

A scenic photograph of a mountain range at sunset. The sun is low on the right side, casting a warm, golden glow across the sky and the silhouetted peaks of the mountains. The foreground is in deep shadow, with some dark shapes that could be trees or rocks.

How life science firms can win in the evolving specialty pharma landscape

Specialty pharma is reshaping the life sciences landscape

Manufacturers are loading up their pipelines with biologics and orphan drugs, while payers are figuring out how to support \$1000-a-pill therapies. Pharmacies are reclassifying themselves as specialty pharmacies. Doctors and other healthcare providers are able to offer their patients innovative treatments that are far more effective than anything previously available.

Life science companies across the value chain know they need to adapt. But given the pace of industry transformation, yesterday's strategy could be obsolete already.

In this piece, we'll explore five key trends that Slalom is seeing in the specialty pharma space that we believe all stakeholders need to be aware of—and adapt to—to win with a specialty therapy:¹

1. The rapidly-evolving specialty landscape
2. The need for manufacturers to design the right channel strategy and the benefits of limited networks for some therapies
3. The continuing power of payers—and why that will help accelerate trends toward value-based healthcare
4. The preeminence of data, and the need for a data strategy
5. The focus on the patient journey and how clinical integration to support the “whole patient” is aligning the interests of patients, payers, and providers

1. The rapidly-evolving specialty landscape

Everyone agrees that the specialty market is growing fast: according to one forecast, the market is projected to grow at a 15% compound annual growth rate (CAGR) from \$55 billion in 2005 to \$1.7 trillion in 2030.² But what exactly is meant by the term “specialty”? As the specialty space evolves, even the meaning of the term continues to be in flux.

When it comes to the therapies themselves, many aspects of the traditional definition continue to apply: high cost, special handling requirements, often a biological derivation, etc. However, in the past, “specialty” was typically reserved for relatively small patient populations (think multiple sclerosis or cystic fibrosis). Today, with the emergence of new specialty therapies like PCSK9 inhibitors (such as Sanofi and Regeneron's Praluent for excess LDL cholesterol), the prevalent population could be as high as 15M patients or more.³ Payers won't be able to handle the nearly \$15K-per-patient price tag for that many patients.⁴ Retail pharmacies won't be able to handle the prior authorization burden for that many patients. For drugs like PCSK9, going the specialty route will require major changes to today's distribution and payment models.

¹ These five themes are by no means the end of the story. Within each therapeutic area, there is a unique therapy pipeline that will affect treatment, competitive positioning, and reimbursement. And both reimbursement and channel strategy are being heavily affected by the growth of 340B contract pharmacies, a topic too complex to be addressed in passing here.

² According to the Pharmaceutical Care Management organization. See: <http://www.managedcaremag.com/archives/0910/0910.medmgmt.html>

³ <http://healthaffairs.org/blog/2015/02/17/in-the-debate-about-cost-and-efficacy-pcsk9-inhibitors-may-be-the-biggest-challenge-yet/>

⁴ <http://www.cnn.com/2015/08/06/cholesterol-drug-cost-worries-linger-even-after-spending-report.html>

The definition of the specialty channel is also in flux. As Adam Fein, CEO of Drug Channels Institute, has emphasized, there's no formal regulatory definition of a specialty pharmacy (SP).⁵ Positioning oneself as one is a business decision made by the pharmacy. As a result, everyone is getting into the game: retail drugstores, pharmacy benefit managers (PBMs), health plans, wholesalers, and providers (e.g., physician practices, hospitals, health systems) are all setting up their own SPs. The big players are losing share while independent SPs, like Diplomat Pharmacy, are growing quickly.⁶ In part, this growth results from everyone wanting to cash in on a growing industry. But in the case of hospitals, which will face penalties for readmissions, there's a financial incentive to keep a close eye on patients and ensure education and adherence.

The changing definition of specialty isn't merely a semantic question. Successfully delivering a specialty drug to a patient requires many more hurdles than a typical therapy, and without a standard definition of specialty, doctors don't necessarily know when their patients will need to jump through all the hoops (and thus provide all the requisite patient information along with the prescription).

The focused expertise of an SP in this fast-evolving marketplace will enable them to create tremendous value. So how do pharmacies join in and become successful? As we'll explore in greater detail below, far more demands are made on SPs than on traditional pharmacies. To win, an SP will likely need to play one of two games: the manufacturer's game of top-flight customer service (including personalized service to best ensure access, adherence, and outcomes) or the payers' low-price game.

Why these will be the two dominant strategies will be the topic of the next two sections.

2. The need for manufacturers to design the right channel strategy

A channel strategy is a manufacturer's plan to get its therapy through the complex distribution and disbursement system into the hands of the end patient (or for physician-administered therapies, to their provider). Traditionally, the optimal channel strategy was to get the product into as many channels as possible to ensure the greatest availability and convenience for patients. This is no longer the case, however, and manufacturers are increasingly adopting limited networks.

With so many specialty pharmacies coming to market, manufacturers can set a high bar for what they expect from their partners. But what are manufacturers looking for in a specialty pharmacy?

It's not enough to hand over a vial and ask if the patient has any questions. Diplomat Pharmacy, the largest independent SP, lists the services they provide and it indicates the complexity of specialty disbursement: prior authorization assistance; personalized refill reminders; data systems for tracking and reporting adherence; drug storage and handling; risk evaluation and mitigation strategy (REMS) execution; 24/7/365 patient support;

⁵ <http://www.drugchannels.net/2013/02/defining-specialty-pharmacy.html>

⁶ This growth trend in specialty has recently been explored by *The New York Times* (http://www.nytimes.com/2015/07/16/business/specialty-pharmacies-proliferate-along-with-questions.html?_r=0) and by blogger Adam Fein (<http://www.drugchannels.net/2015/05/specialty-pharmacys-bright-but-complex.html>). Diplomat Pharmacy was also recently profiled by *Fortune* (<http://fortune.com/2014/10/17/diplomat-pharmacy-flint-michigan/>).

intensive patient counseling; access to a large patient population; care coordination among providers; benefit investigation; patient onboarding; financial assistance support (e.g., helping patients navigate 501c3 financial support and co-pay cards); and ensuring continuity of care throughout the patient journey.⁷ Some therapies also require cold chain support and complex distribution. In some cases manufacturers are even paying a service fee for some of these activities, especially around data collection.

Doctors are not always familiar with the complexities patients face trying to successfully fill and receive their orders, nor with whether their patients are taking their meds as prescribed. Manufacturers are relying on the SP for support with both.

Both manufacturers and pharmacies have an incentive to make sure no patient gets left behind. Given the value of each patient, they can't afford not to. The SP plays a crucial role in making sure the patient gets therapy in the first place (whether through prior authorization or benefits investigation support); ensuring patients are adhering to their regime; not down-dosing for financial reasons (i.e., taking less than the prescribed amount of medicine to draw out time on therapy); and helping patients ensure they're selecting the right benefits plan for their needs to reduce the financial burden of therapy.

Certain therapies require a widespread retail distribution given patient demand; for others, a smaller network that will provide white-glove treatment makes more sense. Imbruvica, for example, launched primarily in smaller SPs.⁸

On a side note, drugs for orphan and ultra-orphan diseases require special support. Widespread retail distribution of the therapy doesn't make financial sense, but relying solely on mail-order support increases the likelihood that patients receive insufficient or even misinformation. A good specialty pharmacy will connect rare disease patients to the advocacy groups who can provide the best network of support.

By not pursuing the right channel strategy, manufacturers may leave billions on the table. Worse still, patients may not get the optimal outcomes that the therapies can provide, thus reducing these therapies' value. As such, the right channel strategy isn't merely a nice-to-have: payers are going to demand it.

3. The continuing power of payers—and why that will accelerate trends toward value-based healthcare

A manufacturer can design a channel strategy, but the payer's channel strategy may override it. Payers will often have preferred networks limited to a few channel partners with whom they have relationships. Often, payers will have their own internal specialty pharmacy that they will prefer to use.

Ultimately, payers are looking out for their own interests in trying to control distribution, and they want to feel they are getting value for what they are paying for (value here is defined as patient outcomes as a function of cost). Given the high cost of specialty medications, manufacturers will have few patients on therapy if they fail to get payer support, and the burden is therefore on them to prove the value of their channel strategy to payers.

⁷ www.diplomat.is

⁸ <http://www.specialtypharmajournal.com/medical-news/business-news/4528-janssen-and-pharmacyclics-select-five-specialty-pharmacy-partners-to-distribute-imbruvica>

So what leverage do manufacturers have to convince payers not to intrude on their (the manufacturers') preferred channel strategy? Manufacturers need to convince payers that they're being penny-wise, pound-foolish to interfere in this aspect of the patient journey. While the introduction of a retail middle man may reduce short-term profitability, there's a strong case to be made that the hands-on service provided by retail SPs will have an even greater long-term impact on values by improving adherence and outcomes.

How can manufacturers and SPs collaborate to improve and demonstrate outcomes?

- Proper onboarding and education to ensure proper compliance with the prescription
- Regular monitoring and outreach to ensure patients are taking their drugs at the right cadence (in some cases both onboarding and outreach may require an in-person visit from a nurse to the patient's home)
- Quickly identifying discontinuation and intervening to determine the cause to make sure patients return to adherence (especially important in a condition like Hepatitis C, where a 12-week therapy at \$100,000 can cure the disease, but where an early discontinuation will mean the therapy was in vain)
- Making the case to payers about the advantage of an earlier start to therapy from a total cost perspective may end up benefiting all stakeholders: patients, payers, pharmacies, and manufacturers

Payers may be getting the message. Slalom has seen examples of partnerships between payers and SPs where the latter (and its patients) could avoid burdensome prior authorizations in exchange for opting-in to surveys where patients self-reported the effect the therapy was having. This initiative is especially useful for therapies where the benefit is quite impactful for some patients, but hardly at all for others (for reasons hard to predict in advance). Patients benefit from avoiding the bureaucratic hurdles payers usually erect. Payers benefit because they can quickly identify where an expensive therapy isn't working and suggest to the providers that they may want to consider an alternative.

Although all these practices are primarily motivated by the payers' desire to limit their own costs, they are ultimately aligned with the general industry trend toward value-based health care. Especially in the post-ACA world, where patients will continually be shouldering an ever-greater portion of their own healthcare costs, patients will benefit when stakeholders are aligned on improving the total value of health care. Specialty is a driving force in this trend, not only because of the cost of the therapies, but because of the abundance of data being tracked.

4. The preeminence of data, and the need for a data strategy

To convince manufacturers that a therapy is delivering value worth paying for, rigorous evidence is required. Getting data is not the problem: a regular practice of SPs is to collect patient data that they send or sell back to manufacturers. The problem is *too much* data.

A health system administrator recently told Slalom, "we have so much data it's as if we have our own internal IMS." A manufacturer of a rare disease therapy told us that "the data coming in has been almost overwhelming." Another has said, "The SP will sell you whatever and however much data you want. If you're not prepared to use it, you're paying for something you don't need. You need a data strategy."

The first step toward building a data strategy is building the capabilities to manage, analyze, and ultimately visualize the data. Complicating this effort is that electronic health

records (complex in their own right, given the current state of IT system interoperability) generally don't include Rx claim filings information. This makes it hard to coordinate all stakeholders.

To help bridge this gap, companies like Prometrics⁹ have stepped in to help manufacturers by functioning as an intermediary between stakeholders and de-identifying personal health information. Highlighting the value of actionable data, companies like Prometrics demand accurate delivery of data within days. The value of accurate data, and the growing competition among SPs to join limited networks, allows them to make such demands. An SP has no choice but to play the data game if it wants to be included in manufacturers' networks.

How will best-in-class manufacturers derive value once they've received and organized their data? A well-designed data strategy would allow them to know:

- What are the characteristics of adherent patients and of those who drop? Are there certain patients to prioritize for engagement efforts?
- What engagement activities most successfully keep patients adherent? What services do patients want and need?
- How do adherence rates and cure rates vary by SP?
- What outcomes trends can we identify to payers? For whom is our therapy delivering greatest value? Is there a patient segmentation we can perform to highlight for whom our therapy should be a first-line treatment?

A gold standard data system needs tracking that resembles FedEx's. Where is every vial today? Where are all my patients today? Are they being adherent? Where do I need to intervene?

That quality of data sounds like an analytics geek's dream. But how will patients respond to hearing that they're being treated like a FedEx package?

5. The focus on the patient journey

The "patient journey" is top of mind for our specialty pharma clients. The most successful manufacturers never lose sight of the fact that beyond the prior authorizations, benefits investigations, gross-to-net ratios, and data tracking, there's a human being—one who just learned he has cancer, or whose child has cystic fibrosis, or who has an orphan disease that her doctor has never encountered before.

The furthest thing from these patients' minds when they hear the news is how to navigate getting a prior authorization. Many of these patients are looking for a support network: for care, for information, and for guidance on where to go from here. This is especially true in rare diseases, where the doctor or pharmacist with whom the patient has previously had a relationship may no longer be able to provide the necessary assistance. This need for support is why the white-glove treatment offered by smaller independent SPs will likely keep attracting patients. While it's not realistic to think that the bureaucracy surrounding specialty will simply go away, SPs, both on their own and in collaboration with providers, will win when they help patients cut through the red tape.

The increased focus on patient journey will mean that healthcare in the United States will gradually shift from the traditional model of many individual points of contact with independent healthcare providers to a new model—one that includes a holistic, clinically

⁹ www.prometrics.com

integrated oversight of the health (and health care spend) of the “whole patient.” This shift toward an integrated care models will hopefully help improve time to initiation of therapy, reduced abandonment, the efficacy and efficiency of care, and the overall patient experience.

We are already seeing the emergence of such new models today with the growth of the patient-centered medical home (PCMH) and accountable care organizations (ACOs).¹⁰ These emerging and still-evolving organizations coordinate treatment for the patient across relevant healthcare providers spanning from general wellness and preventative check-ups to the most advanced specialists, ensuring care delivery is aligned and delivered in a timely and efficient way. Pharmacists play a critical role in these care teams and will be key gatekeepers between patients and therapies. More than independent physicians, these PCMH- or ACO-aligned physicians and pharmacists will be concerned with long-term outcomes—and value—for patients.

The days of sales reps winning over physicians with golf trips and swag are long over. As the care model shifts and providers become more “whole patient” focused, manufacturers offering expensive specialty therapies will need to be able to defend the value of their therapies with robust data presented in a clear and compelling fashion to key decision makers. This is not a capability that the marketing teams of all life sciences companies have today, but those who don’t develop it will be left behind by those who do.

The focus on the journey of the “whole patient” also has important implications for payers: fragmenting patients’ care among a set of independent providers and pharmacies who happen to have privileged relationships with the payer may look at first like a cost-savings measure, but in the long run, may mean a lower cure rate (or faster disease progression) and therefore greater medical costs. In the long run, the payer is likely better off aligning with the interests of clinically integrated care teams— and sharing in the benefits through value-sharing programs.

How Slalom can help

The above themes are all interconnected, and specialty pharma manufacturers should adapt to them in a unified manner rather than take a siloed approach. As such, they need a partner who can bring a cross-functional set of skills to the table. Slalom offers clients:

- A deep understanding of the complete healthcare value chain, from the life sciences companies through providers, payers, and pharmacy channels, who can be a trusted advisor to inform commercial strategy
- The information management and analytics capabilities to process, visualize, and analyze large amounts of data to identify key trends and inform critical business decisions—as well as build predictive models to forecast and optimize sales and distribution efforts
- The marketing (particularly digital marketing) expertise to deliver a patient experience that creates community, drives adherence, and builds awareness via online communities, interactive apps, and social networks

¹⁰ For a more detailed description of and distinction between these types of organizations, see <https://www.advisory.com/research/care-transformation-center/care-transformation-center-blog/2014/09/deciphering-the-reform-alphabet>

By combining business advisory services with technology enablement, Slalom ensures that the right questions are being asked, the right tools are being developed, and that stakeholders across functions are speaking to each other and working synergistically.

Conclusion

In specialty pharma, as in the healthcare industry more broadly, care coordination and collaboration, along with a focus on patient outcomes, can help achieve the triple aim of improving the experience of care, improving the health of populations, and reducing the per capita costs of healthcare.

Given the high cost and typically small patient base of specialty medications, life science and pharmacy stakeholders will need to share in the responsibility of ensuring that the right therapy is going to the right patient via the right channel. Only those who can demonstrate they are delivering outcomes and value will emerge as winners in tomorrow's healthcare landscape.

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