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Dear Colleague,

In 2008, specialty pharmacy was the fastest growing sector of healthcare, and with hundreds of medications in the pipeline, we expect it to remain so in the years ahead. As such, clinical management programs and cost-containment initiatives have never been more important.

We’ve developed this report to keep you informed about the industry and how our organization is responding to this dynamic market. In it you’ll find key industry statistics, including prevalence data and annual drug spend for key conditions and therapies; solutions for managing costs and improving care; and current trends that are influencing the market.

We are committed to providing unique solutions to our clients and their members, as demonstrated in the case studies within this report. Below is a snapshot of each:

For many years we’ve been providing specialty medications through our community pharmacy network and our central fulfillment pharmacies in an effort to increase access and convenience for our patients. Through our therapy management programs, we’ve been able to prove our ability to effectively manage these patients. In a study of patients with rheumatoid arthritis and multiple sclerosis, we saw a significant increase in medication possession ratio (MPR) for those patients who were actively managed as compared with national average adherence rates, regardless of what fulfillment channel was utilized by the patient.

Our cycle management program for oral chemotherapy is another example of how we’re focused on providing unique, therapy-specific solutions to control costs and improve care. With this program, we’ve improved patients’ persistency rates through close monitoring and enhanced communication with their physicians. In addition, through our monitored dispensing program, we were able to help reduce medication waste associated with early discontinuation of therapy and dose reductions.

Research conducted with our hemophilia patients demonstrates the impact our infusion nurses have had on hospital admissions as compared to agency nurses. Additionally, through our assay cost management practices, we can potentially save our clients almost $50,000 a year for one patient.

I hope you’ll find this report to be a valuable resource. As healthcare reform begins to take shape, we stand ready to work with you to continue reducing costs while delivering high-quality care and service to your organization and your members.

Michael A. Nameth, RPh, MBA
Executive Vice President,
Specialty Pharmacy
Walgreens Health Services
National Specialty Pharmacy Expenditure Trends  Specialty drugs are used in the treatment of chronic and complex conditions that have a dramatic effect on quality of life, such as rheumatoid arthritis (RA) and multiple sclerosis (MS), and conditions that are life-threatening, such as HIV/AIDS and cancer. These drugs can be a lifeline to patients whose lives have seemingly been irrevocably changed by a diagnosis—and the medications are often perceived as an essential treatment modality by physicians. The high cost of the medications and the duration of therapy are just two of the reasons why expenditures for specialty drugs increased faster than any other sector of healthcare in 2008 and—with growth forecasted at 18.1% in 2009—are projected to continue outpacing growth in other areas of healthcare. The pipeline for specialty drugs is robust, with more than 600 specialty medications currently under development for a market expected to top $98 billion by 2011, despite an economic downturn affecting the United States.

Top 10 U.S. Therapeutic Classes and Prescription Drugs  According to IMS Health, three specialty therapeutic classes were among the top 10 therapeutic classes by U.S. sales in 2008 (see Table 1). The specialty classes, which ranked seventh, eighth and ninth, respectively, include certain cancer drugs known as antineoplastic monoclonal antibodies; erythropoietins, which stimulate red blood cell production in the bone marrow; and biologic response modifiers (BRMs), which are used in the treatment of conditions such as RA, psoriasis, psoriatic arthritis and Crohn’s disease. BRM sales rose 131% between 2004 and 2008, increasing from $2.6 billion to $6.0 billion. This growth is attributable in part to new indications that expand BRM use. For example, Humira® received a new indication in 2007 for the treatment of moderately to severely active Crohn’s disease in adults.
### Table 1: Top 10 Therapeutic Classes by U.S. Sales (in Billions of Dollars)⁴

<table>
<thead>
<tr>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Antipsychotics</td>
<td>14.6</td>
<td>13.1</td>
<td>11.7</td>
<td>10.5</td>
<td>9.6</td>
</tr>
<tr>
<td>2</td>
<td>Lipid regulators</td>
<td>14.5</td>
<td>16.4</td>
<td>19.9</td>
<td>18.3</td>
<td>16.7</td>
</tr>
<tr>
<td>3</td>
<td>Proton pump inhibitors</td>
<td>13.9</td>
<td>14.2</td>
<td>13.7</td>
<td>13.0</td>
<td>12.8</td>
</tr>
<tr>
<td>4</td>
<td>Seizure disorders</td>
<td>11.3</td>
<td>10.2</td>
<td>8.9</td>
<td>8.0</td>
<td>8.5</td>
</tr>
<tr>
<td>5</td>
<td>Antidepressants</td>
<td>9.6</td>
<td>9.4</td>
<td>10.7</td>
<td>10.3</td>
<td>11.2</td>
</tr>
<tr>
<td>6</td>
<td>Angiotensin II antagonists</td>
<td>7.5</td>
<td>6.6</td>
<td>5.8</td>
<td>5.1</td>
<td>4.5</td>
</tr>
<tr>
<td>7</td>
<td>Antineoplastic monoclonal antibodies</td>
<td>7.5</td>
<td>6.8</td>
<td>5.8</td>
<td>4.0</td>
<td>2.6</td>
</tr>
<tr>
<td>8</td>
<td>Erythropoietins</td>
<td>7.2</td>
<td>8.7</td>
<td>10.1</td>
<td>8.7</td>
<td>8.2</td>
</tr>
<tr>
<td>9</td>
<td>Antiarthritics, biologic response modifiers</td>
<td>6.0</td>
<td>5.3</td>
<td>4.4</td>
<td>3.7</td>
<td>2.6</td>
</tr>
<tr>
<td>10</td>
<td>Antiplatelets (oral)</td>
<td>5.3</td>
<td>4.5</td>
<td>4.2</td>
<td>3.8</td>
<td>3.4</td>
</tr>
</tbody>
</table>

⁴ IMS National Sales Perspectives™, IMS Health. 2008.

Table 2 shows the top 10 U.S. pharmaceutical products by sales. Three of the top 10 products in 2008—Enbrel®, Neulasta® and Epogen®—are specialty drugs. Sales of Enbrel, a BRM, increased 70% between 2004 and 2008; Neulasta sales increased 72% during the same period. (Neulasta is prescribed to maintain white blood cell count in some chemotherapy patients.) At $3.1 billion in 2008, Epogen sales remained below their 2006 high of $3.3 billion as safety concerns continued to affect utilization of this drug along with other erythropoietins.³

### Table 2: Top 10 Pharmaceutical Products by U.S. Sales (in Billions of Dollars)⁴

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Lipitor®</td>
<td>7.8</td>
<td>8.1</td>
<td>8.7</td>
<td>8.4</td>
<td>7.8</td>
</tr>
<tr>
<td>2</td>
<td>Nexium®</td>
<td>5.9</td>
<td>5.5</td>
<td>5.2</td>
<td>4.4</td>
<td>3.8</td>
</tr>
<tr>
<td>3</td>
<td>Plavix®</td>
<td>4.9</td>
<td>3.9</td>
<td>3.0</td>
<td>3.5</td>
<td>3.1</td>
</tr>
<tr>
<td>4</td>
<td>Advair Diskus®</td>
<td>4.4</td>
<td>4.3</td>
<td>4.0</td>
<td>3.6</td>
<td>3.0</td>
</tr>
<tr>
<td>5</td>
<td>Seroquel®</td>
<td>3.9</td>
<td>3.5</td>
<td>3.0</td>
<td>2.6</td>
<td>2.1</td>
</tr>
<tr>
<td>6</td>
<td>Singular®</td>
<td>3.5</td>
<td>3.4</td>
<td>3.0</td>
<td>2.5</td>
<td>2.2</td>
</tr>
<tr>
<td>7</td>
<td>Enbrel®</td>
<td>3.4</td>
<td>3.4</td>
<td>3.1</td>
<td>2.8</td>
<td>2.0</td>
</tr>
<tr>
<td>8</td>
<td>Neulasta®</td>
<td>3.1</td>
<td>3.1</td>
<td>2.9</td>
<td>2.3</td>
<td>1.8</td>
</tr>
<tr>
<td>9</td>
<td>Actos®</td>
<td>3.1</td>
<td>2.9</td>
<td>2.6</td>
<td>2.2</td>
<td>2.0</td>
</tr>
<tr>
<td>10</td>
<td>Epogen®</td>
<td>3.1</td>
<td>3.1</td>
<td>3.3</td>
<td>3.0</td>
<td>3.0</td>
</tr>
</tbody>
</table>

⁴ IMS National Sales Perspectives™, IMS Health. 2008.
Specialty Condition Prevalence and Treatment Costs  Specialty drugs treat a wide array of conditions that affect people at every age and stage of life. One of the defining characteristics of specialty drugs is their high cost as compared with traditional medications. Depending on the condition or therapy, the annual cost per patient for specialty drugs can be $150,000 or more, as shown in Table 3.

<table>
<thead>
<tr>
<th>Condition/Therapy</th>
<th>Approximate U.S. Population Affected(^a)</th>
<th>Average Annual Specialty Drug Cost per Patient(^b)</th>
<th>Notable Specialty Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biologic response modifiers</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crohn’s disease:</td>
<td>500,000(^4)</td>
<td>$12,000 to $78,000</td>
<td>Amevive(^®), Cimzia(^®), Enbrel(^®), Humira(^®), Kineret(^®), Orencia(^®), Remicade(^®), Rituxan(^®), Simponi(^TM)</td>
</tr>
<tr>
<td>Psoriasis:</td>
<td>Between 5.8 and 7.5 million(^5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Psoriatic arthritis:</td>
<td>10% to 30% with psoriasis(^6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rheumatoid arthritis:</td>
<td>1.3 million(^7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ulcerative colitis:</td>
<td>500,000(^8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bleeding disorders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hemophilia A:</td>
<td>1 in 5,000 male births(^9)</td>
<td>$150,000+</td>
<td>Advate(^®), Alphanate(^®), BeneFIX(^®), Humate-P(^®), NovoSeven(^®) RT, Xyntha(^TM)</td>
</tr>
<tr>
<td>Hemophilia B:</td>
<td>1 in 25,000 male births(^10)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>von Willebrand disease:</td>
<td>1% to 2% of population(^11)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatitis C</td>
<td>3.2 million chronically infected(^12)</td>
<td>$23,000 (for interferon alone)</td>
<td>Infergen(^®), Pegasys(^®), Peginteron(^TM), ribavirin</td>
</tr>
<tr>
<td></td>
<td></td>
<td>$33,000 (combination therapy with interferon and ribavirin)</td>
<td></td>
</tr>
<tr>
<td>HIV/AIDS</td>
<td>1.1 million(^13)</td>
<td>$26,000</td>
<td>Atripla(^®), Isentress(^®), Kaletra(^®), Norvir(^®), Prezista(^®), Reyataz(^®), Selzentry(^TM), Sustiva(^®), Truvada(^®)</td>
</tr>
<tr>
<td>Infertility</td>
<td>2.1 million females(^14)</td>
<td>$15,000 (based on 3 cycles)</td>
<td>Gleevec(^®), Cetrotide(^®), Follistim(^®) AQ, Ganirelix(^®), Gonad-F(^®), Gonad-F(^®) RFF, human chorionic gonadotropin, Luveris(^®), Menopur(^®), Ovidrel(^®), Reprovel(^®)</td>
</tr>
<tr>
<td>Multiple sclerosis</td>
<td>400,000(^15)</td>
<td>$36,000</td>
<td>Avonex(^®), Betaseron(^®), Copaxone(^®), Rebif(^®), Tysabri(^®)</td>
</tr>
<tr>
<td>Oral chemotherapy</td>
<td>1.4 million new cancer cases per year(^16)</td>
<td>$42,000 to $130,000 Varies by type of cancer</td>
<td>Gleevec(^®), Nexavar(^®), Revlimid(^®), Sprycel(^®), Sutent(^®), Tarceva(^®), Tasigna(^®), Temodar(^®), Thalomid(^®), Tykerb(^®), Xeloda(^®)</td>
</tr>
<tr>
<td>Respiratory syncytial virus</td>
<td>75,000 to 125,000 infants hospitalized per year(^17)</td>
<td>$6,000 to $12,000 Based on variations in weight-based dosing</td>
<td>Synagis(^®)</td>
</tr>
<tr>
<td>Transplant</td>
<td>&gt; 163,000 persons living with a functioning organ transplant(^18)</td>
<td>$16,000</td>
<td>CellCept(^®), Neoral(^®), Prograf(^®), Rapamune(^®)</td>
</tr>
</tbody>
</table>

\(^a\) Approximate U.S. population affected is not intended to represent the number of patients using specialty products listed. Information on population affected was collected from Atlantic Information Services, Inc.; CDC; National Institutes of Health; and the respective disease-related organizations. Results varied widely by sources; conservative numbers are represented here. Prevalence reporting methodologies also varied.

\(^b\) Cost based on average wholesale price (AWP) as of June 2009 for products listed.
Top Seven Classes Drive Walgreens Specialty Spend  Figures 1 and 2 detail company performance from 2007 and 2008. In most cases, the data in these two figures is consistent with that in the industry; however, some variability may exist due to payor contracts, limited-distribution medications and acquisitions. Listed below are factors that contributed to the data reported.

- **HIV/AIDS** – Increased use of antiretrovirals such as Atripla® and Fuzeon®; new medications introduced in the market; increased number of people diagnosed; increased number of routine HIV screenings; and fulfillment of these prescriptions through our community pharmacies, all contributed to sales growth of 21.4%, with this class representing 21.8% of our total sales.

- **BRMs** – Increased medication utilization; more aggressive treatment for those with early stages of RA; expanded indications for existing drugs; and direct-to-consumer advertising grew sales by 16.4% and accounted for 17.7% of sales.

- **Multiple sclerosis** – Factors contributing to the 16.9% increase in sales include double-digit manufacturer price increases and our strategic acquisitions.

- **Oral chemotherapy** – Representing 9.6% of total sales, the market was driven by expanded indications for existing drugs; new drugs introduced into the market; increased utilization due to off-label usage; and an increase in the number of patients receiving long-term treatment.

- **Organ transplant** – An increase in sales of 11.3% positioned this class as our fifth largest segment in overall sales due to the growing number of transplantations performed as a result of higher organ donation rates.

- **Anticoagulants** – The significant increase in sales of 22.2% is directly attributed to the growing number of our community pharmacies where these medications are primarily dispensed.

- **Respiratory syncytial virus** – The noteworthy increase in sales of 12.1% is the result of our 2007 acquisition of OptionCare which significantly increased our penetration into this market.

![Figure 1: Top Walgreens Classes/Conditions by Sales, 2008](image_url)
Below is a list of the medications that are included for each class/condition in Figures 1 and 2. This is important to understand when comparing these figures to data published by other industry sources.

- **Anticoagulants** – Arixtra®, Fragmin®, Innohep®, Lovenox®
- **Biologic response modifiers** – Enbrel®, Humira®, Kineret®, Orecia®, Remicade®
- **Multiple sclerosis** – Avonex®, Betaseron®, Copaxone®, Rebit®, Tysabri®
- **Oral chemotherapy** – Gleevec®, Nexavar®, Revlimid®, Sprycel®, Sutent®, Tabloid®, Tarceva®, Tarapost®, Tasigna®, Temodar®, Thalomid®, Tykerb®, Vesanoid®, Xeloda®, Zolinza®
- **Organ Transplant** – Azasan®, Azathioprine™, CellCept®, Gengraf®, Imuran®, Myfortic®, Neoral®, Prograf®, Rapamune®, Sandimmune®
- **Respiratory syncytial virus** – Synagis®
Reconstructing the Industry Through Expanded Fulfillment Channels  Our unique fulfillment model has made Walgreens a leading national provider of injectable, infused and oral specialty medications. Unlike some specialty pharmacies, which are limited to centralized fulfillment, Walgreens Specialty Pharmacy has offered an extensive community pharmacy network since our inception. Our enhanced pharmacy network now includes community pharmacies; local infusion pharmacies; and outpatient pharmacies located within academic medical centers, community hospitals and medical office buildings. Patients can choose the convenience of one of these local sites or can have medications delivered to their homes through our central fulfillment pharmacies, depending on their insurance coverage. These options facilitate cost-effective care in the most appropriate setting. At every site, we emphasize consistent clinical support and therapy management to raise medication adherence levels and reduce costs.

Alternate Treatment Sites Offer Three Levels of Service  We now offer patients the option of receiving their specialty medications at an alternate treatment site. These cost-effective, convenient locations are an alternative to hospital outpatient departments, physician office settings and home care. Services provided at these facilities vary by location. They include injections and injection training, infusions, line placement and port and catheter care. Three levels of service are available across alternate treatment site locations (see Table 4).
The level of service and treatment location are determined by patient acuity and the complexity of the specific therapy involved. For patients who need specialty infusible and injectable medications administered by healthcare professionals, our network provides a solution tailored to their individual needs.

**Table 4: Alternate Treatment Site Levels of Service**

<table>
<thead>
<tr>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Injections</td>
<td>• Injections</td>
<td>• Injections</td>
</tr>
<tr>
<td>• Injection training for self injectables</td>
<td>• Injection training for self injectables</td>
<td>• Injection training for self injectables</td>
</tr>
<tr>
<td>• Low-complexity, short-duration infusion</td>
<td>• Low-complexity infusion</td>
<td>• Low-complexity infusion</td>
</tr>
<tr>
<td></td>
<td>• Moderate-complexity infusion</td>
<td>• Moderate-complexity infusion</td>
</tr>
<tr>
<td></td>
<td>• Port maintenance</td>
<td>• Port maintenance</td>
</tr>
<tr>
<td>Example therapies: anticoagulants, osteoporosis treatments</td>
<td>Example therapies: antibiotics, BRMs</td>
<td>Example therapies: chemotherapy, certain MS medications</td>
</tr>
</tbody>
</table>

**Connecting Specialty Pharmacy and Home Infusion**

We have an extensive nationwide network of clinicians—more than 800 nurses and 250 pharmacists—who are skilled in the administration of infused therapies in the home setting (see Figure 3). Home treatment is often a comfortable, convenient choice for patients and a cost-effective approach for payors. Savings can amount to tens of thousands of dollars when a patient receives a therapy regimen at home rather than hospital-based care. In addition, our ability to provide and administer home infusion therapies streamlines the process of coordinating home infusion support, helps promote medication adherence and improves patient satisfaction and treatment outcomes.

**Figure 3: Intersection of Specialty Pharmacy and Home Infusion**

- **Specialty Pharmacy**
  - Growth disorders
  - Hepatitis
  - Infertility
  - Multiple sclerosis
- **Specialty Infusion**
  - Oral chemotherapy
  - Psoriasis
  - Respiratory syncytial virus
  - Rheumatoid arthritis
- **Home Infusion**
  - Anti-infectives
  - Enteral nutrition
  - Hydration
  - Inotropics
- **Bleeding disorders**
  - Crohn’s disease
  - Enzyme deficiencies
  - Immune deficiency
  - Multiple sclerosis
- **Oncology**
  - Osteoporosis
  - Psoriasis
  - Pulmonary arterial hypertension
  - Rheumatoid arthritis
- **Multiple sclerosis**
  - Oncology
  - Pain management
  - Parenteral nutrition
Maximizing Stakeholder Benefits  Regardless of delivery channel, our offerings maximize benefits for all our stakeholders—patients, prescribers, payors and pharmaceutical manufacturers (see Table 5).

<table>
<thead>
<tr>
<th>Benefit</th>
<th>Examples</th>
</tr>
</thead>
</table>
| Quality  | • Clinical support and counseling provided by therapy-specific care teams of pharmacists, nurses and patient care coordinators ensure consistent communication with prescribers and patients  
• Individualized treatment plans promote adherence and help minimize or prevent suboptimal responses to therapy  
• Utilization and outcomes reporting that includes longitudinal data, drug safety information and prescription status reports  
• Medication management helps achieve optimal therapy benefits  
• Dedicated account management teams respond to client-specific needs |
| Service  | • Assistance with managing insurance claims and related issues, including prior authorizations, therapy and assay management programs  
• Managing patients through prescription intake, benefits investigation and order fulfillment processes  
• Patient education materials available in English and Spanish  
• Timely communication regarding medication recalls and newly available medications  
• Ability to infuse medications that require administration by a specially trained clinician  
• Ability to transfer patients’ medication fulfillment to our network of community and infusion pharmacies in case of a natural disaster or other type of emergency |
| Access   | • Multiple delivery channels, including central fulfillment and nearly 7,000 community and more than 100 local infusion pharmacies  
• Ability to communicate with nurses and pharmacists 24/7  
• Extensive access to limited-distribution medications  
• Facilitating patient financial assistance through our relationships with not-for-profit organizations and manufacturers |
| Choice   | • Many delivery channels from which to choose—community pharmacies, central fulfillment pharmacies and home infusion pharmacies as well as alternate treatment sites  
• Multiple delivery location options from which to choose—home, workplace, prescriber’s office and other sites, as clinically appropriate  
• Customized benefit design options allow plans to meet their business needs and maximize patient benefits  
• Ability to manage medication/administration costs under the pharmacy benefit, the medical benefit or both |

In the remaining sections of this chapter, case studies, program highlights and a patient profile provide examples of how Walgreens delivers high-quality and cost-effective care across all fulfillment channels.
**Therapy management programs add value and increase adherence**

**Business Challenge**  Many specialty patients do not take their medications as prescribed. Non-adherence to therapy regimens may result in increases in emergency room visits, hospitalizations, disease-related complications and the need for additional medications to treat secondary conditions associated with chronic illnesses. In fact, national statistics report average adherence rates of 63% and 50% for MS and RA, respectively. This demonstrates the need for a higher degree of therapy management to help ensure better patient outcomes and reduce costs associated with nonadherence.

**Solution**  Walgreens Specialty Pharmacy offers therapy management programs designed to increase medication adherence for many specialty drugs and conditions. All therapy management program participants are contacted regularly by our centrally located Care Teams and receive ongoing clinical services and support, including counseling and educational materials. We offer therapy management programs for several chronic conditions, which include MS and RA.

**Results**  A recent study concluded that regardless of fulfillment channel, adherence rates for MS and RA patients receiving our therapy management services are significantly higher than the national averages (see Table 6).

Among our patients who receive their medication through our central fulfillment pharmacies, their medication possession ratio (MPR) was:
- 33 percentage points higher than the national average for MS
- 43 percentage points higher than the national average for RA

Among our patients who receive their medication through our community pharmacies, their MPR was:
- 31 percentage points higher than the national average for MS
- 42 percentage points higher than the national average for RA

This data supports the value of our therapy management programs.

**Benefits**  By increasing MPR, therapy management programs increase adherence, which in turn helps to:
- Decrease emergency room visits, hospitalizations, disease-related complications and associated costs
- Contribute to decreases in relapses and disease progression

**Methodology**  This study examined data from October 2008 through March 2009 for patients diagnosed with MS or RA. Patients were considered managed if they participated in our therapy management program. Patients receiving a fill in the last month of the observation period were included in this analysis.

<table>
<thead>
<tr>
<th>Therapy Management Program Cohort Groups</th>
<th>Number of Patients</th>
<th>Medication Possession Ratio (MPR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multiple sclerosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Managed patients: central fulfillment pharmacies</td>
<td>453</td>
<td>.96</td>
</tr>
<tr>
<td>Managed patients: community pharmacies</td>
<td>266</td>
<td>.94</td>
</tr>
<tr>
<td>Rheumatoid arthritis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Managed patients: central fulfillment pharmacies</td>
<td>588</td>
<td>.93</td>
</tr>
<tr>
<td>Managed patients: community pharmacies</td>
<td>534</td>
<td>.92</td>
</tr>
</tbody>
</table>

*MPR is a common metric used to gauge a patient’s adherence to a well-defined therapeutic drug regimen.*
**Business Challenge**  A month’s supply of oral chemotherapy drugs typically costs thousands of dollars. Often, a portion of these expensive cancer medications may go to waste because a patient who is struggling to cope with medication side effects, among other challenges, doesn’t complete a full month of therapy. Because there is less physician oversight of self-administered oral chemotherapies as compared with intravenous chemotherapies, there may be a delay before a physician is made aware of a patient experiencing medication side effects and the resultant medication nonadherence. Health plans are seeking strategies to help increase patient adherence to oral chemotherapies and reduce medication waste associated with early therapy discontinuation or dose reductions.

**Solution**  The Walgreens Specialty Pharmacy Oral Chemotherapy Cycle Management Program provides optimized clinical management and support to patients who receive certain oral chemotherapy drugs. Patients are contacted at predetermined intervals during their first month of therapy to educate them about their medication and potential side effects, assess for side effects and confirm medication adherence. If an adverse event is noted, our team responds according to established protocols and contacts the physician as necessary.

Because physicians often have concerns about relying on patients to take these medications as prescribed, the program provides support and communication throughout the patient’s medication cycle. At the conclusion of the first month of therapy, the physician receives a report that details the date the patient started therapy, the stop date and cycle (if applicable), adverse reactions or side effects and interventions performed on the patient’s behalf. All program services are based on drug-specific clinical protocols recommended by our Oncology Advisory Board, composed of nationally recognized oncologists.

Our cycle management program includes an optional monitored dispensing component that helps reduce expenses resulting from the medication waste associated with early therapy discontinuation or dose reductions due to side effects. With this option, a partial supply of the month’s medication is initially shipped. A mid-cycle assessment is performed and once it is determined that the patient is tolerating therapy, the remainder of the month’s supply is shipped.

If serious side effects or problems are identified during the mid-cycle assessment, the remainder of the month’s supply is held, thus preventing medication waste and saving payors between $2,000 and $4,000 per prescription. This option offers payors direct cost savings by significantly reducing the expense resulting from medications that go unused. In addition, increased therapy monitoring may help avert incremental healthcare costs associated with adverse events.

**Results**  After one month in the program, 74% of all participants were persistent with their therapy—that is, they were still taking their medications (see Table 7). Of those who were persistent after the first month, 81% were also persistent after the second month. Of these, 88% were persistent after the third month.

The increase in persistency reflects the benefits of access to clinical support between physician office visits. In the first month alone, the total cost of the three drugs for all program participants would have been $2,723,181 without the monitored dispensing option. If all patients had participated in the monitored dispensing option during the first month, the total medication cost would have been $2,385,093. In this example, the monitored dispensing option would yield a savings of $338,088—12.4% of total medication costs. Potential savings continue into the second and third months of the program with medication cost savings of $178,471, or 9.0% of total costs and $84,720, or 5.3% of total costs, respectively.21
Benefits

- Direct cost savings resulting from reduction of medication waste
- Indirect cost savings achieved through enhanced patient support and physician communication
- Avoidance of incremental healthcare costs associated with unexpected therapy discontinuations, changes in therapy regimens, adverse-event-related hospitalizations and patient medication intolerance
- Patient access to clinical support between physician office visits
- Optimized clinical management that allows early recognition of adverse events
- Timely access to actionable information that enables physicians to improve patient care

Methodology

A study was conducted to identify cost savings that could be achieved by reducing medication waste associated with early therapy discontinuation, dose reductions and changes in therapy regimen. Ten months after program inception, a retrospective claims analysis was performed to identify discontinuations, and potential savings tied to monitored dispensing. A total of 434 claims for Nexavar®, Sutent® and Tarceva® adjudicated between June 1, 2008 and March 31, 2009 were analyzed.

### Table 7: Comparative Persistency Rates and Potential Cost Savings Through Monitored Dispensing Option

<table>
<thead>
<tr>
<th>Medication</th>
<th>Number of New Patients</th>
<th>Number (%) of Patients Discontinuing Therapy During the Month</th>
<th>Cycle Management Program Persistency Rate</th>
<th>Potential Cost Savings (%) Through Monitored Dispensing Option</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>First Month</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nexavar®</td>
<td>223</td>
<td>69 (31%)</td>
<td>69%</td>
<td>14.4%</td>
</tr>
<tr>
<td>Tarceva®</td>
<td>167</td>
<td>38 (23%)</td>
<td>77%</td>
<td>10.6%</td>
</tr>
<tr>
<td>Sutent®</td>
<td>44</td>
<td>8 (18%)</td>
<td>82%</td>
<td>7.8%</td>
</tr>
<tr>
<td>Aggregatec</td>
<td>434</td>
<td>115 (26%)</td>
<td>74%</td>
<td>12.4%</td>
</tr>
<tr>
<td><strong>Second Month</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nexavar®</td>
<td>154</td>
<td>30 (19%)</td>
<td>81%</td>
<td>9.0%</td>
</tr>
<tr>
<td>Tarceva®</td>
<td>129</td>
<td>25 (19%)</td>
<td>81%</td>
<td>9.0%</td>
</tr>
<tr>
<td>Sutent®</td>
<td>36</td>
<td>7 (19%)</td>
<td>81%</td>
<td>8.3%</td>
</tr>
<tr>
<td>Aggregatec</td>
<td>319</td>
<td>62 (19%)</td>
<td>81%</td>
<td>9.0%</td>
</tr>
<tr>
<td><strong>Third Month</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nexavar®</td>
<td>124</td>
<td>10 (8%)</td>
<td>92%</td>
<td>3.8%</td>
</tr>
<tr>
<td>Tarceva®</td>
<td>104</td>
<td>19 (18%)</td>
<td>82%</td>
<td>8.5%</td>
</tr>
<tr>
<td>Sutent®</td>
<td>29</td>
<td>3 (10%)</td>
<td>90%</td>
<td>4.4%</td>
</tr>
<tr>
<td>Aggregatec</td>
<td>257</td>
<td>32 (12%)</td>
<td>88%</td>
<td>5.3%</td>
</tr>
</tbody>
</table>

a. Reasons for discontinuing therapy included intolerance of medication side effects, cancer progression, admission to a hospital or hospice, insurance changes or loss of insurance, changes in medications or pharmacies and the patient’s death.

b. Potential savings for the monitored dispensing option were calculated by multiplying the per diem AWP for the designated drug at a typical dosing level by the number of days that could be saved by a split fill, resulting in the potential monthly savings for that drug.

c. This is a weighted average across all therapies.
As a provider of both home infusion and specialty pharmacy services, we are uniquely positioned to serve the varying needs of patients who are living with bleeding disorders, including hemophilia A and B and von Willebrand disease. Patients may receive their medications through Walgreens central fulfillment pharmacies or at home through our local infusion pharmacies, depending on their acuity level.

The following services simplify medication regimens and enhance quality of life for bleeding disorder patients:
- Individual, comprehensive, multidisciplinary care plans
- Ongoing monitoring
- In-depth, practical educational materials and tools
- Assistance with managing insurance claims and related issues
- Support with medication and supply management
- Access to clinicians 24/7
- Local nursing support as needed through Walgreens local infusion pharmacies
- Same-day delivery, as needed

Our teams work with patients to develop treatment goals, maintain individualized action plans for preventing bleeding episodes and reinforce the importance of therapy regimen adherence. Each team includes a nurse, pharmacist, insurance specialist and patient care coordinator.

**Acuity-Based Fulfillment Options** For pediatric patients, those who are newly diagnosed and patients who are experiencing acute episodes, home treatment through our local infusion centers is invaluable. Specially trained infusion nurses and infusion pharmacists are accessible day and night to deliver and manage high-touch, high-tech infusion therapies to those in need.

Patients who are adept at managing their condition and trained to self-infuse can be effectively managed through our central fulfillment pharmacies. They receive ongoing support and monitoring from our Care Team. However, if a self-infusing patient’s circumstances change, our central fulfillment pharmacy coordinates additional nursing support with our community-based infusion nursing staff.

To demonstrate the expertise provided by our infusion nurses, we conducted an analysis of hospital admissions data for patients receiving care for hemophilia, one of the primary bleeding disorders we support (see Figure 4)\(^\text{22}\). Patients cared for by our infusion nurses were hospitalized significantly less often than those under the care of home health agency nurses, contributing to improved quality of life and considerable cost savings.

**Assay Cost Management** Prescriptions for factor products are written in a range of units per dose based on a patient’s weight. Vials containing factor, known as assays, are produced in varying ranges.
Industry practice has been to fill and bill prescriptions for as much as 10% over the prescribed amount. However, our practice is to fill these prescriptions at no more than 2.0% over the prescribed amount. We achieve this through our rigorous inventory management procedures and comprehensive agreements with manufacturers. This gives us access to a wide array of products and assays in different sizes to prevent waste, minimize unused or unneeded assays and reduce cost. As a result, we deliver substantial cost savings on the blood clotting factors hemophilia patients need on a lifelong basis.

As an example, consider a factor prescription for 3,000 units per dose; we can dispense 3,020 units rather than the industry practice of 3,300. Based on an AWP of $1.49 per unit, our assay management program could save more than $24,000 on a factor prescription for one patient over a six-month period, or almost $50,000 annually (see Figure 5).

All for one, one for all
Managing hemophilia is often a family effort. When one family member is affected, everyone pitches in. To our patients, Walgreens can seem like one of the family too. “Walgreens has always been there for anything we’ve needed, even with our family’s hectic lifestyle,” said Jennifer Rentschler, mother of 3-year-old Cooper, who was diagnosed with hemophilia A at birth. “Our nurse has been great. I look at her as a friend.”

For the Rentschlers, Cooper’s first year was tough. “I was scared to pick him up, scared when he started crawling and walking,” Jennifer said. “Once he started receiving preventive care, it made me feel more confident.” Cooper has not had any bleeding episodes since his prophylaxis treatments began. He is able to play, run and act like any other child.

Now Walgreens supplies everything the Rentschlers need for Cooper, from blood clotting factor to helmets, knee pads and more. “You name it, they do it,” Jennifer said. “Walgreens has provided so much in terms of support and resources. Their willingness and ability to put me in contact with other families has been a tremendous comfort. It’s always helpful to talk to people who understand what we’re going through.”
At Walgreens Specialty Pharmacy,
we know that people who live with complex,
chronic medical conditions, such as MS face many
challenges, including side effects that can make
it hard to stay on track with their medications.
Our patient-centered support and disease-specific
clinical management are designed with those
challenges in mind.

The following patient profile tells the story of
Pamela, Doug and Snickers Beaudry (pictured at
right). With our help, Pamela lives her life to its
fullest and is able to concentrate on her
passions instead of her disease.

Life is good!

Diagnosed with MS in 1994, Pamela has learned how to
handle her condition with grace, tenacity, optimism and an
unfailing generosity of spirit. Over the years, she has used a
walker and a motorized scooter and has worn a brace on her
left leg. She has survived two heart attacks, has high blood
pressure and was diagnosed with microvascular disease in
2008. She also has severe migraine headaches and
experiences seizures. Many days, tremors in her hands leave
her unable to do simple tasks. Pamela currently receives
Copaxone® (glatiramer acetate) from our specialty pharmacy
and administers the daily subcutaneous injections herself.

Despite the many challenges she has faced, “Life is good!”
continues to be the mantra Pamela uses to describe her
circumstances. Walgreens has been there with her every
step of the way.

“My life has been so enriched with the addition of
Walgreens,” Pamela says. “I can consider my disease a
good thing because of the wonderful people I have met
and the amazing activities I have been involved with.”

Together with her Walgreens Specialty Pharmacy Care Team,
Pamela is making the most of her medication therapy regimen.
She has developed a strong relationship with her care coordinator,
Amy, and now considers her to be part of a vital support system.

“I feel fortunate in my heart to call Amy my friend,”
Pamela says. “She helps me address any problem I have.”

Patient support is just one element that makes our services
stand out. In an active, ongoing clinical management program,
Amy schedules Pamela’s orders, coordinates deliveries and
helps address questions or medical concerns by connecting
her with pharmacists or nurses when needed. This high-touch approach to specialty pharmacy makes a difference when it comes to medication adherence.

Another vital part of Pamela’s support system is her family. She and her husband Doug have five grown sons and four daughters-in-law and are enjoying four new grandsons. “This is a family disease and my family is extremely supportive, accepting, understanding and helpful. Doug is the most loving, caring man I know. He is my everyday support, and he’s really handsome, too!”

Pamela continues to thrive and smile. She and Doug have volunteered at the National Multiple Sclerosis Society for more than 20 years. They started their involvement before Pamela was diagnosed. For years she has been a Power Partner for the Annual Bike MS 150 Ride in mid-Michigan, a two-day event covering 150 miles.

Pamela sums up her message this way: “I believe we all gain so much in our lives by giving to others. Give of yourself and you receive in return. My family, church, everyone at the MS Society and the Walgreens team of pharmacists, nurses and care coordinators, like Amy, are all priceless to me. If I am not doing well, they want to know. They warm my heart and give us strength through their dedication and love. I am so blessed because . . . life is good!”
Specialty Pharmacy Pipeline  The specialty pipeline is expected to remain robust into the foreseeable future. As many as 30% to 40% of medications in Phase II and Phase III trials are specialty products. According to a report by the Pharmaceutical Research and Manufacturers of America, a total of 633 biotech drugs were in human clinical trials or under FDA review in 2008 for treatment of more than 100 conditions (see Figure 6).

The single largest area of research and development is oncology drugs, which comprise approximately 40% of the pipeline. Many of the nearly 2,000 individual molecules for cancer treatment that are in late-stage development are being evaluated for multiple cancer indications. In many cases, pharmaceutical companies are introducing new molecules for niche indications, or low-incidence tumors, and subsequently pursuing label extensions for use in other, higher-incidence tumors.

A shift to oral chemotherapy agents is one of the emerging trends in cancer care. Oral drugs make up 35% of the oncology pipeline. It is projected that the percentage of oncology drugs available in oral form will reach 25% by 2013, up from 10% today.
Notable specialty drugs approved by the FDA in the first half of 2009 include Afinitor®, an oral chemotherapy drug which is the first approved treatment for patients with advanced kidney cancer for whom other treatment agents have failed; and Simponi™, a monthly self-administered BRM for treatment of rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis.

Our Quarterly Pipeline Report Keeps You Informed
The Walgreens Specialty Pharmacy Pipeline Report provides a summary of specialty medications in Phase III review by the FDA along with highlights of a few recently approved or soon-to-be-approved medications that may have a significant impact on therapeutic classes and treatment for specific conditions. To view the full report visit WalgreensHealth.com/pipeline.

*Some medications are included in more than one category.*
Select medications in the specialty research and development pipeline that are currently in Phase III studies or under FDA review are presented in Table 8. Among these drugs, fingolimod is notable as potentially the first oral drug to treat MS.

Table 8: Key medications in the specialty pipeline

<table>
<thead>
<tr>
<th>Therapeutic Use</th>
<th>Brand Name (Generic Name)/Manufacturer</th>
<th>Route of Administration</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bone loss</td>
<td>Prolia™ (denosumab)/Amgen</td>
<td>SC injection</td>
<td>Under FDA review</td>
</tr>
<tr>
<td>Cystic fibrosis</td>
<td>NA (denfosol)/Inspire Pharmaceuticals</td>
<td>Inhalation</td>
<td>In phase III studies</td>
</tr>
<tr>
<td>Hepatitis C</td>
<td>Albuferon® (albinterferon alfa-2b)/Human Genome Sciences and Novartis</td>
<td>Injection</td>
<td>In phase III studies</td>
</tr>
<tr>
<td>HIV/AIDS</td>
<td>NA (vircriviroc)/Schering-Plough</td>
<td>Oral</td>
<td>In phase III studies</td>
</tr>
<tr>
<td>Infertility</td>
<td>NA (corifollitropin alfa)/Schering-Plough</td>
<td>SC injection</td>
<td>In phase III studies</td>
</tr>
<tr>
<td>Inflammatory diseases</td>
<td>Actemra® (tocilizumab)/Roche</td>
<td>IV infusion</td>
<td>Under FDA review</td>
</tr>
<tr>
<td></td>
<td>Stelara® (ustekinumab)/Centocor</td>
<td>SC injection</td>
<td>Under FDA review</td>
</tr>
<tr>
<td>Multiple sclerosis</td>
<td>NA (dirucotide, MBP8298)/Eli Lilly and BioMS Medical</td>
<td>IV infusion</td>
<td>In phase III studies</td>
</tr>
<tr>
<td>Oncology</td>
<td>Provenge® (sipuleucel-T)/Dendreon</td>
<td>IV infusion</td>
<td>Under FDA review</td>
</tr>
<tr>
<td></td>
<td>Zactima® (vandetanib)/AstraZeneca</td>
<td>Oral</td>
<td>In phase III studies</td>
</tr>
</tbody>
</table>

* As of July 2009

>> our perspective on the pipeline  Access to new drugs as they come to market and the capability to provide comprehensive therapy management and deliver strong clinical outcomes is essential for a specialty pharmacy partner. Walgreens Specialty Pharmacy has a team of dedicated pharmacists and nurses who monitor the biotech pipeline and analyze new market entrants. Walgreens works with an extensive network of biotech manufacturers to ensure we have access to new FDA-approved therapies. <<

Limited-Distribution Drugs  Many specialty drugs are only dispensed by certain designated specialty pharmacy providers. Medications can be categorized as limited-distribution for any of the following reasons:

- A higher level of patient interaction is required (for example, due to a black box warning)
- FDA requires dispensing under strict guidelines and reporting on key clinical information
- A limited supply of raw materials is available
- Manufacturers require closely monitored inventory
- There are special dosing or lab monitoring requirements

To dispense its product, a pharmaceutical manufacturer typically selects a specialty pharmacy with the ability to:

- Manage medication adherence and side effects
- Provide patient counseling and distribute educational materials
- Provide highly trained and clinical staff on key therapies
- Conduct benefits investigation
- Provide reimbursement support
- Produce detailed outcomes reporting and analytics
As of May 2009, Walgreens Specialty Pharmacy had access to more than two dozen limited-distribution medications (see Table 9) with additional agreements in process.

### Table 9: Limited-Distribution Medications Available Through Walgreens Specialty Pharmacy

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Manufacturer</th>
<th>Therapeutic Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>H P Acthar® Gel</td>
<td>Questcor Pharmaceuticals, Inc.</td>
<td>Multiple indications including acute exacerbations of multiple sclerosis</td>
</tr>
<tr>
<td>Apokyn®</td>
<td>Ipsen Pharmaceuticals, Inc.</td>
<td>Advanced Parkinson’s disease</td>
</tr>
<tr>
<td>Cimzia®</td>
<td>UCB, Inc.</td>
<td>Crohn’s disease and rheumatoid arthritis</td>
</tr>
<tr>
<td>Dacogen®</td>
<td>Eisai Inc.</td>
<td>Myelodysplastic syndromes</td>
</tr>
<tr>
<td>Epoprostenol</td>
<td>Teva Pharmaceuticals</td>
<td>Pulmonary arterial hypertension</td>
</tr>
<tr>
<td>Hycmatin® (oral)</td>
<td>GlaxoSmithKline</td>
<td>Small cell lung cancer</td>
</tr>
<tr>
<td>Increlex™</td>
<td>Tercica Inc. an affiliate of The Ipsen Group</td>
<td>Insulin-like growth factor-1 deficiency</td>
</tr>
<tr>
<td>Kuvan™</td>
<td>Biocorin Pharmaceuticals Inc.</td>
<td>Phenylketonuria</td>
</tr>
<tr>
<td>Letairis®</td>
<td>Gilead Sciences, Inc.</td>
<td>Pulmonary arterial hypertension</td>
</tr>
<tr>
<td>Lucentis®</td>
<td>Genentech, USA, Inc.</td>
<td>Neovascular (wet) age-related macular degeneration</td>
</tr>
<tr>
<td>Macugen®</td>
<td>Eyetech, Inc.</td>
<td>Neovascular (wet) age-related macular degeneration</td>
</tr>
<tr>
<td>Naglazyme®</td>
<td>Biocorin Pharmaceuticals, Inc.</td>
<td>Mucopolysaccharidos is VI</td>
</tr>
<tr>
<td>Nexavar®</td>
<td>Bayer HealthCare Pharmaceuticals Inc.</td>
<td>Renal cell carcinoma and hepatocellular carcinoma</td>
</tr>
<tr>
<td>Promacta™</td>
<td>GlaxoSmithKline</td>
<td>Immune thrombocytopenic purpura</td>
</tr>
<tr>
<td>Revlimid®</td>
<td>Celgene Corporation</td>
<td>Myelodysplastic syndromes and multiple myeloma</td>
</tr>
<tr>
<td>RiaSTAP™</td>
<td>CSL Behring L.L.C</td>
<td>Congenital fibrinogen deficiency</td>
</tr>
<tr>
<td>Supprelin® LA</td>
<td>Endo Pharmaceuticals Inc.</td>
<td>Central precocious puberty</td>
</tr>
<tr>
<td>Synagis®</td>
<td>MedImmune, Inc.</td>
<td>Respiratory syncytial virus</td>
</tr>
<tr>
<td>Tracleer®</td>
<td>Actelion Pharmaceuticals US, Inc.</td>
<td>Pulmonary arterial hypertension</td>
</tr>
<tr>
<td>Tykerb®</td>
<td>GlaxoSmithKline</td>
<td>Breast cancer</td>
</tr>
<tr>
<td>Tysabri®</td>
<td>Elan Pharmaceuticals, Inc. and Biogen Idec, Inc.</td>
<td>Multiple sclerosis and Crohn’s disease</td>
</tr>
<tr>
<td>Visudyne®</td>
<td>Novartis Pharmaceuticals Corporation</td>
<td>Age-related macular degeneration</td>
</tr>
<tr>
<td>Vivaglobin®</td>
<td>CSL Behring L.L.C</td>
<td>Primary immune deficiency</td>
</tr>
<tr>
<td>Xolair®</td>
<td>Genentech USA, Inc. and Novartis Pharmaceuticals Corporation</td>
<td>Allergic asthma</td>
</tr>
<tr>
<td>Zorbitive®</td>
<td>EMD Serono, Inc.</td>
<td>Short bowel syndrome</td>
</tr>
</tbody>
</table>

*As of May 2009

> Our perspective on limited-distribution drugs  Many limited-distribution drugs are used for rare conditions with low incidence and prevalence. Through key client relationships with many of the Blues plans, national and regional managed care organizations, as well as our own pharmacy benefit manager, Walgreens Specialty Pharmacy has exclusive/preferred contracts providing access to more than 110 million lives. We have partnered with key pharmaceutical manufacturers to ensure access to limited-distribution therapies to support our payors and their members’ needs. Since 2007, Walgreens Specialty Pharmacy has increased access to limited-distribution medications by more than 70%, from 14 in 2007 to 25 in early 2009. This growth continues as manufacturers recognize our comprehensive therapy management services, strong clinical outcomes and other proven capabilities in this arena. <<
REMS: An Enhanced FDA Safety Protocol
In 2008, the FDA updated its safety plan, formerly known as a risk minimization action plan, to an enhanced safety protocol now called a Risk Evaluation and Mitigation Strategy (REMS). This requirement for an updated safety plan applies to drugs or biological products that have certain known or potential serious risks, such as fetal harm, if not taken properly. A REMS must be submitted when a drug first enters the marketplace or when new safety information becomes available. Drugs required to have a REMS must contain FDA-defined “elements to assure safe use” in their prescribing or dispensing plan, including one or more of the following:

• Prescribers have particular training or experience, or are specially certified
• Pharmacies, practitioners or healthcare settings that dispense the drug are specially certified
• The drug is dispensed to patients with evidence or other documentation of safe use conditions, such as laboratory test results
• The drug is dispensed to patients only in certain healthcare settings, such as hospitals
• Each patient is subject to certain monitoring
• Each patient is enrolled in a registry

>> our perspective on REMS  Walgreens Specialty Pharmacy provides high-quality patient management services for therapies that require high-touch prescription oversight. Our disease-focused teams of pharmacists and nurses have a comprehensive understanding of patient and physician needs. These specialized teams help ensure compliance with therapy-appropriate REMS while providing superb patient management, including individualized counseling, education and adverse drug event monitoring. Our ability to manage a patient through the prescription intake, benefits investigation and fulfillment process creates the optimum pharmacy experience for complex therapies. Our proprietary system provides the flexibility that allows us to tailor our programs to meet the unique needs of drugs requiring a REMS. Our fulfillment system can generate and transmit reports that include longitudinal data, drug safety information and prescription status reports as frequently as daily. <<

Biogenerics and Biosimilars  In March 2009, H.R. 1427, the Promoting Innovation and Access to Life-Saving Medicine Act, was introduced in the House, followed by a companion bill (S. 727) in the Senate. These bills authorize the FDA to approve abbreviated applications for biosimilar and biogeneric drugs. This proposed legislation provides for five years of market exclusivity for original products with novel molecular structures and, in most cases, three years of exclusivity for modifications of previously approved products (including new uses, new dosage forms and modifications in molecular structure), consistent with currently available exclusivity periods. A competing bill, H.R. 1548, the Pathway for Biosimilars Act, calls for a 12-year market exclusivity period, with a two-year extension period available once a further indication for the product is approved by the FDA.

>> our perspective on biogenerics and biosimilars  During 2009 and 2010, healthcare reform advocates will continue to promote the passage of legislation creating a new regulatory approval pathway for biogenerics and biosimilars. Walgreens believes that it is important to strike the right balance between fostering pharmaceutical innovation and making affordable biogenerics available and accessible to patients in a timely way. No matter which approval pathway is enacted into law, when biogenerics and biosimilars become available we will leverage our proven clinical management and utilization strategies to maximize the potential billions of dollars in savings these drugs are expected to yield in the marketplace. Walgreens longstanding track record of effecting steady and significant increases in the generic dispensing rate will serve payors and patients well in the specialty arena. <<

SPECIALTY DRUGS REQUIRING A REMS

| Cimzia®   | Soliris®   |
| Enbrel®   | Thalomid®  |
| Intron-A® | Tracleer®  |
| Letairis® | Tysabri®   |
| NPlate™   | Vimune®    |
| Peg-Intron® | Xezine   |
| Revlimid® | Zagen®     |
Cost Sharing  Patients share the cost of specialty drugs through copays and coinsurance, multitiered pharmacy benefits, split fills, specialty prior authorizations and consumer-directed healthcare. The rapid growth of specialty drugs along with their high costs and financial barriers to access have made affordability a focus of efforts for healthcare policy makers in recent years. There is a concern that the patient’s share of specialty drug costs is often prohibitive, reducing adherence to therapy and increasing overall healthcare costs. Going forward, policy solutions must take a wide range of issues into account, including the need to protect patients against catastrophic expenses, benefits structure, coverage under the medical versus the pharmacy benefit, physician “buy and bill” reimbursement and the potential for evidence- or outcomes-based pricing.

>> our perspective on cost sharing  Copays and coinsurance can affect patients’ ability to be adherent to their specialty therapy. Walgreens Specialty Pharmacy offers comprehensive support services to help patients find the funding they need. We have established relationships with many not-for-profit organizations, including the American Cancer Society, the Arthritis Foundation and others, to help minimize therapy interruptions due to financial constraints. In addition, we serve as a liaison with manufacturers to enroll patients in their financial assistance programs. We also recognize that making affordable healthcare accessible to all Americans is a primary impetus behind the proposed federal healthcare reform initiatives. Reform is likely to usher in new approaches to prescription drug cost-sharing that make specialty medications more affordable and eliminate longstanding barriers to access for uninsured and underinsured populations. This would include addressing the coverage gap in Medicare Part D, commonly referred to as the “Donut Hole,” which would help ensure health plan beneficiaries have access to the medications they need for as long as they need them. Walgreens Government Affairs is actively engaged in the healthcare reform debate. We welcome opportunities to help meet today’s healthcare delivery system challenges. Wider utilization of home infusion and pharmacist-based medication therapy management are among the ways that Walgreens can be part of the solution.

Pay for Performance  Pay for performance (P4P) is an extension of evidence-based medicine that holds drug manufacturers financially accountable for achieving targeted patient outcomes. In performance or risk-based models, reimbursement rates would vary, depending on outcomes. Manufacturers risk being responsible for more of the cost of a drug if defined patient outcomes are not achieved. Benefits to this type of system, also known as pay for outcomes (P4O), include the ability to share financial risk between manufacturers and payors in situations when treatment responses cannot be predicted. P4P and P4O allow payors to link reimbursement to a defined outcome in specific patient populations and align incentives for all stakeholders—patients, payors, prescribers and manufacturers. Challenges, which are significant, include building consensus about outcome choices, definitions and metrics, as well as developing protocols for the process. In addition, this model requires a high level of coordination among all parties involved.

>> our perspective on pay for performance  P4P and P4O programs offer opportunities for specialty pharmacies to prove the value of patient monitoring and adherence services that are supported by patient education and a high-touch approach. As healthcare moves to a more evidence-based, quality- and outcomes-focused treatment model, specialty pharmacies that are adept at gathering data and reporting outcomes will be better positioned to enter into risk-sharing agreements. Walgreens Specialty Pharmacy has the ability to identify areas where P4P or P4O agreements will bring enhanced value and savings to payors.
In the coming years, specialty pharmacy will continue to evolve in response to the pressure to contain costs and improve patient access to affordable healthcare services. At the same time, a growing number of pipeline drugs will enter the market and new indications will be approved for existing specialty drugs. These factors require new ways of thinking about how to manage this dynamic segment of the pharmaceutical marketplace. Walgreens Specialty Pharmacy is reconstructing the industry through expanded fulfillment channels, integrated technologies, and comprehensive therapy management programs to offer consistent, customized and convenient solutions. Our unique approach leads to improved clinical and financial outcomes—benefiting patients, physicians, payors and pharmaceutical manufactures alike.
Appendix 1: Definitions

AWP: average wholesale price. A calculated average price of a medication to a pharmacy based on a survey of wholesalers and manufacturers.

Biologics: isolated from living organisms (human, mammals, plants, microorganisms); may be living entities such as cells and tissues; mimic the effects of substances naturally made by the body’s immune system. Includes vaccines, blood and blood components, tissues, monoclonal antibodies (e.g., Humira®, Xolair®), immunoglobulins.

Biosimilars: follow-on versions of original biological medications; independently developed after a product’s patent has expired. Biosimilar medications are intended to have the same mechanism of action as the original biological medications, and are designed to treat the same diseases as the innovator’s product.

Biotech medications: medications that are produced using biotechnology.

Biotechnology: the fusion of biology and technology. The use of recombinant DNA, cell fusion, or other DNA manipulations to produce useful molecules or to alter biologic processes to enhance a desired property.

Black box warning: FDA-mandated warning for pharmaceuticals, designed to highlight serious problems and give healthcare professionals a clear understanding of a potential medical complication associated with the medication. Named for the thick black border surrounding the text, black box warnings provide physicians with important insights as to how to prescribe a medication that may have serious side effects in a way to maximize benefits and minimize risks.

Infusibles and injectables: require special handling, clinical oversight or outcomes monitoring.

Medication possession ratio (MPR): the number of days’ supply of medication dispensed during a designated period divided by the total number of days in the period.

Monitored dispensing: a cost-containment program in which a partial fill of medication is initially dispensed and patients are closely monitored to assess their response to therapy.

Trend: the average annual increase in sales of specialty pharmacy medications.

Specialty drugs: a definition

Specialty drugs are identified by some or all of the following characteristics:

- Complex treatment regimens
- Biotech derived
- Special delivery, storage and handling
- Medication administration training for patients
- Higher cost than traditional medications

- Ongoing monitoring of medication adherence, side effects and dosage changes
- Supported by coordinated case management
- Available through limited-distribution channels

Specialty medications may be manufactured through biotech or traditional drug development processes. For this report, the term “specialty medication” refers to the category as a whole; whereas the term “biotech” refers specifically to those medications created through genetic manipulations such as recombinant DNA technology. In the specialty pharmacy industry, the terms “biotech” and “specialty” are often used interchangeably.
Appendix 2: References


Appendix 2: references (continued)


21 Potential savings are based on the recommended dosing and average wholesale prices for these three drugs during the study period.

22 This study did not control for disease severity, comorbidities and other patient characteristics.


29 Manufacturer web sites.


To Our Clients and Patients We extend our sincere gratitude to our clients and patients for the trust you place with us. You are the foundation upon which our business has grown over the years and will always be the inspiration for the development of our ideals, programs and services.

Walgreens Specialty Pharmacy wishes to acknowledge the many professionals from the departments that contributed to this report: Client Services, Clinical Program Development, Health Outcomes, Marketing and Communications, Reporting and Analytics, Sales and Trade Relations.