like a six-rail billiard shot, requiring the conveners and stakeholders to navigate the following:**

- At least six supply chain sectors and consumers;
- Two regulatory regimes under the federalist construct of the U.S. Constitution (states and the federal government);
- Partisan politics between Democrats and Republicans blended with congressional and Administration separation of powers interests;
- Diverse technological and digital solution options, some of which had not yet been invented or tested, or proven to be financially viable;
- A range of voluntary, discretionary, or compelled compliance regimes; and
- Time horizons by which to accommodate the various dimensions above.

One of the challenges with the proposed California initiative was that the supply chain tried to lobby against regulation and to have the initiative reversed, and failed. As conventional wisdom has it, if one is going to seek to kill the king, one had better succeed.

The failure to overturn the initiative created an interesting dynamic for supply chain participants in their role as stakeholders seeking improved security for their products. That dynamic had to be managed along with others: supply chain participants were subject to state and federal regulation, California was a state regulator, California was a stakeholder unable to act on its own, and the Congress was a federal regulator with interests and roles at once overlapping with and distinct from California and other state regulators. The supply chain participants, having failed to agree to a solution with one regulator, were now threatened with burdensome, even impossible, regulatory requirements…but the regulator needed supply chain insights and participation to achieve its consumer protection objectives.

A couple of approaches presented themselves prior to, and in the course of, the Leavitt Partners alliance. One approach involved trying to bring stakeholders together to figure out a solution that kept various options for technology solutions open. The thinking being to allow a supply chain-developed solution built on its own uniform standards, technology, and interactions. An alternative approach included working with regulators, whether state or federal, around model state legislation (which risked 50 diverse regulatory requirements) related to interstate exchange of goods. And a third approach involved uniform and well-informed federal legislation, whether with preemptive effect against conflicting state requirements or not.

Ultimately, alliances may face a crucial strategic call: do the members define a precise objective upfront and close off what may prove to be more useful alternatives, or do the members keep all their pathways open, but risk diversion and distraction.

PDSA decided to start with an open view of possible solutions, given the eight-year history of failed negotiations. Indeed, the group started with an eye toward a solution grounded in private-sector technology commitments that might persuade regulators of the supply chain's good intentions. To the surprise of most participants in the 30-organization room, consensus developed during that initial year around the use of two-dimensional (2D) data carriers, or barcodes, and initial systems-and-processes requirements.

The 2D carrier option raised the prospect of something more than just a hope-and-pray model to hold state regulators at bay; the group began to contemplate the exceedingly rare federal legislative objective of express federal preemption of every divergent state regulatory scheme on the grounds that effective protection of patients receiving drug product, wherever manufactured, required the structure and standards under Section 8 of Article I of the U.S. Constitution—the interstate commerce clause.

Why did policymakers view this alliance process as something valuable to them given it risked serving supply chain interests with a sector-developed technological, and even policy, solution? Perhaps because the average congressional staffer on Capitol Hill doesn't have the time, let alone the experience or expertise, to work simultaneously with pharmaceutical companies, wholesale distributors, third-party logistics providers, pharmacies, and providers to create a solution, or even assess where agreement might sit in relation to a little barcode on a pharmaceutical package.

Indeed, experienced state and federal agency regulators also struggled to find the path to a solution. Ultimately, they needed some way to look to an outside resource with confidence in a process and the initial results.

In the end, the relevant state and federal regulators were able to affirm the consensus results, given the breadth and expertise of stakeholders around that table, given that the convener runs a good process, and given the transparency of the process (agencies were permitted an "observer" seat at the alliance table). And while the ultimate result could not displace the government's independent authority to specify the new regulatory regime, PDSA's consensus proposal served as the definitive starting point, and ultimately moved across the finish line with only limited modification.

What becomes an important component of alliances then is the ability for a multi-sector group to speak with a single voice, which adds to its credibility on the Hill and elsewhere.

## The Role of an Independent Convener Among Multi-Sector Stakeholders

The participation in the alliance by companies involved throughout the drug supply chain means participants at the alliance table are often in adverse client-customer relationships or in intense competition for services and products. For example, manufacturers often used third-party logistics companies (3PLs) (whether or not owned by distributors) to move product, as opposed to distributors, but only with specific products; wholesalers competed with manufacturers to offer services and insights to pharmacy customers; and pharmacies had distribution operations that competed with wholesale distributors. And everyone competed for information about markets and pricing, provider volumes, and patient profiles. Ultimately, the intensely competitive environment created the need for a core convening and leadership role with its hallmark independence from any one participant and its dedicated balance among stakeholders.

While PDSA lacked the traditional high-profile convener of stature described in the first book, the Leavitt Partners team brought leadership skills, subject matter expertise, and insight into agency and congressional perspectives on the topic, as well as good standing with virtually every participant in the room. As a result, it could act as the trusted intermediary that no sector saw as biased or ill-informed and could play that role of keeping the group together, focused, and marching forward towards a common strategic plan (and for no short period of time). Indeed, the alliance's ultimate proposal evolved through consensus development over the course of about two years. (The process led some participants to note that the consensus-developing skill sets involved in herding cats and in raising a large number of ill-mannered children, were barely sufficient for the PDSA members.)

Not all the key stakeholders became members of PDSA. Some large market leaders who could navigate burdensome regulation, or the complexity of multiple state laws, or who had a proprietary interest in a particular approach, remained outside of the alliance until the Food and Drug Administration (FDA) and Congress embraced the alliance proposal. Therefore, given the ability of stakeholders outside the

alliance to complicate the legislative process, PDSA leadership had to understand and be able to collaborate with those outside the alliance. In addition, several key stakeholder interests were not at the table, even if they followed and informed it closely: Pew Charitable Trusts, with its consumer perspective, and California, Florida, and a couple of other states with obvious regulatory and public health interests.

Left to their own devices, pharmaceutical companies alone would have continued to develop siloed legislative solutions. Leavitt Partners brought together all sectors of the supply chain to create a unified, practical, and effective solution that all sectors recognized as valid.

## The Role of Government Actors in the Solution and Leveraging the Alliance

Best practices point to early and frequent interaction with the government, which ultimately has the authority, if not responsibility, to act on such matters. Of course, such interaction benefits from the stakeholders presenting a concrete proposal or solution. At the same time, development of a detailed approach may not be able to precede engagement with the government, especially if the proposal is complex. In line with this, PDSA spent a lot of time with FDA and relevant congressional committees offering early assurance of the effort's merits, even before a complete solution was reached. This allowed PDSA to bring government stakeholders into the process, build their confidence in the process, and prepare them to accept the group's solution.

In the early stages of solutioning, the big picture and broad environmental context should receive the initial attention, and then the core principles, whether four or ten or however many in total, can emerge for group consideration. When PDSA came together, the solution development process involved establishing core principles—or cornerstones of the policy foundation—and then proceeding to put policy details into place. In this instance, the group framed a small set of core principles for FDA, Congress, the States, and other external stakeholders, as PDSA sought input and worked to build buy-in. Ultimately, the core principle of the PDSA proposal involved express and complete federal statutory preemption of individual state laws that intended to regulate in the same subject matter area. Without preemption, the supply chain would not gain the single, uniform set of requirements that would ensure effective and efficient patient protection. The hurdle was that express federal preemption of state

statutes has historically been very difficult to attain. Would Congress in this case be willing to preempt states to achieve a single national way of achieving supply chain security? Could Congress hit the mark in a way that could justify preventing states' ability to put different or stronger requirements in place?

While preemption aligned nicely with the U.S. Constitution's grant of authority to Congress to regulate interstate commerce, it also risked impeding a state's interest in securing the health and safety of its citizens through drug supply chain regulation. The dynamics related to preemption set up a compelling and interesting debate around the contours of what constitutes genuine federalism. Congressional interest in the topic was not always aligned with FDA's interests, let alone individual states' or the supply chain's. Would pro-states'-rights Republicans want to impose unachievable regulation on the private sector? Would liberal Democrats seeking to protect consumers oppose a strong and centralized regulatory regime designed to close loopholes and ensure strong minimum standards?

As PDSA navigated these straits, political and stakeholder dynamics increasingly pointed to the value of efficient interstate commerce operating under a uniform set of rules that would be sufficiently robust to ensure strong patient protection and preservation of national security interests. As the contours of PDSA's policy consensus came into focus, the alliance came to be recognized as the northbound train, setting off the domino effect in which federal government officials increasingly pointed to PDSA's table as the place where a solution could and would be developed, and eventually as the solution that would be codified into federal law.

Ultimately, the legislation PDSA proposed passed as the Drug Supply Chain Security Act (DSCSA). Remarkably, the legislation went through Congress without a single negative vote,[5] an outcome that indicates there was a significant amount of buy-in ahead of time.

## Continuity and the Value of Representatives of Substance for the Agency

Following passage of the statute, the burden of developing a guidance and regulatory architecture for implementation of the statute came to the fore. Implementation created a potential fork in the road for PDSA members: Should they disband the alliance and pursue their individual implementation interests to their own competitive advantage, or should they remain together for the difficult work of pursuing ongoing consensus recommendations to the agency?

There was powerful impetus, and indeed opportunity, to declare "mission accomplished," to count the cookies consumed, the battle scars, the budgets expended, and even the several members who had retired or died in the course of the several-year effort, and free up time and resources for new endeavors. Such accounting could easily have led to a decision to close the doors and go home. But the power of collaboration had taken hold. Ultimately, the group came to realize there is more power in a collective group than in combative, disjointed individual sectors. Many members found that the regular interaction with and learning from each other created a strong marketplace and personal relationships, beyond the financially valuable policy outcomes. That single table where sectors could come together to pursue shared interests motivated the group (and additional new members, including the 800-pound gorillas of two different sectors, and some emerging alpha males in others) to stay together through the implementation process and continue to work with FDA on the regulatory implementation of that law.

On the other side of the table, as it was developing its regulatory regime, FDA soon realized the evident power of unified multi-sector players who were proposing solutions developed by representatives of substance who really understood the nitty gritty of their business, the regulatory requirements, and the operational implications of policy. The agency soon recognized PDSA as the single best place to access supply chain security expertise and cross-sector consensus. While FDA would promulgate guidance to secure comments from the public, including individual companies and trade associations, it became apparent that the comments PDSA submitted to the guidance docket reflected diverse but unified and well-considered views reflective of a wide variety of people who had come together and collectively determined on what it was possible to agree.

## Continuity and the Value of the Alliance in Ongoing Business Work

In addition to cementing a position as a strong partner to government, PDSA reveals several dimensions of value to multi-sector participants in continuing to work together as representatives of substance. The group developed a particular interest in the value of collaboration in the business environment as they sought to ensure efficient and effective compliance among trading partners who were dedicated to superior compliance with the DSCSA.

PDSA has also served as a place to surface and spin out policy insights into adjacent topics, work which might be picked up by other alliances. This included work on international supply chain security topics (PDSA focused on domestic U.S. applications), supply chain security for medical devices, and work on digital versus paper physician labeling of pharmaceuticals.

## Defining Consensus and Knowing When to Put Success Above Perfection

As momentum builds, consensus becomes more integral, yet more attainable. As with all alliances, the pursuit of consensus was critical to PDSA's success. Member mindsets flipped from "What do I want?" to "Is what I want worth derailing the entire initiative?"—a switch that happens when alliance members begin to focus on their core imperatives and develop a willingness to concede other points for the good of the whole. Consensus can be defined in many ways, but most important is that it is defined and understood and that it serves to push members forward to that point of alignment on critical issues without enabling members to retreat and entrench on lesser issues.

Although the rules of consensus should remain stable, member approaches to consensus will evolve throughout the alliance. In particular, as the alliance nears success, pressure builds to sacrifice perfection for success around the good. Over the course of many months, PDSA members spent countless hours negotiating and crafting consensus on myriad nuances. For example, it became relevant, if not important, to distinguish the date a drug product is shipped versus the date legal ownership of that product changes. There was also extended discussion about whether a small pharmacy should be defined by its number of employees or its number of full-time employees. But as the PDSA proposal neared legislative success, members became more willing to sacrifice those detailed points

for the success of the overall package. Even as the eventual legislative text was debated on the floor of the United States Congress, alliance members continued to identify nuanced points of ambiguity or technical imprecision. Crucially, their willingness to set those aside was necessary to get the bill across the finish line.

## The Double Life of an Alliance Member

The members of an alliance do not cease to be fierce competitors in the marketplace simply because they have come together in an alliance to solve a shared problem. But just as true is that the members of an alliance have recognized that the only—or at least most viable—pathway to solving their problem is to lay down their competitive swords and collaborate. Throughout the life of an alliance—both the periods of progress and optimism and the periods of difficulty and uncertainty—alliance members must balance their ongoing interests as competitors with their commitment to collaborate on the problem at hand. Trust in and dedication to process are essential to maintaining that balance.

When entering into an alliance, it is important that each organization recognize that their first commitment with regard to the issue at hand is to the alliance. That said, this commitment is not an absolute requirement never to diverge from the alliance's consensus view. The convener plays an essential role in setting this expectation up front and defining clear processes that are expected to be followed if a member is to diverge from the alliance.

In advocacy alliances, we often say that an organization's commitment to the alliance does not require that organization to surrender its First Amendment right to petition the government. Rather, the commitment is to work assiduously to reach consensus within the alliance and to provide the alliance prior notice when they conclude that consensus on an essential component of the alliance's policy position is infeasible, leading the organization to desire to take a public position that is at odds with the alliance.

All members of the alliance must recognize that repeated divergence from acting collectively as an alliance will rapidly cause internal fraying and erode the external perception of the alliance's ability to speak collectively from a place of authority. Before reaching the point of divergence, each member must first work earnestly to resolve any substantive issues within the alliance and the convenor must push members to seek a mutually beneficial resolution. If an alliance member simply cannot see any viable pathway to consensus within the alliance, they maintain the autonomy to carry their own position forward outside

of the alliance, but it is essential they do so with full transparency to the alliance. Covert efforts to carry one's own position forward will quickly erode trust and undermine the cohesive message necessary to create a northbound train.

Just as each individual member maintains the right to carry its own position forward at odds with the alliance, the alliance too maintains the right to carry its consensus position forward at odds with a member. Where the issue is a small component of the larger, overall alliance solution, these battles can play out without disrupting the progress of the war. But if the issue is too large or too integral to the overall solution, the battle risks undermining the war effort. As with so many dynamics, the convener must be attuned and strategic in recognizing when to allow a member to walk away from consensus and go it alone and when to continue to push ***all*** of the members toward consensus inside the alliance.

## Alliance Composition:
### Enough of the Right Members to be Effective

Almost by definition, the membership of an alliance does not include every individual stakeholder in the broader marketplace or political economy, even if they are impacted by the issue at hand. A successful alliance has the right stakeholder participants; a delicate balance of broad enough membership to ensure the alliance's consensus represents the northbound train, yet narrow enough participation to be nimble, flexible, creative, and efficient. This is a critical strategic question in the formation of an alliance: Which stakeholders need to be part of the alliance at which points in time?

This seemingly straightforward question plays out in myriad ways. For example, many industries or sectors are dominated by what is commonly referred to as an 800-pound gorilla. These organizations often view alliances as a threat; the 800-pound gorilla believes they can get the result they desire alone and on their own terms. For them, participation in the alliance would only force them to make concessions or help level the playing field for potential competitors. The alliance must either be strong enough to overpower the 800-pound gorilla or must forge a path proximate enough to the 800-pound gorilla's desired result to avoid major contention. In PDSA, this challenge played out in the wholesale distribution sector, and the alliance persisted through the latter strategy of alignment. More than 90 percent of the nation's pharmaceuticals are distributed through three wholesale distributors—Cardinal Health, Cencora (previously known as Americource Bergen Corporation, or ABC), and McKesson—which are collectively represented by a highly

effective and nimble trade association, the Healthcare Distribution Alliance. Two of those companies and the Healthcare Distribution Alliance were instrumental members of PDSA, but the third company felt they could be more influential and better serve their own interest by maintaining some distance from PDSA. Ultimately, the breadth of wholesaler representation within PDSA allowed the core of PDSA's policy solution to advance with momentum while limiting contention with the outside company over nuances around the fringes. Battles were fought, but strategic collaboration among the members inside of PDSA assured alignment between PDSA and the outside company in the broader war.

## The Rise of PDG

PDSA is an advocacy alliance; its goal is to develop policy recommendations and persuade government actors, like Congress and FDA, to adopt and implement those policies through governmental authority. As implementation of the DSCSA progressed, the supply chain reached another crossroad—interoperability. Because interoperability requires coordination and consistency across supply chain sectors, there was a need for an authoritative actor to set the interoperability framework that must be followed. At the same time, the implementation had reached a point of technical nuance where the supply chain did not see a governmental actor as able to establish the needed framework as a regulatory mandate, nor did FDA want to regulate at that level of technicality. Stakeholders needed an authoritative mechanism to define and drive adoption of an interoperability framework. The solution was a governance alliance which came to be called the Partnership for DSCSA Governance (PDG).

The supply chain's vision for a new nonprofit that could draw authority from its critical mass of membership to develop and drive adoption of a framework for interoperability was not new—multinational drug manufacturers had banded together in Europe to create a similar organization, the European Medicines Verification Organization. The supply chain knew that for stakeholders to cede authority to this new nonprofit, it would need to be a new entity, independent of any one stakeholder group. Over the course of 2019, Leavitt Partners helped stakeholders define the structure for this new governing body and launch its operations.

In addition to drawing upon a critical mass of stakeholder support, PDG's ability to have its framework viewed as authoritative would rely on broad stakeholder trust in the PDG process. A supply chain actor not directly engaged in PDG's work would need to be able to look at PDG outputs and say, "I may not have been part of developing this

framework, but it was developed by a broad and diverse set of members using a process that was fair and balanced, so I am going to follow it." This required the development of detailed work group structures, document review procedures, and voting rules to ensure each set of documentation truly reflected a comprehensive, cross-sector view of how interoperable pharmaceuticals tracing technologies should be implemented.

The nonprofit structure of PDG afforded other advantages as well. First and foremost, it allowed PDG to enter into a formal public-private partnership with FDA. Through this arrangement, PDG and FDA have been able to engage consistently and collaboratively on issues of mutual importance to support the technical implementation of traceability. While a public-private partnership does not convey formal blessing of the PDG work, it does further the perception of its authority to drive its framework for interoperability into practice.

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# ABOUT THE AUTHORS

## Eric Marshall

Eric Marshall is a principal in the Washington, D.C. office of Leavitt Partners, an HMA company. A seasoned facilitator and consensus-builder, Eric leads Leavitt Partners' robust alliance practice, helping the firm and clients build, convene, manage, and advise numerous industry collaboratives committed to advancing sound health policy initiatives. He is the Executive Director of the Partnership for DSCSA Governance (PDG), a public-private partnership between industry and FDA committed to implementing supply chain security protections in the U.S. At Leavitt Partners, Eric advises complex health care coalitions on health policy and provides consulting services to drug and device companies. A regulatory lawyer by training, Eric is an industry specialist in the areas of drug, device, and diagnostics regulation. A portion of Eric's practice is focused on domestic and international supply chain security, an area in which he is a recognized thought leader.

Eric graduated Order of the Coif from the University of Minnesota Law School and has a bachelor's degree from the University of Northern Iowa.

## Vince Ventimiglia

Vince Ventimiglia founded the D.C. office for Leavitt Partners in 2014. Now a Health Management Associates company, Leavitt Partners is a premier health policy and government affairs firm in Washington, D.C. that has been at the forefront of health policy development for decades and leads the nation in federal affairs work, and developing and running federal policy alliances. After leading the office for ten years, Vince is now a Senior Advisor.

With over four decades of Administration, congressional, and private-sector health policy experience, Vince plays an integral role in facilitating relationships with congressional and executive branch offices and providing in-depth analysis of federal government action. He also advises complex, multi-disciplinary collaborations among multi-sector health care organizations seeking to implement significant health care policy initiatives.

In previous roles, Vince was the assistant secretary for legislation at the U.S. Department of Health and Human Services (HHS). In this capacity he served as the department's liaison to Congress and as the Secretary's chief advisor on all legislative matters affecting the department. Prior to his time at HHS, Vince served on the Senate Health Education Labor and Pensions (HELP) Committee as Health Policy Director of the Chairman's Health Policy Team. In 2005, he moved with Chairman Gregg to serve as Policy Director for the Senate Budget Committee, where he also worked on entitlement programs, including Medicare, Medicaid, Social Security, and welfare.

From 1998 to 2001, Vince served as director of the Government Affairs Office for Medtronic, Inc., one of the world's leading medical technology companies. Before joining Medtronic, Vince a held a variety of health policy positions on Capitol Hill, serving as counsel to the United States Senate Labor and Human Resources Committee for Senator Dan Coats of Indiana. He previously worked with the committee on health issues from 1985 to 1988.

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# The Long-Term Power of Alliances:

## Supply Chain Collaboration for Patient Safety

LEAVITT CENTER FOR ALLIANCES
An HMA Initiative

The Leavitt Center for Alliances is an initiative of Health Management Associates and Leavitt Partners, an HMA Company. The Center aims to elevate the national discourse on health care and help health care organizations solve their most complex challenges through consensus-based alliances.

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