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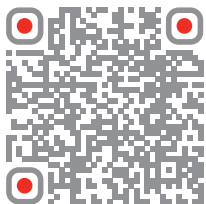
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3PLs and New Voices

2025 is upon us, officially marking a quarter of a century since Y2K and the midpoint of the decade. There is no doubt that time does quickly fly by, and with that, the February issue of *Pharmaceutical Commerce* has arrived just as swiftly.

The first edition of the year is powered by a look at pharmaceutical third-party logistics providers (3PLs)—those organizations responsible for handling the logistics for a range of products that are unable to be accomplished by a manufacturer, distributor, or dispenser. This year, Editor Nicholas Saraceno once again provides a deep dive into the fluid role of 3PLs, the lessons they learned post-COVID-19, the key trends impacting industry, and more via a roundtable-type discussion with leaders in the sector (page 20).

Also examined this month is an issue impacting communities throughout the US—retail pharmacy closures. In fact, a December 2024 study from researchers at UC Berkeley School of Public Health and USC found that about one in three retail pharmacies in the country have closed their doors since 2010. As a result, pharmacy deserts—areas where city residents live more than a mile away from the nearest pharmacy—are increasing in frequency. In her piece (page 17), Jenni Zilka of Good Neighbor Pharmacy and Cencora elaborates on the troubling trend, sharing that pharmacy deserts are located in areas that are up to 40% more likely to have fewer primary care providers and higher social vulnerabilities, such as poverty and lack of access to transportation.

Switching gears to some of our column highlights: in part two of his new “Popping the Gross-to-Net Bubble” series (page 14), Bill Roth of IntegriChain describes the steps that pharma manufacturers can take to address these revenue gaps. One is to revisit history to determine what approaches have been successful, including, for example, cross-functional collaboration.

And I would be remiss not to announce a sincere welcome to two new KOL voices to the regular *Pharma Commerce* commentary slate in 2025. Sean O’Hearne of 1st Line Partners will present unique insights on brand protection and product integrity challenges in pharma, while Chris Dowd of ConnectiveRx will dig into the always changing and deeply layered issues prevalent in patient support. Both columns debut this month (pages 11-13).

Thanks for reading.

MIKE HENNESSY JR
President and CEO,
MJH Life Sciences

Beyond the GLP-1 Headlines



NICHOLAS SARACENO

Editor

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I am pleased to welcome you all to the first *Pharma Commerce* issue of 2025. As mentioned in the publisher's note on facing page, this edition marks the debuts of new guest columnists, Chris Dowd of ConnectiveRx and Sean O'Hearen of 1st Line Partners, who will be zeroing in on the topics of patient support and brand protection, respectively.

Dowd's background includes almost 30 years in leadership roles across Big Pharma, healthcare startups, and the patient support space. As for O'Hearen, after spending 20-plus years building brands in marketing and business development roles, a decade ago, he decided to shift his focus to protecting products from illicit trade. We are excited to have Chris and Sean aboard.

Shifting a bit, as Dowd references in his first installment this month, the Centers for Medicare & Medicaid Services is fresh off revealing its choices for the 15 latest drugs to be covered under Part D for price negotiations. Headlining that list is Ozempic, Novo Nordisk's branded semaglutide—which, as most of you know, is a type of glucagon-like peptide-1 (GLP-1) receptor agonist. GLP-1s have traditionally treated type 2 diabetes, but surged in popularity for battling weight loss; they have also recently been approved in other indications, such as cardiovascular disease prevention and sleep apnea. Their influence cannot be ignored; in fact, a KFF Health Tracking Poll found that about one in eight adults (12%) report taking a GLP-1 drug.

I wanted to dig further into this phenomenon and found a cohort study published in *JAMA Network Open*, with more of a focus on individuals with obesity but without diabetes, a smaller subgroup of users. The study explores the drivers of semaglutide initiation in this patient group. Researchers “identified sociodemographic, healthcare, and clinical factors associated with semaglutide initiation within six months after obesity diagnosis using a novel machine learning approach. The associations ... were quantified using multivariable logistic regression, and use of common medications, insurance plan structure, employer industry type, and sex were all significantly associated with semaglutide initiation.”

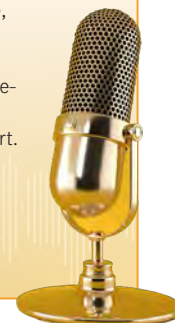
The fact that there is currently limited evidence on clear factors associated with uptake in this subgroup leads me to believe that there is plenty left to be done in this setting, but AI, as chronicled in many other areas, appears to have the potential to make waves here as well.

I look forward to seeing what other GLP-1 clues surface in the New Year. **PC**

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**The Path Forward for
Infused Biosimilars in US**

VIBHU TEWARY, project director, IQVIA Institute for Human Data Science, offers insight on this market segment, including a behind-the-scenes of what goes into designing a report.



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Navigating the Future of Pharma Trade

Trade & Channel Strategies conference explores the frontline issues related to strategy, distribution, and reimbursement—while digging into creative solutions to solve them.

By *Nicholas Saraceno*

Industry professionals in the trade and channel space convened at the W Philadelphia for Informa Connect's Trade & Channel Strategies to discuss a plethora of topics, including channel strategy, distribution, reimbursement, and product strategy, to name a few.

Pharmaceutical Commerce was in attendance, providing behind-the-scenes coverage. The sessions covered included:

- "2024 Year-in-Review and Preview of 2025" (Keynote)
- "Pharmacy Evolved—Aligning Commercialization to the Changing Pharmacy Channel"
- "Securing the US Supply Chain and Managing Global Products"
- "Patient-Centric 3.0 — How Direct-to-Patient is the New Commercialization Model"
- "Actions Needed to Mitigate and Prevent Drug Shortages"
- "Health System Specialty Pharmacy Perspective: Lessons Learned and Considerations with Humira"
- "Balancing the GTN Bubble with Market Access Priorities"

It's important to note that no specific session was more valuable than another, but aside from Bill Roth's keynote—which

set the table for what's to come this year—the "Actions Needed to Mitigate and Prevent Drug Shortages" seminar was successful in providing an overview of this vital issue impacting pharma supply chains today. During her presentation, Amy Sonderman, senior director of US advocacy and stakeholder engagement, US Pharmacopeia (USP), offered a look into the sources of shortages; shared approaches to holistic solutions; and presented potential ways that pharma supply chain stakeholders can work with Congress and one another to help mitigate and prevent shortages in the US.

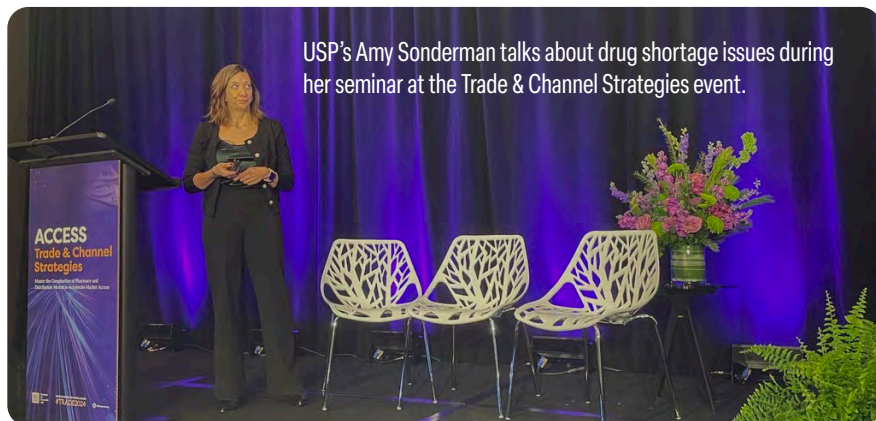
A couple of eye-opening statistics were shared during the session. One was that the sterile injectable medicines that are in

shortage cost 8.5 times less than those that are currently not in a shortage—to put it into perspective, imagine \$46 per unit compared to \$392 per unit. As for solid orals in shortage, they cost five times less than those not in shortage, which would be \$3.40/unit compared to \$17.50/unit. These types of factors are contributing to the discontinuations of these products, a trend that increased by 40% last year, according to Sonderman. She put it into perspective by offering a real-life example.

"Think about that—if you have a child who needs ADHD medicine and your pediatrician prescribed it, you go to the pharmacy and they don't have it. You then spend hours as a caregiver calling around to pharmacies. The pediatrician has to then spend hours calling around to the pharmacy. The pharmacist, who should be assisting other patients, is spending hours calling wholesalers, calling hospitals. This is a huge waste of resources. It's a huge time-stop for the healthcare industry to just try to mitigate one shortage."

The editorial team also conducted various video interviews with multiple key opinion leaders, including Kevin O'Meara, William Trombetta, PhD, Cheryl Allen, Jon Hamrick, and Lisa Arthurs.

For the latest in conference coverage, please visit pharmaceuticalcommerce.com/latest-conference. **PC**



USP's Amy Sonderman talks about drug shortage issues during her seminar at the Trade & Channel Strategies event.

A bipartisan government funding deal at the end of last year initially included reforms of pharmacy benefit managers (PBMs) that would limit their ability to use rebates as a major profit center. PBM reform was excluded from the final government funding deal, but there continues to be strong support in Congress to address the subject. Focus is now on what the incoming Trump administration will do, and how this may impact the pharmaceutical market in the US.

The problem with rebates

A handful of PBMs handle patient access to prescription drugs on behalf of health insurance companies, extracting rebates in exchange for a favorable position on the drug formulary. Particularly for drugs that are deemed “interchangeable,” PBMs extract substantial rebate payments without affecting the publicly visible price. Rebates have formed a substantial part of PBMs’ incomes, although some of the rebates are claimed to be passed on to the payers.

In my opinion, there are a few problems with the rebate model:

1. Formulary choices are based on drug rebate maximization, not patient benefit and clinical goals.
2. PBMs are potentially skimming profits but add limited value beyond claims handling.
3. Patients pay copays based on list price rather than net price. In some cases, the copay can be higher than the cost to the PBM.

A world without rebates

Many refer to European countries as cheaper options to provide patients access to Rx. These countries fix price through either cost-effectiveness analyses (England, Sweden, etc.) or by scoring the added

Rebates or Patients?

Finding the optimal balance in pharmacy benefit manager reform.



ABOUT THE AUTHOR

Ed Schoonveld is a value & access advisor for Schoonveld Advisory, LLC and author of *The Price of Global Health*.

benefit over a “comparator” drug (France, Germany, etc.). It seems attractive to use European style controls. However, there are some challenges:

- A. Price-controlled countries demand full evidence of long-term outcomes value at time of negotiation, i.e., prior to launch. For true innovations, this is practically impossible without much longer development timelines, which, considering competition and patient lives, is often not feasible.
- B. Smaller countries use their monopsony power to extract steep price concessions. However, given the dominant size of the market, US monopsony behavior would harm early drug development, and venture capital funding for early drug research would be diverted to other more profitable business areas.
- C. Governments do not adequately budget for the impact of aging populations and poor lifestyles on healthcare needs.

The US is burdened with rapidly rising healthcare costs. Drugs have reportedly accounted for a constant 12%-13% of healthcare costs since 2000. The solution is in addressing healthcare effectiveness and efficiency, including the role of drugs.

Focus on patients

Payers and PBMs have deflected an increasing share of drug cost to patients through rapidly increasing copays. Charging copays makes sense when a patient wants a higher cost option that has no additional benefit, but why charge a substantial percentage of the cost of a drug to a patient, when there is no good alternative?

Efficiency through AI

As artificial intelligence (AI) is emerging, we are better able to direct the most effective care to each patient. Treatment pathways are increasingly used by payers and provider groups to inform treatment decision-making. As we can increasingly power pathways with experience on distinct subpopulations, we can generate cost savings without a negative impact on patient outcomes.

Don't cut new drugs short

While clinical evidence and AI can inform optimal treatment with existing drugs, there's no such alternative for new drugs. When making reimbursement decisions, we must make sure to not be rigidly focused on the perfect, almost impossible evidence, but have the medical community make informed judgments on expected long-term benefits, in combination with drugmaker commitments to longer-term outcomes trials post-launch. **PC**



Fair Market Value vs. Current Market Leverage

How pharmaceutical manufacturers should consider their Fair Market Value cost assessment compared to their negotiation leverage when contracting for distribution services

Fair Market Value (FMV) is a legal concept in the pharmaceutical industry that defines the appropriate amount to pay for services. It's a critical component of compensation arrangements and a regulatory compliance issue. FMV reports help determine the value of bona fide service fees rendered during government price reporting and provide financial guardrails during wholesaler distribution service agreement negotiations. They are often referenced to justify certain fees the manufacturer cannot exceed. While no single formula is defined by law to guide the development of FMV calculations, should an entity be investigated for violating the False Claims Act or Anti-Kickback Statute, its FMV calculations will be highly scrutinized. Therefore, FMV calculations are typically created using analyses and feedback from internal compliance, outside legal counsel, and consultant firms and must be carefully documented with regular internal and external reviews.

Given the rigor and expense of developing FMV calculations and the sensitivity of pricing negotiations, they are treated as highly confidential information. Their existence is often shared with wholesalers in service fee negotiations to justify arguments for lower price points. Wholesalers frequently push back against FMV arguments during negotiations, insisting that these fees do not account for the full range of services they provide. They are keenly aware of their own costs thus are motivated to maximize fees during manufacturer negotiations to achieve margins consistent with “like” brands.

Before these negotiations commence, each party must assess its Current Market Leverage (CML), which we are redefining from a financial debt risk metric to the degree

of leverage each party believes they can exert. This can be a valuable strategic effort by pharma to help align financial and operational expectations within the organization.

How do wholesalers make money?

Distribution Services Agreements (DSAs) between wholesalers and pharmaceutical manufacturers were designed to create financial and operational service terms for which a wholesaler would be compensated and create more predictable inventory management and performance expectations for both parties. Wholesalers analyze each deal to determine if the DSA will produce a positive net profit consistent with their anticipated gross margins.

Wholesalers' buy-side economics are extracted through distribution fees and prompt pay discounts, which depend entirely on the drug's Wholesale Acquisition Cost (WAC). Wholesalers are highly motivated to understand the WAC, patient population and target customers for every new drug they distribute. Managing inventory levels is crucial since significant wholesaler capital can be tied up in product and price increases may lead to inventory appreciation.

Wholesalers' sell-side economics are heavily influenced by a customer's overall revenue potential, prescription purchase share commitments (ideally >90%), product mix (generic, biosimilar, specialty, and brand—in that order of profitability), and contract utilization. The ideal wholesaler account purchases high percentages of generics and biosimilars, utilizes 340B or government contract pricing, and agrees to short customer invoice terms. The resulting financial proposal will

include discount tiers differentiated by invoice terms and contract type that will be regularly “graded” and re-evaluated.

When does pharma have a higher degree of Current Market Leverage?

We recommend that pharmaceutical manufacturers consider the following questions when determining their CML:

What is my WAC price?

This is a hot topic in the industry. As mentioned earlier, wholesalers primarily make money as a percentage of WAC applied to distribution fees and prompt pay discounts. These fees and discounts consume most operating costs. Low WAC prices, low units/orders overall demand, and the aforementioned sell-side economics can indicate that wholesalers may lose money on every sale. This creates more pressure to increase fees, which can counter FMV assessments. It has also created significant concern when manufacturers significantly lower their WAC pricing long after the fees were negotiated.

How will patients access my drug?

Patient access to therapy is the ultimate goal. Denying legitimate access to a patient in need is a lose/lose scenario. It is essential to meet the patient where they will be treated and not force alternate models that can cause undue pressure on the patient, their caregiver, or health care professional. If a new drug is an oral preparation dispensed at a retail pharmacy, ensuring access at chains, independents, and/or mail-order pharmacies via their preferred vendor wholesaler may be critical. If a new drug is a cold chain biologic that will be infused at

an oncology clinic, ensuring access through their preferred Specialty Distributor may be critical. The financial agreement between each customer and their wholesaler will unlikely change to fulfill a manufacturer’s desire to pay less. This does not mean the wholesaler holds all CML, and there are other access factors to consider.

Does my therapy have any significant brand or generic alternatives that would create less urgency for the wholesaler to make it available at launch?

Wholesalers cannot influence purchases directly. They can auto-substitute (per customer approval) or make therapeutic suggestions for AB-rated generics via their ordering systems. They can use their GPO entities or paid marketing efforts to make specific therapies more visible, but their main goal is always to have the drug available. The more unique the therapy, the more pressure on the wholesaler to stock the product immediately at launch. But the opposite can also be true. If alternatives are readily available, the sense of urgency by the wholesaler may lessen, putting more pressure on the pharma company to compromise during negotiations to achieve launch access. But this leads to the next question.

How much revenue am I currently distributing through each wholesaler, and what is my fee structure by existing brand?

Given their buying power and higher overall customer demand, larger pharma companies have more CML over smaller ones. They expect to pay less and generally do. Wholesalers are motivated to keep

existing fee structures static or raise fees if CML allows. Emerging manufacturers with unknown demand should expect to pay more—and generally do. Wholesalers will argue that emerging manufacturers gain instant entry to the same highly efficient distribution systems that much larger manufacturers already access.

Is my product temperature-sensitive, or do we have any regulatory concerns?

Drugs that require cold chain storage and shipping cost more to handle. Controlled substances have more DEA and state regulatory risks and costs. These risks are especially true in light of the national opioid settlements.

These are just a few of the questions pharma should ask before wholesaler negotiations. Unless alternate distribution models can be made more viable, the vast majority of drugs will continue to be distributed by McKesson, Cencora, and Cardinal. These entities have invested significant infrastructure capital in enhancing efficiency and cost-effectiveness and are unlikely to adjust their negotiation approach or manufacturer-calculated FMV rates.

Aligning realistic financial and operational expectations using the scenarios above and a strategic plan may result in a win/win scenario for both parties, thus preserving precious patient access to effective therapies. Contact Archbow Consulting today if our expertise in this space can help your team. **PC**



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Closing the Health Literacy and Diversity Gaps in Clinical Trials

New engagement approaches can help drive treatment gains in underrepresented communities.

By *Amy Niles*, PAN Foundation

There is no doubt that diversity of those who participate in clinical trials is of utmost importance, but, unfortunately, people of color, females, and those identifying as LGBTQ+ have historically been left out of them. This lack of diversity means we don't learn enough about the impact potential treatments may have on these communities, meaning a treatment may not be as effective or safe for all communities.

According to a national poll¹ of nearly 5,000 adults across the US conducted by the PAN Foundation's Center for Patient Research, more than half (61%) stated that they are interested in participating in a clinical trial in the future. However, when those who have never participated in a clinical study were asked why, the No. 1 reason for all populations is simply that no one had asked them to participate. Specifically, only 22% of people of color and 20% of LGBTQ+ adults say their healthcare provider (HCP) has discussed the option of a clinical trial with them.

Also of note, at least two-thirds report that they would consider participating in a clinical trial if their HCP would have encouraged them, or if they knew the findings would help people who look or identify like them. That's why improving

health literacy about clinical trials, for both patients and HCPs, is critically important. The PAN Foundation recently launched its "Opening Doors to Clinical Trials" national educational initiative,² which offers three services, all working toward the goal of encouraging people from diverse communities to learn how clinical trials may help them.

- Increasing health literacy with digital education.** The content gives people the knowledge they need to better understand the basics of clinical trials, while also addressing medical mistrust and misconceptions, along with the urgent need for greater participant diversity.
- Empowering people to take action.** An online clinical trial finder that removes barriers to trial access by providing a streamlined, user-friendly approach to searching for a trial.
- Providing personalized assistance.** Clinical trials can be difficult to navigate alone, which is why navigators can provide one-on-one help by addressing concerns and connecting patients with community resources that can help remove common barriers many may face when accessing clinical trials, such as transportation.

At PAN, we're dedicated to ensuring everyone has equitable access to the healthcare they need, including clinical trials. We hope to debunk the perception that these communities are hard to reach when it comes to them. What we are finding is they aren't hard to reach; instead, they are hardly reached. We all must work together to change that.

In 2025, we look forward to expanding our "Opening Doors" initiative further. Our goal is to reach more patients nationwide, support HCPs with the tools they need to help their patients, expand collaborations with patient and provider groups, and continue to provide patients with real-time support to remove barriers to their access to care. **PC**

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ABOUT THE AUTHOR

Amy Niles is Chief Mission Officer at PAN Foundation.

Welcome to the Dark Side

Introducing a new *Pharma Commerce* column focused on combating illicit trade and protecting product integrity—and ultimately patients.

By **Sean O’Hearen**, 1st Line Partners

Illicit trade activity (ITA) in the pharmaceutical industry has been on a steady rise globally since the Pharmaceutical Security Institute (PSI) began reporting annual incident statistics more than 22 years ago. According to PSI data, in 2023, pharmaceutical crime hit an all-time high, with 6,897 incidents reported. Over the five years of 2019-2023, incidents climbed about 8% yearly. These incidents cut across every therapeutic category and every region of the world. Risks related to ITA include activities such as counterfeiting, diversion, tampering, theft, and trademark infringement. As the problem grows, both the pharma industry and the public sector continue to direct more attention and resources toward dealing with this challenge and protecting patients, along with the integrity of our drug supply chains.

With this challenge in mind, *Pharmaceutical Commerce* is introducing this new column to address issues related to ITA and to promote a dialogue regarding what we, collectively as an industry and through collaboration with the public sector, can do to combat the problem and protect patients and product integrity.

Unsurprisingly, criminals and bad actors involved in ITA prioritize profits over patient safety and health. They operate in the shadows, clandestinely, seeking to avoid detection, exposure, and accountability for their crimes. They comprise the “dark side” of pharmaceutical commerce, which we will aim to shed light on, stimulate discussion

about, and help readers understand best practices, both proactive and reactive, for managing and controlling ITA risk.

It’s important to understand that ITA risk, to varying degrees, touches virtually every phase of pharmaceutical product development, manufacturing, and distribution—from “make to take”—and every segment of a product’s lifecycle—from “launch to legacy.” Bad actors spot market opportunities and exploit vulnerabilities throughout the system with alacrity, ingenuity, and sophistication, not to mention greater agility than those of us who play by the rules. Their fraudulent schemes and methods are innumerable and dynamic, and it’s difficult for the good guys, the protectors, to prevail.

To effectively oppose the dark side, we have to think differently than we do when thinking about our legitimate business activities. We have to view our manufacturing and distribution system holistically and through a “product integrity lens,” meaning we have to ask ourselves: how can bad actors exploit and/or circumvent the regulated delivery system to achieve their nefarious aims?

Thus, the objective of this column will be to broaden the aperture of our product

integrity lens and look at this problem and solution set from various angles, through case studies and exploration of current events, hot topics, and themes raised by the *Pharma Commerce* editorial team.

On that note, this issue covers topics such as retail pharmacy closures, pharmacy deserts, and third-party logistics (3PLs). To emphasize my point, all three topics have significant product integrity concerns related to them, which we don’t have the column space to get into now. However, I’ll briefly highlight some of the issues as an example of more to come in this space.

A key knock-on effect of pharmacy closures and subsequent pharmacy deserts is that people turn to the internet for their medicines. From a product integrity perspective, this is generally a bad idea. As the Alliance for Safe Online Pharmacies states on its home page, “At any given time, there are around 35,000 active online pharmacy websites—about 95% of which do not comply with applicable laws and pharmacy standards.” Online pharmacies are rife with illicit products, and manufacturers must invest significant resources in online monitoring and enforcement.

3PLs are a key area of focus of product integrity programs, mainly due to cargo theft risk, especially in certain parts of the world, such as Brazil, Mexico, and South Africa. Proper vetting, auditing, and oversight of 3PLs is critical, as well as having processes and procedures in place for route planning, incident response, and regulatory compliance, to name a few. **PC**



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Breaking Point: How 2025 will Reshape Patient Support Services

From matrix programs to anti-abandonment strategies, predictions for a new era.

By *Chris Dowd*, ConnectiveRx

2024 was a pivotal year for the patient support landscape, as the space underwent a substantial shift shaped by market dynamics, regulatory changes, and the evolving needs of patients.

After a quarter marked by intense discussions at industry conferences and candid conversations with pharmaceutical leaders grappling with unprecedented change, one thing is clear: 2025 will fundamentally transform how drugs are covered, paid for, and filled in America.

Here are five predictions for how the landscape will shift in the year ahead:

1. The dramatic IRA rollback

By mid-2025, we'll witness the most significant healthcare policy battle since the Affordable Care Act. The Republican-controlled Senate, pursuing Trump administration priorities, is likely to substantially challenge key Inflation Reduction Act (IRA) provisions, particularly around drug price negotiations. While the slim Senate and House majorities could make it difficult to institute a full repeal of the IRA, parts of it are vulnerable.

As North Star Opinion Research Vice President Jon McHenry noted in a recent panel discussion, Republicans will likely use unspent IRA funds to help

offset the continuation of Trump-era tax cuts expiring in late 2025. However, the \$2,000 out-of-pocket cap for Medicare beneficiaries will likely survive, creating an interesting dynamic where manufacturers must navigate a hybrid policy landscape.

To stay ahead of the IRA roller coaster in the coming year, stakeholders in the patient support ecosystem—from providers to hub and patient services teams—need to work overtime to understand the evolving nuances of what's changing and communicate it effectively. A PDR survey of US healthcare providers (HCPs) reveals that 38% of providers “know nothing” about the pharmaceutical provisions in the IRA, while an additional 55% only know “a little.” This highlights myriad opportunities for pharma manufacturers to also provide welcome education to HCPs about changes in access to their branded drugs.

2. The rise of matrix support programs

The death of the dominance and attention on “traditional” copay programs, the surge in prevalence of accumulator adjustment and maximizer programs, and the continued usage of alternative funding programs will force a complete reimagining of manufacturer support.

By Q3 2025, we'll see the emergence of matrix support programs that combine product access, procedure coverage, treatment-journey assistance, and patient success programs in entirely new ways.

Buy-and-bill programs already account for half of specialty product assistance. With the gross-to-net (GTN) pressure on brands to do more with less, including the evolution of copay affordability programs over the last five years, these matrix support programs will only continue to grow in necessity. High-end specialty medications are a prime example: In the same way biologics took the market by storm over the last seven to 10 years despite initial skepticism, cell and gene therapy pipelines and approvals are continuing to escalate—and programs supporting their adoption and adherence will be key.

As the market shifts from traditional copay programs to more sophisticated matrix programs, pharma brands need to seek out best-in-class support options to serve patients. They should consider establishing working groups in their organizations to meet with their field reimbursement managers as well as marketing and managed care teams to stay on top of what patients and providers are expecting (and demanding) in order to build programs that raise the bar.

3. The PBM revolution

Pharmacy benefit managers (PBMs) currently “don’t have any friends in Washington,” as McHenry noted in the recent panel. Pressure on PBMs by both federal and state governments in the form of anti-PBM legislation is unprecedented, and, considering RFK Jr.’s reformist views and the power he could wield, their influence will likely wane in the coming year.

With that in mind, the bipartisan “Patient Before Monopolies Act” will pass in 2025, fundamentally restructuring the PBM industry. As Sens. Elizabeth Warren and Josh Hawley’s unlikely alliance pushes the legislation forward, we’ll see initial steps to dismantle vertical integration between insurers, PBMs, and pharmacies. This will create immediate market disruption but ultimately lead to more transparent drug pricing models by year’s end.

Staying on top of these developments is paramount. Whether through internal or external resources, manufacturers should remain in ongoing contact with state government relations teams to understand how legislation is evolving and how they can react.

4. The rise of ‘anti-abandonment’ programs

Even with a mature patient services model, fewer than half of specialty patients make it through payer controls to fill their prescriptions at 90 days, according to the IQVIA Institute.

With new-to-brand abandonment rates hitting 35% to 40% and the industry losing billions in potential revenue, 2025 will see manufacturers pivot away from traditional adherence programs, toward sophisticated early-intervention models. These programs will leverage predictive analytics to identify at-risk patients before they abandon therapy, combining financial support, behavioral interventions, and digital

engagement in novel ways. This shift is particularly crucial as the industry grapples with expanding formulary exclusion lists from major PBMs such as CVS Caremark, Express Scripts, and OptumRx.

Leveraging patient data and AI-driven targeting models can help brands build effective anti-abandonment programs. By scoring key demographic information such as age, drug class, prior experiences, and previous adherence (or lack thereof), early-intervention algorithms can help determine the likelihood of abandonment. From there, brand teams can build tailored programs to improve adherence.

5. The impact of GLP-1 prescriptions

In 2025, GLP-1 agonists will face unprecedented restrictions and rejection rates from payers due to cost, demand, and indication alignment (e.g., trends that include moves by Kaiser, Independence Blue Cross, and Blue Cross Blue Shield of Michigan). While Medicare may expand coverage under the new administration, commercial payers will simultaneously implement a new generation of sophisticated access barriers that go far beyond traditional prior authorization—requiring documented participation in behavioral health programs, mandatory step therapy through lower-cost alternatives, and possibly even time-limited authorizations tied to demonstrable outcomes. And to further complicate the long-term GLP-1 reimbursement landscape, the US Department of Health and Human Services has announced that Ozempic, Rybelsus, and Wegovy will be included in the 2025 round of Medicare drug price

negotiations, with adjusted prices becoming effective in 2027. Taken together, these multiple challenges will push pharmaceutical manufacturers to repeatedly reimagine GLP-1 access and support.

Learning from oncology’s experience with advanced patient support programs that integrate financial, clinical, and behavioral support, we will see companies move away from traditional copay assistance toward more holistic “lifestyle support hubs” that combine financial assistance with digital coaching, behavioral modification tracking, and outcomes documentation. Traditional support models that “help with copays and prior authorization” will be enhanced by end-to-end patient success programs that help patients navigate increasingly complex payer requirements while supporting long-term therapy success. According to Kevin Herwig, health policy manager at the HIV + Hepatitis Policy Institute, we’ve already seen this evolution in HIV treatment support programs, where successful adherence increasingly depends on providing comprehensive social, behavioral, and financial support—GLP-1s will accelerate this trend dramatically across all chronic conditions.

The multiple disruptions looming this year will create a clear divide between brands that embrace these changes and those that maintain traditional commercial approaches. For brand leaders, the time to prepare is now, while there’s still opportunity to gain first-mover advantage in their therapeutic areas. The future belongs to the bold. **PC**



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Chris Dowd is Senior Vice President, Market Development, at ConnectiveRx. With a nearly 30-year career spanning leadership roles across Big Pharma, healthcare startups, and the patient support space, Dowd is a preeminent industry voice in patient access and adherence.



Popping the Gross-to-Net Bubble, Part II: What Manufacturers Can Do About It

A look at the actionable steps needed to elicit change.

By *Bill Roth*, IntegriChain

Welcome to the second installment of the “Popping the Gross-to-Net Bubble” series. In this column, I’ll dive into actionable steps pharmaceutical manufacturers can take to address this issue. This series is not intended as an academic review of the concept or problem but rather as a practical toolset for commercial teams, drawing from my 25 years of experience working on these challenges.

The manufacturer’s role in expanding gross revenue

The concept of gross-to-net (GTN) optimization has been central to the

pharmaceutical industry since the mid-to-late 1990s. However, the problem on the net revenue side stems directly from challenges on the gross revenue side, which arguably accelerated in the early 2000s with the rise of specialty pharmaceuticals. While it may be uncomfortable for some to acknowledge, pharma manufacturers have naturally and willingly participated in the inflation of the GTN metric.

First, let’s take a step back. When I launched my consulting practice in late 2001, I noticed several key drivers of pricing decisions.

Scientific and commercial disconnect. Manufacturers were experts in their science and in selling to physicians

and consumers. However, payers were beginning to flex their influence, and manufacturers were unprepared.

Lack of coordination on pricing. Commercial functions were often siloed, with little collaboration around pricing strategy. Finance and government pricing have typically only been involved to measure the impacts of decisions but is not part of the strategic rationale or decision-making process of how and when discount levels were decided.

Discounting without net revenue strategy. Few leaders of manufacturers could effectively articulate the nuances of their discounting strategies. As an example, why was the rebate to a

payer 40% and not 37%? The role of market access, which has the biggest impact of the GTN phenomenon, is tasked with formulary positions. Some market access teams had unchecked authority to discount at will. Field sales could establish discounting strategies to provider offices for medical benefit products, as they were the primary influencers of product choice for this type of product. Distributors relied on speculative buying margins, and manufacturers often couldn't calculate the cost of the distribution channel, but some distributors were able to buy as much as six months of product (pre-Sarbanes Oxley) against double-digit price increases.

At the time, the GTN calculation wasn't a strategy; it was the measurement of the pricing decisions made by disparate teams, and the role of finance and government pricing was simply to measure the impact of the decisions—not to provide guidance or counsel.

One of our first service offerings was to document all spending and package it in a way that allowed senior leaders, brand managers, and finance teams to understand costs by payer, pharmacy/site of care, distributor, and patient. However, most manufacturers dismissed the need for optimization, relying instead on annual price increases of 9% to 10% in order to maintain margins. It was hard to argue with their logic, as it had worked at the time.

The turning point: Medical benefit and the Medicare Modernization Act

Between 2003 and 2005, everything changed. The precursor documents for the Medicare Modernization Act from the Government Accountability Office and the Congressional Budget Office signaled a shift. The government planned to

Manufacturers began to rationalize discounts to align wholesale acquisition cost with average selling price.

transition medical benefit products from an average wholesale price-based model to an average selling price (ASP)-based model.

This shift introduced a reimbursement mechanism that required manufacturers to think holistically about their broad discounting strategies and accurately captured discounts. Furthermore, the ASP model, with its two-quarter lag, acted as a natural limiter on price increases. If a manufacturer raised prices beyond 1.5% twice a year, provider offices administering the product could face significant losses, as reimbursement would lag behind the price increase. For products reimbursed at ASP plus 6%, this created a major disincentive for aggressive price hikes.

This change marked the first real example of GTN optimization, and remains the playbook for GTN optimization for medical benefit. Manufacturers began to rationalize discounts to align wholesale acquisition cost (WAC) with ASP. Here's how it played out.

Eliminating payer discounts.

For medical benefit products, payers didn't manage discounts as aggressively as they do now. Discounting to a payer only reduced ASP and, therefore, reimbursement. Removing these discounts was an easy decision. The contemporary view here is very important. While there were 30 or so medical benefit products that received payer discounts about 10 years

ago, this number crept into the low 100s in the 2020s with the arrival of biosimilars. Like a siren on the rocks, manufacturers that are lulled into payer discounts on medical benefit products find themselves in a very precarious position with providers. As many biosimilar manufacturers are realizing now, one of the first questions a buy-and-bill provider office will ask is "are you contracted with payers?" If the answer is yes, the opportunity to detail the product is typically over as the provider's office will understand that the WAC:ASP ratio will likely be off, and the net cost recovery of the product is expected to be negative.

Pulling back distributor discounts. Distributors were already moving away from speculative price increase models. By removing prompt-pay cash discounts and shifting to bona fide fair market value (FMV) service fees, distributors could retain margin without competition—as FMV fees cannot legally be passed on to downstream buyers. This is still an important aspect of managing not only the GTN but the total net value of the sale. Overspending for distribution does not yield any incremental value. The company that spends 10% gets the same, and often less, than the company that spends 1.25%. This can be a little trickier to maneuver, but the use of exclusive distribution networks in specialty or highly limited networks are great tools. With

Blaming any one party is nothing more than propaganda and misses the systemic nature of the issue.

the growth of exclusive distribution networks, with rare exception, all clinics and all hospitals buy from all specialty distributors. This is harder with products with more commoditized products—such as biosimilars and specialty generics—but practical for reference products.

Gradually reducing provider discounts. This was the most challenging area, especially when group purchasing organizations (GPOs) were involved. Manufacturers adopted multi-year strategies, pulling back discounts incrementally by 25-50 basis points per year. While potentially painful in the short term, this proved to be powerful in the long term. This remains the hardest of the areas to optimize GTN, especially if the manufacturer has been discounting aggressively. For buy-and-bill products, however, usually as the WAC:ASP ratio widens, the use of the Assignment of Benefit (AOB) model increases, and the alternative sites of care come into the picture. Unwinding these scenarios are not impossible, but it's a lot to unwind. Even with a modest differential in the WAC:ASP, it will take roughly 18 months to undue short-term discounting.

Collaboration as a success factor

As we have now been doing this for products on market and new products, going through this process reveals a

critical insight for GTN optimization: cross-functional collaboration was essential. Marketing, field sales, market access, trade, and patient services teams have to work together to develop comprehensive pricing strategies, but unfortunately, these groups don't naturally align together. Going forward, it is our firm's strong belief that the best laid out plans need to be completed by new product planning early in the development cycle, either Phase II or very early in Phase III, and finance and government pricing teams need to be in a strategic, not a supporting role, governing these decisions and not simply measuring them. This collaborative approach, while still relatively rare, proves highly successful.

Challenges in pharmacy benefit

On the pharmacy benefit side, the dynamics are different. Pharmacy benefit managers (PBMs) have consistently consolidated and gained power as drug classes become more and more crowded. Despite price increase caps set by PBMs

and government penalties like the Medicaid unit rebate amount consumer price index (CPI-U) penalty (introduced in 1993), manufacturers will often still raise price above the CPI for a given period, take the short-term win, and pay the longer-term penalty.

Not surprisingly, payers, pharmacies, distributors, and GPOs all tolerate and encourage these price increases because they benefit from higher prices. This is exemplified in all of their warnings in the market today related to lowering WACs. It's obvious to anyone in the industry, but any entity earning a percentage of the list price profits from the inflation. The true burden falls on plan sponsors (governments, employers, and unions) and patients.

The entire industry enables the inflation of GTN. Blaming any one party is nothing more than propaganda and misses the systemic nature of the issue.

Looking ahead

In the next installment, I'll explore the pharmacy benefit landscape in greater detail, examining examples of pricing strategies for first-in-class drugs versus those in mature categories with years of price increases.

For those frustrated by the system, it's worth noting that several key loopholes have been closed through legislation at both the federal and state levels over the past 15-20 years. I'll cover these reforms in upcoming columns. **PC**



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YOUR SUCCESS COMMERCIAL

The Prominence of Pharmacy Deserts

How chain and local closures are impacting healthcare access.

By **Jenni Zilka**, Cencora and Good Neighbor Pharmacy

In recent years, the landscape of retail pharmacy has changed significantly due to massive financial, legislative, and social pressures, creating a challenging environment for both large and small pharmacies, and resulting in some having to close their doors.

With news of pharmacy closures frequently making headlines, questions have arisen about the consequences for communities that rely on pharmacies for care. Moreover, there are growing concerns that continued closures will lead to an increase in pharmacy deserts—or areas where access

to essential pharmacy and healthcare services is severely limited—particularly in underserved communities.

What is a pharmacy desert?

Pharmacy deserts are defined as areas where residents live more than a mile away from the nearest pharmacy in cities, more than two miles in suburbs, and over 10 miles in rural areas. According to data aggregated by Cencora, approximately 35 million people in the US live in pharmacy deserts.¹

THE ABSENCE OF PHARMACIES IN A COMMUNITY MOST LIKELY MEANS A SYNONYMOUS LACK OF OTHER CARE OPTIONS.

In communities with pharmacy deserts, people cannot easily access a pharmacy to fill prescriptions and obtain necessary health services. These deserts, found in both rural and urban settings, are located in areas that are up to 40% more likely to have fewer primary care providers² and higher social vulnerabilities, such as poverty and lack of access to transportation. In short, the absence of pharmacies in a community most likely means a synonymous lack of other care options.

The value of pharmacies and pharmacists

The rise of pharmacy deserts contrasts starkly with the reputation of pharmacists as accessible healthcare providers (HCPs), especially in underserved communities. Independent pharmacies, in particular, are known for their organic care of underserved and socially vulnerable populations, due to the high-touch nature of their services and their natural presence in these communities. For example, 20% of Good Neighbor Pharmacy stores directly serve or are adjacent to pharmacy deserts, according to data from the National Council for Prescription Drug Programs, CDC Social Vulnerability Index, and the US Census and American Community Survey.

In underserved communities, where other HCPs may be scarce, patients depend on their pharmacies not only for

prescriptions, but also for comprehensive health advice and services. Pharmacists in those settings serve as a critical resource, addressing health questions and concerns that extend well beyond dispensing medications. But this perception of pharmacists as care providers isn't limited to these communities. The pharmacist's role was highlighted during the COVID-19 pandemic, when local pharmacists played a pivotal role in testing, treatment, and vaccination services. Today, their role extends beyond medication dispensing to address a broader range of public health needs, with patients increasingly relying on them for various care services.

According to a 2023 study,³ nearly half (45%) of Americans regularly visit their local pharmacy for care, and 58% are likely to turn to pharmacies as their first stop for non-emergency medical issues. Pharmacies remain the most common sites for COVID vaccinations,⁴ administering 31.3 million doses between September 2023 and April 2024, compared to 2.5 million doses administered by physician medical offices during the same period. There is a similar trend for flu vaccinations, with pharmacies administering 38 million doses, compared to 26 million by physicians' offices between August 2023 and May 2024.

Beyond vaccines, pharmacists have also shown they can effectively address other gaps in medical care, consultation,

and education for various health conditions. A 2020 national study⁵ found that pharmacists improved medication adherence for diabetes patients, increased the use of statin medications, ensured annual flu vaccinations, completed HbA1c tests, and helped patients maintain a tobacco-free status. Their interventions closed 79.8% of care gaps, suggesting that collaboration between physicians and local pharmacists can be an effective strategy to engage patients and deliver essential care.

What is driving pharmacy closures?

Despite their accessibility and proven ability to provide essential patient care services beyond dispensing medications, pharmacies are struggling to remain financially viable, primarily due to inadequate reimbursement rates for the medicines they dispense and the care services they provide. As these reimbursement rates decline—or even disappear altogether with the expiration of the COVID public health emergency—pharmacies are finding it increasingly difficult to remain financially solvent and maintain the high level of care they provide to patients.

For example, on the national level, Medicare Part B does not currently recognize or reimburse pharmacists as providers. With the expiration of the public health emergency status from the

pandemic, Medicare beneficiaries are no longer covered for services provided by pharmacists. Congressional legislation to remedy this—the Equitable Community Access to Pharmacist Services Act—had been introduced last Congress with robust bipartisan support, aiming to ensure Medicare beneficiaries’ prompt access to essential services for vaccination, testing, and treatment of common infectious diseases by establishing Medicare Part B reimbursement for pharmacists to deliver these services. However, the bill was not included in the end-of-year health package passed by Congress in December 2024. As a new Congress convenes this year, Cencora will be engaged as part of a coalition to address this important reform.

Overall, with positive industry changes not guaranteed, pharmacists, along with their industry peers and trade organizations, must actively advocate for changes in scope of practice and reimbursement legislation at both state and national levels. Such advocacy is essential to ensure accessible healthcare for patients nationwide. This effort is unquestionably the industry’s primary defense against the spread of pharmacy deserts.

Diversifying revenue and meeting patient needs

Although dispensing medications was once the primary source of income for pharmacies, declining reimbursement rates have necessitated the diversification of their revenue streams. A significant opportunity to increase revenue and enhance patient care lies in offering additional clinical services, such as expanding vaccination programs and point-of-care testing, thanks to the organic proximity and accessibility of pharmacies. Despite variations in the

PHARMACISTS MUST ACTIVELY ADVOCATE FOR CHANGES IN SCOPE OF PRACTICE AND REIMBURSEMENT LEGISLATION AT BOTH STATE AND NATIONAL LEVELS.

authority to provide certain services and receive reimbursement across states, pharmacists are skillfully navigating these inconsistencies to identify and deliver more care services to their communities.

Many pharmacies have excelled in compounding prescriptions, providing nutritional counseling, and stocking over-the-counter (OTC) products such as cold medications and nutritional supplements. These OTC products, part of the pharmacy’s front end, can help diversify revenue amid reimbursement challenges and cater to patient needs.

The importance of maintaining a robust front-end store presence—stocking consumable products in a sustainable way for the pharmacy, while catering to the unique wants and needs of their patient base and demographic—is a prominent industry topic and distinct area of focus for us.

As the industry faces financial, legislative, and social pressures leading to closures and the rise of pharmacy deserts, it is crucial for pharmacies, organizations, advocates, and other peers to relentlessly

push for legislative changes that protect and enhance the profession. **PC**

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From Resilience to Sustainability

Leaders with top third-party logistics providers discuss the evolving landscape for the sector in 2025—and the new strides made in their quest to help transform the pharma supply chain.

By **Nicholas Saraceno**



Third-party logistics providers (3PLs) have an essential role in the pharmaceutical supply chain: handling the logistics of certain products that are unable to be accomplished by a manufacturer, distributor, or dispenser, whether that be due to lack of resources, cost, product complexity, or other reasons.

For the second consecutive year, *Pharmaceutical Commerce* sought to uncover the most pressing issues impacting pharma 3PLs—this time in 2025—while also investigating how the COVID-19 pandemic has affected the market’s current climate and may impact its future outlook through 2035.

Those interviewed include:

- Veronique Dameme, Global Head of Vertical Market Healthcare, DB Schenker
- Scott Szwast, VP of International Strategy, UPS
- Joel Wayment, Vice President/General Manager, Cardinal Health Third-Party Logistics and Packaging Solutions
- Danny Williams, President, Channel Management, EVERSANA
- Chris Armstrong, Vice President and General Manager, McKesson Third-Party Logistics

The following roundtable-style discussion has been edited for length and clarity.

Q: *Pharma Commerce:* Could you provide a general overview of how the third-party logistics process works?

A: **Scott Szwast:** Now more than ever, a company is only as good as its supply chain. For some companies, a well-run third-party logistics solution can be the fastest path to reducing costly inventory, shortening the net trade cycle, and significantly reducing capital expenses.

However, this approach is not “one size fits all,” and it is certainly not a passive endeavor. Success relies upon driving economies of scale through the deployment of optimized multi-client operations, which enable client companies to benefit from infrastructure and technology investments, procurement experience, and capacity advantages that they would not be able to attain independently. It also allows for a turn-key solution that flexes when and where business conditions need it to, with coverage and capabilities already in place to enable accelerated growth. It all begins with collaboration. Partnering effectively means we can help companies move beyond seeing their supply chains as cost centers, rather than a strategic resource.

Chris Armstrong: Third-party logistics offers a complete range of supply chain management services for biopharma that are adaptable and scalable to help businesses swiftly respond to market demands. One critical element in partnering with a 3PL is the ability to maintain compliance with constantly changing laws and regulations, which can pose a significant challenge for manufacturers at launch. An ideal 3PL partner offers efficient and cost-effective solutions to



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DB Schenker



Scott Szwest
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Joel Wayment
Cardinal Health



Danny Williams
EVERSANA



Chris Armstrong
McKesson Third-Party Logistics

assist companies that lack the infrastructure to handle warehousing, distribution, and order management.

Q: What factors should manufacturers consider when selecting a 3PL, and what array of services should a quality 3PL provide?

A: **Danny Williams:** When manufacturers consider selecting a 3PL partner, I suggest a careful assessment to ensure they have the right partner to meet their specific goals and their customers' needs. Having a partner that can operate free of conflict provides great flexibility in providing solutions unique to a specific manufacturer or their specific product.

That said, the tenets of speed, scale, and certainty come to my mind. First, speed comes from having a true partner that the manufacturer trusts and a provider that can quickly deploy the resources needed to implement the manufacturer's program. Second, scale should be viewed as not only the provider's infrastructure and technology, but also its personnel. Is that 3PL right-sized for today's manufacturer? What happens if growth comes faster than planned? What about future products in the portfolio or indications of the product?

Companies should seek out a provider that can offer tangible evidence through long-standing relationships with other manufacturers that have proven to grow with them.

Certainty is third. Will the provider deliver with confidence? What does their track record of success in launching products look like? What about launching new companies into the marketplace? Are the regulatory and quality controls in place? Are their operations resilient? Is the management team entrenched and engaged with the day-to-day, as well as with the manufacturers they serve?

While 3PL services in the pharmaceutical industry have been around for decades, the successful 3PL partner of today is more than just a service provider. They are a business collaborator that aligns with the manufacturer's goals.

Veronique Dameme: Manufacturers should consider factors such as providers' expertise, technology, compliant processes, and geographic footprint. Their choice should be driven by patient well-being, along with the 3PL provider's ability to maintain the integrity of the product from end to end. This includes ensuring on-time, in-full delivery in the right conditions, as there is a patient at the end of the supply chain. Account management and training programs in place are also critical. Their portfolio of services should include inventory management, order fulfillment, transportation, freight management, customs, tracking, and reporting capabilities in a GxP (good practice)-compliant network.

Joel Wayment: When considering a 3PL provider, organizations should consider one with a strong focus on the customer experience. Selecting a 3PL that thinks through the customer lens is crucial to ensure your business is represented in a way that aligns with your company's mission and vision. Biopharma organizations should also assess things like the provider's integrated packaging solutions, expertise in organization and leadership, and the nuanced capabilities a product may require. It's important to ensure your provider has the facilities,

equipment, capabilities, and specialized knowledge to scale and grow.

Q: Although we're about five years removed from its onset, what valuable lessons did you learn during the COVID-19 pandemic that have helped improve efficiencies?

A: **Szwast:** During the pandemic, we saw how serious impacts on supply chains can be fully outside a company's control. Taking a multi-modal approach isn't just a good bet against managing disruption and risk; it also allows for the reality we're all facing, as more fragile, complex, and temperature-sensitive treatments hit the market.

To make that work, however, you must have control and visibility. We have access to more data than ever before, but do you have the transportation and storage capabilities to act on it and vice versa? Less guesswork, less loss, and more deliveries made where they need to be at the right time and temperature. Rethinking supply chains also opens exciting opportunities for the future of patient care. These new levels of agility and resiliency can help spread and improve home health offerings, keeping patients out of clinics and hospitals, improving lab diagnostics for speedier, more accurate treatment plans, and increasing the speed and depth of clinical trials for new products.

Dameme: Lessons from the COVID period include accelerated digitalization, enabling real-time tracking and data-driven decisions; faster transitions from concept testing to implementation for quicker logistics solutions; building more resilient supply chains to withstand disruptions; and enhancing adaptability and agility to react swiftly to changing demands.

Armstrong: Several valuable lessons have been learned that have significantly improved 3PL efficiencies within the mar-

ket. One of the most critical lessons is the importance of a strong and resilient supply chain infrastructure, which is essential for managing large-scale distribution efforts. The ability to quickly adapt and respond to unprecedented challenges has set a new standard for biopharma 3PL providers, emphasizing the need for flexibility and agility. Undoubtedly, the driving force behind the ongoing expansion of our technological and distribution capabilities is our most crucial asset: our people. Without a team of experienced, dedicated, and passionate professionals, a 3PL's services mean nothing.

Q: Heading further into 2025, which trends affecting the pharmaceutical industry will 3PLs be on the lookout for?

A: **Armstrong:** In 2025, 3PL companies will be on the lookout for several key trends:

1. Advanced cold chain solutions are no longer a competitive advantage but a basic requirement for participating in the 3PL space, given the increasing demand for temperature-sensitive medications. Expect increased attention and focus on cryogenic, frozen, and refrigerated storage capacity.
2. As the regulatory landscape continues to grow more complex, 3PLs must be quick to adapt and expand their compliance capabilities to ensure they meet all necessary standards. The FDA has extended the deadlines and offered exemption waivers for manufacturers [and their 3PLs] to fully meet the Drug Supply Chain Security Act requirements. 2025 will be a big year to ensure pharmaceutical supply chains are fully serialized, traceable, and compliant.

Additionally, service providers must be willing to innovate to meet the unique

requirements of personalized medicines, which often involve more intricate logistics and handling processes. These trends will shape the strategies and services of 3PLs to better serve their clients and maintain a competitive edge.

Williams: As 3PLs, our heads are constantly on a swivel. There is so much change that it can be difficult to know where to focus. From changing delivery models due to shifts in retail drug chains, to online pharmacy fulfillment, continued consolidation of buying entities and acquisition of the providers/prescribers, pricing pressures on the manufacturers, ESG initiatives for sustainability, and more, new trends are constant across the industry, and manufacturers are looking to their 3PL partners to help collaborate and determine how to best address them.

In addition, [let's not forget] the rise of biologics and cell and gene therapies, which will increase the demand for specialized cold chain logistics and highly coordinated support for 3PLs. Advanced technologies such as AI, machine learning, and blockchain will continue to enhance supply chain visibility and security. Sustainability initiatives revolving around reducing carbon footprints and using eco-friendly materials will remain a focus. We also cannot underestimate potential regulatory and market changes due to the arrival of the new administration.

Szwast: The innovation in next-gen treatments is not only transforming the healthcare industry but also its underlying supply chain. Complex goods, including biologic drugs, will make up an ever-growing share of the international healthcare logistics market.

At the same time, these more complex pharma products are being more broadly distributed than ever before, creating a greater need for temperature control, digital visibility, and precisely timed delivery.

Thanks to rising global living standards, there are rapidly growing international markets as well as growing home health-care opportunities, where new channels for pharma distribution will accelerate with the aging population and prevalence of chronic disease. These trends bring ample opportunities, but also new challenges on how to serve that demand effectively and efficiently.

Q: What level of impact do you anticipate 3PLs and their role within the industry having over the course of the next decade?

A: **Dameme:** 3PLs will have a significant impact in the next decade and beyond. COVID highlighted their crucial role, and as we face more disruptive events, their ability to ensure resilient, efficient, and adaptive logistics will be essential for global pharmaceutical supply chains.

Szwast: Until now, supply chain excellence has been a differentiator and business advantage for those who possess it. Going forward, and especially for healthcare companies, it will be a requirement to be viable in the market. We're seeing a real shift in debates about "outsourcing vs. insourcing" to more well-rounded assessments, in which combinations of integrated solutions create the most sustainable business and care advantage for patients, companies, stakeholders, and shareholders.

Williams: The need for 3PLs will only strengthen over the next decade as manufacturers seek to make better use of capital to ultimately focus on developing the therapies patients need. The expertise and operational efficiencies 3PLs provide will be of great benefit to manufacturers in a more complex and geographically expanding supply chain.

As 3PLs adopt newer, more advanced technologies, manufacturers and their

end customers will benefit from enhanced efficiency and reduced costs. 3PLs also have the potential to facilitate global market expansion and manage international logistic complexities by putting an emphasis on sustainability and implementing eco-friendly practices. Strong partnerships between 3PL providers, manufacturers, and stakeholders will be crucial for addressing industry needs and positioning pharmaceutical manufacturers for success. In the end, a successful partnership is a win for everyone—for the manufacturer, the 3PL provider, and, most importantly, patients in need.

Wayment: 3PLs have the ability to revolutionize the client experience by how well they flex and scale with the biopharma organizations they support. Putting processes in place to review evolving client needs over time will be critical as we operate in a dynamic and rapidly changing environment. 3PLs have the ability to make a positive impact on environmental sustainability, ultimately resulting in keeping patient costs low.

Armstrong: I believe 3PLs will have a significant impact over the course of the next decade and beyond. Market research by Nova One Advisor estimates suggest that the biopharma 3PL market will nearly double over the next 10 years, primarily driven by the increasing demand for specialty therapeutics and personalized medicines. The growing need for expertise and innovation in cold chain logistics will be crucial for long-term success, as these solutions are becoming a fundamental requirement rather than a competitive edge.

Additionally, regulatory challenges are not going away, and 3PLs must be prepared to adapt and flex to ensure continuous and compliant distribution. These factors will position 3PLs as indispensable partners in the pharmaceutical industry, driving efficiency, reliability, and innovation. **PC**



M&A in Pharma: Balancing Growth and Risk

What factors should be considered—and how can both parties benefit long-term?

By **Justin Kozak**, Founder Shield

The pharmaceutical industry has witnessed a resurgence of mergers and acquisitions (M&As) as companies seek to gain a competitive edge, accelerate innovation, and drive growth. By consolidating resources, expanding market reach, and acquiring valuable intellectual property, pharmaceutical organizations are reshaping the industry landscape. However, these deals come with significant risks that must be carefully managed to ensure long-term success.

The resurgence of M&As in pharma

M&As are making a significant comeback in the life sciences. Companies are leveraging M&A strategies to strengthen their market positions, diversify pipelines, and access innovative technologies. This trend in dealmaking reflects the growing need for efficiency and competitive advantage.

Pipeline diversification remains a key driver of M&A activity, allowing companies to broaden their product offerings and mitigate risks tied to single-drug portfolios. Additionally, acquisitions often accelerate time-to-market for ground-breaking treatments by bypassing lengthy R&D phases. Another motivating factor is cost synergies, achieved through shared resources and economies of scale, which reduce operational expenses. Accessing emerging platforms, particularly in biotech and AI-driven drug discovery, also pushes companies toward strategic deals.

Recent notable deals underscore this resurgence. For example, Pfizer's acquisition of Seagen in 2023¹ highlighted its focus on advancing cancer therapies. Similarly, Amgen's purchase of Horizon Therapeutics in the same year² aimed to expand its presence in rare diseases, aligning with a long-term growth strategy. Each deal exemplifies the industry's commitment to combining strengths and adapting to market demands.

The strategic rationale for these transactions is clear: companies are seeking to maintain relevance in a rapidly evolving landscape. Whether by enhancing product pipelines, reducing costs, or securing cutting-edge technologies, M&A activity is shaping the future of pharma. This resurgence signals an exciting phase of innovation, collaboration, and growth for the industry.

Risks associated with M&As in small pharma companies

M&As in smaller-sized organizations can drive growth and innovation, but they also carry significant risks. Addressing these challenges requires careful planning and strategic execution to ensure success post-merger.

- **Regulatory hurdles.** Navigating the complex regulatory landscape is one of the biggest challenges in M&As for small pharma. Each merger involves aligning with different regulatory frameworks, which can delay deal completion or increase costs. Post-merger, ensuring ongoing compliance is equally daunting, especially as regulations evolve across global markets. Failing to address these issues can lead to costly penalties or loss of market access.
- **Integration challenges.** Combining two distinct organizations often brings cultural and operational conflicts. Merging diverse workforces and integrating different IT systems can cause disruptions, leading to inefficiencies and delays. Without proper planning, these challenges may result in productivity losses, potentially derailing the intended benefits of the merger.
- **Market volatility.** Economic downturns and geopolitical events can significantly impact the value of M&A deals. Fluctuating valuations may lead to higher deal premiums, making transactions

riskier for small companies. Furthermore, unexpected market shifts post-merger can compromise the financial stability of the combined entity.

- **Dilution of shareholder value.** Shareholder dilution is a common concern in M&A transactions. When deals involve issuing new shares or acquiring debt, existing shareholders may experience reduced ownership percentages, which can impact long-term value and investor confidence.
- **Operational risks.** The practical aspects of combining supply chains and manufacturing processes also pose challenges. Supply chain disruptions, quality control issues, and operational bottlenecks are potential risks that can delay product delivery and harm brand reputation. These problems are particularly pronounced in those industries with strict compliance standards, such as the pharma sector.

M&As in small pharma companies can unlock growth and innovation, but only if the associated risks are carefully managed. Addressing regulatory, integration, market, and operational challenges with proactive strategies ensures that these transactions deliver their intended value. For small pharma, success lies in preparation, adaptability, and a keen understanding of the unique challenges inherent in the industry.

Mitigating risks and ensuring a smooth exit

M&As can be transformative for companies, offering growth and market expansion opportunities. However, to ensure a successful and smooth exit, careful planning and post-acquisition risk management are essential.³ Addressing key factors in strategic planning, due diligence, integration, risk management, financial planning, and legal considerations can significantly improve outcomes.

Strategic planning and due diligence

A successful M&A begins with a well-defined strategy that aligns with the company's long-term objectives. This involves identifying potential acquisition targets that offer strategic value, such as complementary products or market presence. Assessing the strategic fit ensures that the merger strengthens the company's position while minimizing the risk of misalignment.

Due diligence is crucial to uncovering hidden risks and liabilities. This process involves analyzing the target company's financial health, intellectual property, and regulatory compliance.⁴ For example, reviewing contracts and patents helps identify potential legal issues, while evaluating operational practices ensures compatibility with the acquiring company. Thorough due diligence lays the groundwork for a seamless transition and avoids surprises post-merger.

Proactive risk management

Integration challenges often derail the benefits of an M&A deal. A comprehensive integration plan can mitigate this risk by addressing key operational and cultural differences. Clear communication channels should be established to foster collaboration and align teams across both organizations. Leveraging technology, such as unified IT systems, can streamline processes, improve efficiency, and reduce disruptions during the transition.

Identifying and managing risks early in the M&A process is critical. Companies should develop contingency plans for potential disruptions, such as supply chain interruptions or regulatory hurdles. Implementing robust risk management frameworks allows for agile responses to

unforeseen challenges, ensuring stability throughout the integration process.

Legal and financial considerations

Adequate financing is essential to cover acquisition costs and post-merger integration expenses. Life sciences companies must evaluate the financial impact of the deal on cash flow and the balance sheet, ensuring sustainability. This analysis helps prevent over-leverage, which can strain resources and jeopardize long-term success.

Navigating complex legal and tax implications requires experienced advisors. Ensuring compliance with relevant regulations and addressing potential tax liabilities are critical to avoiding penalties or delays. Proper legal guidance ensures

a smoother transaction and safeguards against unforeseen complications.

Mitigating risks in M&A transactions demands strategic planning, detailed due diligence, and proactive integration and risk management.

By aligning financial, legal, and operational frameworks, companies can ensure a smooth exit and maximize the value of their merger. A well-executed approach not only reduces risks but also sets the stage for long-term success. **PC**



ABOUT THE AUTHOR

Justin Kozak is the Executive Vice President at Founder Shield, a tech-enabled commercial insurance brokerage. He leads the life sciences practice, having 10+ years of experience in risk management with Hub International, PBC, and now Founder Shield.

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Why Pharmaceutical Products Need Sustainable Packaging

By Bradley Dunlap, Shurtape Technologies



ABOUT THE AUTHOR

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There is a growing, widespread desire for sustainable products across industries, and the pharmaceutical sector is no exception. Patients, healthcare providers, and regulators are putting increasing pressure on drug manufacturers to adopt environmentally friendly practices. In fact, a 2024 consumer survey by PwC found that 85% of respondents are seeing the impact of climate change on their lives firsthand, while 46% said they were buying more sustainable products as a way to reduce their impact on the environment. More than 80% of consumers said they were willing to pay more for these “green” products, with an average 9.7% sustainable premium, even with the rising cost-of-living and inflation.

One packaging component that is oftentimes overlooked when determining sustainable alternatives in manufacturing is tape, an essential part of packing and shipping. Tape is also a simple and seamless transition from virgin plastic to a more sustainable alternative, but consumers are paying attention. The aforementioned PwC survey

also found that buyers are assessing producers' sustainability practices through tangible attributes, with 40% of those surveyed saying they pay attention to production methods and recycling, 38% to eco-friendly packaging, and 34% indicating they want to know if companies are making a positive impact on nature and water conservation.

Fortunately, with new products on the market, suppliers can adjust their traditional packaging methods to utilize sustainable sealing options to meet consumer demand, while also keeping the strength and resilience they are accustomed to from their tape.

The value for pharma

In the pharmaceutical sector, packaging plays a critical role not only in protecting products but also in maintaining compliance with strict safety regulations. Sustainable packaging—including recyclable packaging tape and packaging tapes made from 90% post-consumer recycled polyester—offers a unique opportunity for companies to reduce their use of virgin plastic and minimize waste while ensuring the safety and security of their products during transit. As consumers and businesses alike prioritize sustainability, adopting greener packaging practices can help drugmakers enhance their brand image and bottom line while supporting their environmental goals.

Tale of the tape

Recyclable tapes are often made from performance-grade paper and can be recycled alongside the packaging materials they seal, which significantly reduces the use of plastic in pharmaceutical packaging. This aids in the conservation of natural resources and reduces the waste footprint that is often associated with the pharma industry. Making the switch to a tape made from post-consumer recycled materials results in individual shippers significantly reducing their use of virgin plastics. **PC**

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