The specialty pharmaceutical market is changing rapidly, and it’s growing at approximately twice the rate of the small-molecule-product market. For manufacturers of complex biologics and specialty products, partnering with specialty pharmacies (SPs) can be an important part of their commercial and distribution strategies. To partner effectively, not only must they understand the market changes taking place, they also need to appreciate the requirements of the physicians who administer these products as well as the needs of the patients who receive them.

SPs distribute products, typically to clinics, doctors’ offices and patients, that have complex or special requirements for handling, storage, or administration. Often, these products are designed to treat serious or chronic diseases such as cancer, HIV, and rheumatoid arthritis. SPs are in a unique position to provide services and support to patients while capturing data for payers, manufacturers, and others. As a result, they often provide a number of additional but related services and programs to patients, physicians, and manufacturers.

For complex products, SPs serve as the backbone of manufacturers’ distribution networks, and they can be very important to their commercial performance. It should be obvious, then, that companies marketing such products should take a measured and systematic approach to developing their strategies for working with SPs. In today’s environment, failure to do so can adversely affect a product’s commercial prospects.

The challenge is that the environment has been changing and becoming more complex, making it increasingly more complicated for drug companies to develop effective SP strategies. This article will outline some of the changes that have taken place, describe some ongoing trends and their implications for manufacturers, and outline a framework that manufacturers can use to develop their optimal SP strategies.

**Key market changes**

As the SP market continues to grow at a 20%+ annual rate, driven by both the number and cost of new specialty product introductions, it has attracted the attention of managed care and affixed itself to the radar screen of many leading health plans. While the projected overall spend on specialty products in the US healthcare market remains less than that of traditional products—26%, or $73 billion, of a $283-billion market—the growth in the specialty product market has required health plans to re-evaluate their current approach to managing these agents. Healthcare spending in the top 10 specialty therapeutic areas totals $54.6 billion (see Table 1).

Moreover, further examination of specialty products by health plans and other healthcare intermediaries (e.g., distributors, pharmacy benefit managers, retail pharmacy) has contributed to several recent and notable trends, including market consolidation. These trends have created various business partnerships that facilitate the introduction of new value-added services.

**Specialty pharmacy consolidation**

The market has evolved through acquisitions and consolidation, resulting in five key SP business types (see Table 2):

- Pure-play—specialty pharmacies that have maintained a stand-alone business model and that have not been acquired by a pharmacy benefit manager, distributor, retail pharmacy chain, or other healthcare intermediary
- Distributor-affiliated—organizations that are a division or subsidiary of a larger drug distributor parent (e.g., McKesson)
Pharmacy benefit manager (PBM)-affiliated—organizations that are a division or subsidiary of a PBM (e.g., Medco)
Retail-affiliated—organizations that are a division or subsidiary of a retail pharmacy chain (e.g., Walgreens)
Managed care organization (MCO)-affiliated—organizations that are a division or subsidiary of a health plan (e.g., CIGNA-Tel-Drug)

As the number and size of organizations entering the SP market have increased, both the role and presence of pure-play SPs have somewhat diminished. This evolution has made life more complicated for pharmaceutical and biotech companies, requiring them to understand new and varied relationships between SPs and payers, as well as face new options and questions regarding contracting. Each of the SP business types offers manufacturers a different value proposition, which in turn requires a manufacturer to thoroughly understand the needs and requirements of its customers (i.e., physicians, patients, health plans) in order to identify an SP that can adequately address specific customer needs.

**Development of new business models**

Given the entry of new players to this market (e.g., PBMs, MCOs, retail pharmacy), a number of new business models within the SP sector have evolved. These models can involve a complex web of agreements, associations, and networks between SPs, PBMs, payers, and others. Understanding this web can be a challenge for a drug company attempting to optimize its efforts related to SP. It is important to understand the fundamental business drivers of each SP business model (e.g., what is the dominant business and how might it affect the SP component) in order to determine the relative value that these organizations offer. For example, SPs that are part of a health plan, such as CIGNA-Tel-Drug, may approach the management and handling of specialty products from a different perspective from an SP that is part of a PBM, like Accredo.

In the case of an MCO-affiliated SP like CIGNA-Tel-Drug, the organization is well positioned to manage drug utilization—due to health plan core competencies—as one approach to maximizing margins with manufacturers. As in the example of Accredo, the PBM-affiliated SP approach facilitates a broader book of business than SPs that are part of a health plan, akin to the PBM business model, and the potential to secure both rebates and discounts from manufacturers without necessarily managing product utilization. As characterized in these two examples, different SP business models afford manufacturers varying degrees of competitive market access, demanding that manufacturers be diligent in aligning their SP channel-partner strategy with the needs of the brand and its downstream customers—physicians and patients alike.

**Expansion of value-added services**

SPs now offer an expanded array of value-added services, such as patient education and support, adherence and disease management programs, reimbursement assistance, physician education and support, and data products for payers and manufacturers. The majority of these services and programs can be beneficial for patients and manufacturers. However, they can also make it difficult for manufacturers to determine which ones are truly value-added when deciding with which SPs to work, as well as if—or how—to contract with them.

Programs that focus on patient compliance continue to be in demand by specialty product manufacturers. In certain instances, SP providers have been able to demonstrate an improvement in medication adherence rates in conditions such as multiple sclerosis and rheumatoid arthritis when patients were participating in disease management programs.

**Ongoing market dynamics**

The ongoing evolution of the SP market has brought to light a number of consistent themes, which require manufacturers to not only stay abreast of these dynamics, but also systematically evaluate the potential opportunities and implications thereof. SP market consolidation, in conjunction with an increasing focus on SP’s securing preferred MCO status (particularly among the large national health plans), continues to escalate market competition. Accordingly, manufacturers need to thoroughly evaluate their relationships and competitive positioning with their SP partners in order to ensure appropriate distribution reach and payer coverage. The market dynamics highlighted above and further described below are a constant reminder to manufacturers that the SP market playing field is continuing to evolve.

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**Table 2. Examples of leading specialty pharmacy providers**

*Merged in 2007*

<table>
<thead>
<tr>
<th>Business Model</th>
<th>Company</th>
<th>Specialty Business</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pure-Play</td>
<td>Bioscrip</td>
<td>Bioscrip</td>
</tr>
<tr>
<td>Distributor-Affiliated</td>
<td>AmeriSource Bergen Group</td>
<td>AmeriSource Bergen Specialty Pharmacy</td>
</tr>
<tr>
<td></td>
<td>Cardinal</td>
<td>Cardinal Specialty Pharmacy</td>
</tr>
<tr>
<td></td>
<td>McKesson</td>
<td>McKesson Specialty</td>
</tr>
<tr>
<td>PBM-Affiliated</td>
<td>CareMark</td>
<td>CareMark Specialty</td>
</tr>
<tr>
<td></td>
<td>Express Scripts</td>
<td>Curascript/Priority</td>
</tr>
<tr>
<td></td>
<td>Medco</td>
<td>Accredo</td>
</tr>
<tr>
<td>Retail-Affiliated</td>
<td>CVS</td>
<td>ProCare</td>
</tr>
<tr>
<td></td>
<td>Walgreens</td>
<td>Walgreens Specialty Pharmacy</td>
</tr>
<tr>
<td>MCO-Affiliated</td>
<td>Aetna</td>
<td>Aetna Specialty</td>
</tr>
<tr>
<td></td>
<td>CareMark Health Solutions</td>
<td>CIGNA Tel-Drug</td>
</tr>
<tr>
<td></td>
<td>WellPoint</td>
<td>Precision Rx</td>
</tr>
</tbody>
</table>

**Table 3. Sampling of recent specialty pharmacy acquisitions**

<table>
<thead>
<tr>
<th>Company</th>
<th>Acquisition(s)</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>McKesson</td>
<td>Oncology Therapeutics Network</td>
<td>2007</td>
</tr>
<tr>
<td>CareMark</td>
<td>ProCare (CVS), Advance PCS</td>
<td>2007</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2004</td>
</tr>
<tr>
<td>Express Scripts</td>
<td>Priority Health Curascript</td>
<td>2005</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2004</td>
</tr>
<tr>
<td>Medco Health Solutions</td>
<td>Accredo</td>
<td>2004</td>
</tr>
<tr>
<td>Walgreens</td>
<td>Schrafts, CV Medical Solutions, Medmark</td>
<td>2005</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2005</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2005</td>
</tr>
</tbody>
</table>

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Continued consolidation

As consolidation continues, leading SPs—regardless of any affiliation—are working aggressively to secure preferred distributor arrangements with leading MCOs, as well as offer them additional services. As time goes on, manufacturers, in turn, may need to maintain relationships with a variety of key SPs in order to develop or maintain strong relationships with key MCOs, because ultimately these relationships are critical to commercial success.

Due to consolidation, some MCOs are now establishing preferred distributor arrangements with two to four SPs. These network arrangements could encourage SPs to more closely align their plans and services with the needs of their MCO clients rather than manufacturers.

Continued integration may bring some SPs closer to the drug utilization risk being managed by their parent organizations and could increase their participation in utilization management efforts. This could make access and reimbursement more challenging for manufacturers.

SP strategy framework

As mentioned earlier, in order to develop an SP distribution strategy, it is essential that a manufacturer thoroughly and systematically evaluate the needs and requirements of its brand or portfolio, including those of physicians and patients, so that it can identify SPs with the requisite capabilities to meet these needs. Specifically, the brand team members, in conjunction with their colleagues in Trade and Managed Markets, need to do the following:

- Identify objectives of SP strategy
- Address key questions
- Identify and select SP(s)
- Develop relationship(s)
- Identify objectives

When developing a specialty pharmacy strategy, decision makers within a pharmaceutical or biotech company must collect information on current SP provider performance (e.g., fulfillment, compliance/adherence) and service offerings (e.g., patient education, compliance/persistence programs, reimbursement support) and assess it in accordance with their brands’ requirements in order to make informed decisions regarding the following:

- How many SP partners they need
- Which specific SP partners they need
- How to structure relationships with their SP partner(s) (e.g., exclusive, limited access network, open access)

Table 4. A sample performance evaluation grid. *Using a 1-to-5 scale where 1=poor, 3=average, and 5=excellent

<table>
<thead>
<tr>
<th>Measure Type</th>
<th>Measure</th>
<th>Definition</th>
<th>Baseline</th>
<th>Target</th>
<th>Actual Performance</th>
<th>Performance Rating*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quantitative</td>
<td>Fulfillment</td>
<td>Time to fill</td>
<td>12 days</td>
<td>8 days</td>
<td>10 days</td>
<td>4</td>
</tr>
<tr>
<td>Qualitative</td>
<td>Working Relationship</td>
<td>Issues and services</td>
<td>3.0</td>
<td>4.0</td>
<td>4.0</td>
<td>5</td>
</tr>
<tr>
<td>Score</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

Address key questions

Decision makers must address a number of questions. Answering those questions will take some work, but it will help to guide and advance the strategy development process:

- How broad of a distribution network do we need (i.e., closed or open)? For example, closed or limited distribution networks are useful for organizations with smaller account management teams, as this model minimizes the management of product inventory requirements while affording some cost savings and providing reasonably good access to patients.
- What services will we require (patient support, adherence programs, reimbursement support)? For example, patient self-administered products have needs different from physician-administered products (e.g., patient education, delivery reach) and a brand team needs to incorporate such requirements into its SP evaluation process.
- How critical is it that our SP partner(s) have specific expertise in our therapeutic area?
- What distribution model is most appropriate for our product (buy-and-bill, direct-to-patient)? For example, brand teams with oncology products have traditionally favored a buy-and-bill model given the physician-administration component. However, as the government and health plans continue to evaluate their approach to reimbursing specialty products (e.g., average sales price, medical vs. pharmacy benefit), manufacturers will need to closely evaluate their distribution model decisions in conjunction with health plan reimbursement and patient and physician requirements.
- How are current trends likely to affect our assessment and decision-making process?

Identify and select SPs

After gaining some idea of the level of coverage needed and the services required, the team should identify and collect information on all SPs that might fit its needs. This can involve three components:

- Attribute analysis – Identify fundamental attributes such as whether or not a specific SP has therapeutic area expertise, the ability to offer specific services, or relationships with MCOs.
- Scoring system – For each attribute, determine its relative importance and assign a weight to it. Score each attribute at each SP, and then apply weights. Arrange at a weighted score for each attribute at each SP, as well as an overall score for each SP itself.

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Selection and prioritization – List the top-scoring SPs and prioritize them based on their scores and on other, more subjective measures. In other words, prioritize them based on strategic fit.

Develop relationships
In this stage, decision makers must determine if it makes sense to contract with various SPs. To do this, the manufacturer must:

• Identify pros and cons of contracting
• Model likely impacts of potential contracting scenarios
• Decide on contracting strategy or strategies
• Determine what performance metrics are critical to success and define how to measure them
• Incorporate metrics and measurement methods into any contracting strategy

Case example
The case example outlined below characterizes many of these key SP activities and brings into context the real-world application of systematically developing a strategy to optimize a manufacturer’s approach to partnering and driving value from such a business partnership.

Decision makers at a pharmaceutical company needed a way to objectively monitor the performance of their specialty pharmacy partners in order to better manage their contracts and get the most out of the fees and rebate dollars paid to specialty pharmacies. The organization has several in-line specialty products marketed in extremely competitive therapeutic areas and was interested in assessing potential approaches to improve SP partner performance and, in the process, generate appropriate product demand and fulfillment opportunities.

The company conducted an evaluation of its current SP partners to determine which providers were capable of and interested in participating in a more progressive approach to evaluating each partner’s overall performance. After identifying a short-list of key SPs that had the necessary service offerings and level of interest in working with the manufacturer, the company developed an array of quantitative and qualitative metrics for measuring the performance of specialty pharmacy partners (e.g., time to fill).

These measures became the basis for creating a pay-for-performance (P4P) system, or SP scorecard, to effectively hold its partners accountable for attaining certain performance levels. Each performance measure had various attainment thresholds corresponding with an agreed-upon rebate level (i.e., number of basis points). Accordingly, SPs that were more effective in meeting and exceeding these performance measures stood to reap the benefits of greater rebates than those SPs that did not perform as well.

The pharmaceutical company’s final step in developing its SP strategy was designing a comprehensive process for monitoring the selected SP providers’ performance on an ongoing basis to ensure that the SPs met or exceeded their performance commitments. This objective performance evaluation measurement of its SP partners allowed the manufacturer to get the most value for the contracting dollars spent in that channel.

Sustainable business
Given the dramatic growth in the SP market and the ongoing consolidation and integration among these providers, a number of SP business models have emerged. But regardless of the particular SP business type, not all of the SPs provide manufacturers with the same service offerings. Therefore, it is crucial that manufacturers thoroughly evaluate the specific needs of their brands, along with the needs of key physician specialties and patients who use their brands. It is also important that manufacturers develop performance measurement tools that appropriately and fairly reward performance in order to foster productive and sustainable business relationships with SPs. Ultimately, such an approach will help manufacturers ensure that the SP providers and distributors they select ultimately meet the needs of their organization and optimize product distribution and utilization strategies and tactics. PC

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