Emerging Trends in the Specialty Drug Industry
Specialty drugs have revolutionized medicine in the last two decades, helping improve survival and quality of life for untold numbers of patients with chronic diseases. Only a handful of specialty drugs were available in the mid-90s, but since then, the marketplace has received a regular injection of new agents in recent years. While in 2016, only 22 new drugs were approved by the U.S. Food and Drug Administration—down about 50 percent from 2014 and 2015—approximately half of the new approvals are considered specialty pharmaceuticals.1

While there is no universally accepted definition, specialty drugs are generally defined as having one or more of the following characteristics:2
- Complex to manufacture and store
- Difficult to administer, often coming in injectable or infusible formulations (although oral specialty drugs are becoming more prevalent)
- High in cost, both in total and per-patient cost
- Challenging for patients to take without ongoing clinical support

Initially, specialty drugs were used exclusively to treat chronic conditions such as cancer, rheumatoid arthritis, and multiple sclerosis, but in the last few years, their use has expanded to touch additional disease states (SEE TABLE 1).

According to data from IMS Health, specialty drugs accounted for 36 percent of total drug spending in the United States in 2015, or approximately $155 billion of the $428 billion spent annually on medicines. In just 3 years, the amount spent on specialty drugs has nearly doubled.3 Spending for specialty drugs grew by 23 percent between 2014 and 2015, compared to growth of 7.8 percent for traditional medicines.

And its growth is not expected to slow down anytime soon. By 2018, specialty drugs are expected to account for half of the total drug spend in the United States. Current estimates indicate that annual spending on specialty drugs could reach $400 billion by 2020.3

Clearly, the use of and spend on specialty drugs in the United States appears to be on a fast track with little expectation of slowing down. Of course, the benefits of specialty medicines for patients are significant and should not be understated. However, their explosion in growth has forced payers and providers to develop strategies to help mitigate overall costs and reduce waste.

TABLE 1
Disease States that Tend to be Managed Within Specialty Pharmacies

<table>
<thead>
<tr>
<th>Disease State</th>
<th>Specialty Pharmacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer</td>
<td>HIV/AIDS</td>
</tr>
<tr>
<td>Crohn’s Disease</td>
<td>Immune Disorders</td>
</tr>
<tr>
<td>Gaucher’s Disease</td>
<td>Infertility</td>
</tr>
<tr>
<td>Growth Hormone Deficiency</td>
<td>Multiple Sclerosis</td>
</tr>
<tr>
<td>Hemophilia</td>
<td>Pulmonary Hypertension</td>
</tr>
<tr>
<td>Hepatitis C</td>
<td>Rheumatoid Arthritis</td>
</tr>
</tbody>
</table>

TABLE 2
Specialty Pharmacy Mergers and Acquisitions—2016

<table>
<thead>
<tr>
<th>Acquiring Entity</th>
<th>Acquired Specialty Pharmacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACON Investments and Triton Pacific Capital Partners</td>
<td>BioMatrix Specialty Pharmacy</td>
</tr>
<tr>
<td>Apothecary by Design</td>
<td>Village Fertility Pharmacy</td>
</tr>
<tr>
<td>Apothecary by Design</td>
<td>Healy Pharmacy</td>
</tr>
<tr>
<td>Avella Specialty Pharmacy</td>
<td>Advanced Pharma Inc.</td>
</tr>
<tr>
<td>Avella Specialty Pharmacy</td>
<td>Oncology Plus</td>
</tr>
<tr>
<td>Diplomat Pharmacy</td>
<td>TNH Advanced Specialty Pharmacy</td>
</tr>
<tr>
<td>Kroger</td>
<td>ModernHEALTH</td>
</tr>
<tr>
<td>Maxor National Pharmacy Services</td>
<td>Pharmaceutical Specialties</td>
</tr>
<tr>
<td>McKesson</td>
<td>Biologics, Inc.</td>
</tr>
<tr>
<td>Premier</td>
<td>Acro Pharmaceutical Services</td>
</tr>
<tr>
<td>Premier</td>
<td>Community Pharmaceutical Services</td>
</tr>
<tr>
<td>ReCept Pharmacy</td>
<td>F&amp;M Specialty Pharmacy</td>
</tr>
</tbody>
</table>

The Role of Specialty Pharmacies

As specialty drugs have gained a stronger foothold in the United States, the creation and utilization of specialty pharmacies has also expanded. Specialty pharmacies are designed specifically to manage the necessary handling, storage, and distribution of complex therapy drugs that require high-touch patient management. While initially often opened independently, many specialty pharmacies have been acquired by traditional chain pharmacies and investment firms in recent years. TABLE 2 includes a snapshot of specialty pharmacy mergers and acquisitions in 2016.4

To properly serve their patients, pharmacists working in the outpatient setting—whether or not they are directly involved in the distribution and management of specialty drugs—must be well
versed in the breadth of medications available to treat chronic diseases and strategies that have been developed to improve medication adherence. Because of the complex therapy associated with specialty drugs, patient adherence to filling prescriptions and properly administering their medications is vital. A number of specialty pharmacies have programs in place to help monitor refills and intercept patients before nonadherence becomes a significant issue. Current strategies include medication synchronization programs where patients pick up all of their prescribed medication on the same date each month, periodic monitoring and coaching calls from a clinical team, and in-store screening for medication-related side effects.

One pharmacy chain recently reported adherence rates of greater than 90 percent across four key disease states where specialty medications are most prevalent—immunology, HIV, cancer, and hepatitis C—demonstrating the impact that targeted education and monitoring can have in the specialty setting.3

**Specialty Drugs in Oncology: Emerging Trends**

Of all the chronic conditions covered by specialty pharmacies, cancer drugs take up the largest percentage and are perhaps the most complex for pharmacists to manage. In 2017, an estimated 1.7 million new cancer cases are expected to be diagnosed in the United States, along with approximately 600,000 cancer-related deaths.5

What makes the management of cancer patients particularly challenging for pharmacists is the breadth of drugs available and the various combinations prescribed for many patients. Additionally, specialty pharmacies must have available a broad range of clinical capabilities such as:

- Patient education and intensive disease state counseling
- Support and monitoring for side effects, safety, and efficacy
- Medication Therapy Management (MTM), case management, and adherence programs

Current cancer-related specialty medications include self-injectables, oral oncolytics, parenteral chemotherapy, and biologic agents. There are many nuances related to dosage, adverse events, and drug-drug interactions within this armamentarium, making it challenging for even the most informed patients to keep on top of their drug therapy—and emphasizing the role of the pharmacist as a key component of the clinical care team.

One of the hottest current trends in oncology is immunotherapy, which uses medications to boost or trigger a patient’s own immune system to attack cancer cells. Immunotherapy drugs include monoclonal antibodies, cancer vaccines, and, one of the most exciting recent options, checkpoint inhibitors.

Checkpoint inhibitors are unique in that they work by basically “taking the brakes” off the immune system, helping it recognize and attack cancer cells. Until last year, Yervoy® (ipilimumab; FDA approved to treat melanoma) was the only approved checkpoint inhibitor. However, numerous recent approvals have come in within the last 12 months, including Keytruda® (pembrolizumab; lung cancer), Opdivo® (nivolumab; melanoma), Tecentriq (atezolizumab; lung cancer), Bavencio® (avelumab; Merkel cell carcinoma) and Imfinzi™ (durvalumab; urothelial cancer), with several more checkpoint inhibitors in late-stage clinical trials.

Pharmacists must play a key role in educating patients who are prescribed immunotherapy. Because of specific autoimmune toxicities related to their use, patients should be educated about the possibility of specific adverse events such as gastrointestinal reactions, skin rashes, and lymph related reactions, and be instructed to report signs of any of these events as soon as possible. Typically, these adverse reactions can be treated and reversed with prompt intervention.

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**FIGURE 1**

**Specialty Medication Utilization Forecast**

The specialty drug market is forecast to continue to be dominated by medications that treat cancer, multiple sclerosis, HIV, and autoimmune diseases.

What About Biosimilars?
While slow to grasp a foothold in the United States, biosimilars are another emerging area in cancer care for pharmacists to stay abreast of. As of May 1, 2017, there were only four FDA-approved biosimilars, only one of which—Zarxio® (filgrastim-sndz), a biosimilar of Neupogen® used to deal with chemotherapy-related side effects—is applicable to cancer patients (the other three approved biosimilars are used primarily in rheumatology practices). However, with the FDA’s long-awaited publication of draft guidance in January 2017 detailing the agency’s expectations for demonstrating biosimilar interchangeability, there is expected to be significant growth in coming years.

Biosimilars are defined as agents that are highly similar to, but not identical, to a licensed biologic agent. According to one estimate, the introduction of biosimilars has the potential to save the U.S. healthcare system $44.2 billion over the next 10 years. However, the true savings will depend on how well these products are accepted by physicians and patients, their safety, and other factors.

Payer reimbursement for biosimilars remains controversial. The 2016, the Centers for Medicare & Medicaid Services (CMS) issued a payment rule that groups all biosimilars sharing the same reference product into a single billing and payment code, or J-code. Under this policy, all biosimilars that share a J-code will be reimbursed based on a volume-weighted average sales price (ASP). The reference product is not factored into the volume-weighted ASP of the corresponding biosimilars. In making this rule, CMS followed the model for reimbursement of multi-source generic drugs despite the fact that biosimilars are single-source drugs and fundamentally different from generics. Since the four current FDA-approved biosimilars each match to different reference biologics, this is not yet a major issue, but it is expected to be a source of future contention.

Specific to oncology, there are three biosimilars in the near-term pipeline:
- Biosimilar to Herceptin® (trastuzumab), used in breast and gastric cancers
- Biosimilar to Avastin® (bevacizumab), used in a variety of cancers, including lung and colorectal cancers
- Biosimilar to Rituxan® (rituximab), used in non-Hodgkin’s lymphoma as well as rheumatoid arthritis

The biosimilar marketplace is still evolving. While the FDA offered a “interchangeable designation” in its recent draft guidance that would allow a pharmacist to substitute a biosimilar for a biologic without a physician’s specific permission, prescribing and dispensing regulations are currently set at the state level and will require significant state regulatory action to sort out the final role of the pharmacist.

Summary
The specialty pharmacy marketplace continues to grow by leaps and bounds, with further expansion expected in the near future. As providers and payors adapt to changes, pharmacists will be expected to play a key role in helping with care coordination and adherence programs. Remaining abreast of trends in specialty drug research, immunotherapy and biosimilars will be vital to serving the needs of patients.

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