Health care spending was a major topic of the 2012 presidential race and promises to remain in the spotlight as the United States addresses the need to cut spending in the face of the federal deficits in 2013 and beyond. In 2013, health care expenditures are expected to grow 3.82%, reaching $2915.5 billion, or 17.8% of the gross domestic product. While this rate of growth was slightly lower than that in 2012, by 2014, major coverage expansions mandated in the Patient Protection and Affordable Care Act are expected to drive growth by 7.4% (to $3130.2 billion). This will result in a greater proportion of national health care expenditures being paid by the federal government (30% in 2014). This growth in federal spending on health care combined with the current focus on federal debt and deficit reduction may result in meaningful changes to Medicare and other key health care programs.

Prescription drug expenditures remain an important component of overall health care expenditures. While growth in prescription expenditures has slowed in recent years, many factors influence future drug
spending. Increased utilization and access to drugs attributable to the increased aging population and expanded insurance coverage, along with the launch of new and expensive medications, are the primary factors raising drug expenditures, while patent expirations and the availability of less-expensive generic products are the primary factors reducing drug expenditures.

This article discusses factors likely to influence drug expenditures, describes drug expenditure trends in 2012, and projects drug expenditures for 2013. Our intent is to provide information and analysis that will aid health-system pharmacy executives and other health-system leaders who are responsible for developing hospital and clinic drug budgets in determining how future changes in medication use will affect drug expenditures in their own institutions. We examined trends in pharmaceutical expenditures, both generally and by setting (with an emphasis on nonfederal hospitals and clinics), that may help predict expenditures in 2013. We also examined other factors that may influence future pharmaceutical expenditures, including new drugs and newly available generics. Finally, drug expenditures by sector (total, hospital, and clinic settings) for 2013 were projected.

Methods

Our forecast of pharmaceutical expenditures in 2013 was based on examination of both historical trends in drug expenditures and expected changes in the drug marketplace that may influence drug expenditures in hospitals and clinics, including recent drug approvals and expected patent expirations. First, we analyzed prescription drug expenditures in 2011 through September 2012. Data for this analysis were obtained from the IMS Health National Sales Perspectives (NSP) database. NSP is a statistically valid projected audit that describes 100% of the sales in every major class of trade and distribution channel for prescription pharmaceuticals, nonprescription products, and select self-administered diagnostic products in the United States, measuring both unit volume and invoice dollars. The NSP sample is derived from over 1.5 billion annual transactions from over 100 pharmaceutical manufacturers and more than 700 distribution centers. As of September 2012, NSP tracked sales into 5,789 nonfederal hospitals, 145,812 clinics, 59,674 retail pharmacies, 323 mail-service pharmacies, 5,050 home health facilities, and 3,307 long-term-care outlets, in addition to thousands of other entities. All data from NSP were used in the analysis (e.g. nonsystemic formulations were used), and drug class groupings were based on IMS Health’s proprietary Uniform System of Classification.

When examining drug expenditures, we reported total dollars spent as well as growth, the latter being the percentage change (increase or decrease) in expenditures from one period to the next. We categorized the factors that drive changes in pharmaceutical expenditures as (1) new products, (2) price inflation, and (3) volume and mix. The “new products” category represents growth in expenditures attributable to products that were not on the market in the comparison time period (i.e., previous year). Growth in prescription drug expenditures attributable to price inflation refers to changes in the unit cost of drugs that were previously on the market in the comparison time period (i.e., the change in price from one year to the next). Last, the “volume and mix” category combines changes in volume of utilization of existing products (i.e., changes in the number of users, number of days of therapy, or number of doses of therapy per day) and changes in usage patterns (i.e., from one product to another). An example of mix is when prescribing moves from brand to generic products, resulting in reduced expenditures. Additional analyses were conducted focused on oncology therapies because of the importance of these therapies to overall drug expenditures. The proportions of expenditures incurred in retail settings, mail-order pharmacies, long-term-care facilities, health maintenance organizations, nonfederal facilities, federal facilities, and clinics between 2007 and 2012 were estimated separately for oral and injectable oncology agents to examine shifts in distribution channel for these products.

Recent drug approvals and drugs in development were reviewed, since these often increase drug expenditures. Drugs and biological agents anticipated to be approved by the Food and Drug Administr-
tion (FDA) in 2013 were identified by searching pharmaceutical and biotechnology business news for articles of interest to investors in the industry. Once products were identified, their Prescription Drug User Fee Act (PDUFA) dates were determined by examining information in official press releases by the respective companies sponsoring the drugs or biological agents. If no explicit PDUFA date was mentioned in the official press release, the date was extrapolated by adding a 6-month (for priority reviews) or 10-month time frame (for standard reviews) to the new drug application (NDA) or biological license application (BLA) submission date. Drugs or biologicals that had negative FDA committee reviews at the time this article was prepared were not included. In addition, agents with FDA-approved labeling for other indications (without major differences in drug delivery) were also excluded.

Pharmaceuticals anticipated to lose patent protection were reviewed to estimate their impact on drug expenditures. Drugs and biologicals whose patent protection is expected to end in 2013 or the first quarter of 2014 were identified from several sources, and confirmed by searching business news for articles of interest to investors in the pharmaceutical and biotechnology industry. The list of potential future patent expirations provided in the 2012 forecast was examined to determine if these agents were delayed or expected to lose patent protection during 2013 or the first quarter of 2014. The list of potential patent expirations was further limited to pharmaceuticals that represent substantial expenditures for the entire market or those that are particularly important to the hospital or clinic setting.

Finally, we projected drug expenditure growth in 2013 for nonfederal hospitals, clinics, and all sectors. These estimates were generated through a combination of quantitative and qualitative analyses and our opinions. An analysis of past expenditure patterns using linear least-squares regression was performed to estimate 2013 expenditures in the absence of major changes. We also developed qualitatively based estimates of growth, considering major factors that are believed to influence future drug expenditures, as discussed in this article. Projections from other sources were also examined. Once we evaluated these estimates, consensus regarding anticipated drug expenditure growth rates for 2013 was reached.

Results

Historical trends in prescription expenditures. Total prescription sales in the United States for the 12-month period ending September 2012 were $326.0 billion, a 0.8% increase from the previous 12 months. This rate of growth is the lowest in recent history and can be attributed to modest increases in expenditures for new products (3.3%) and the prices of existing products (5.9%), coupled with a marked decline in overall volume and mix (−8.4%). The decrease in expenditures attributable to volume and mix reflects the continued trend of greater use of generics over brand-name products.

The $326.0 billion spent on prescription drugs from October 1, 2011, to September 30, 2012, occurred across various sectors of health care (Table 1). The retail pharmacy sector accounted for the largest portion of prescription expenditures ($169.2 billion, or 51.9% of total expenditures), followed by mail-order pharmacy ($65.1 billion, 20.0%) and clinics ($39.3 billion, 12.1%). Other sectors, including nonfederal hospitals ($27.9 billion, 8.6%), each accounted for less than 10% of total expenditures.

The greatest growth in prescription expenditures on a percentage basis from the previous 12 months ending September 30, 2012, occurred

<table>
<thead>
<tr>
<th>Table 1. Prescription Drug Expenditures and Growth by Sector</th>
</tr>
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<tbody>
<tr>
<td><strong>Sector</strong></td>
</tr>
<tr>
<td>Retail pharmacies</td>
</tr>
<tr>
<td>Mail-order pharmacies</td>
</tr>
<tr>
<td>Clinics</td>
</tr>
<tr>
<td>Nonfederal hospitals</td>
</tr>
<tr>
<td>Long-term care</td>
</tr>
<tr>
<td>Federal facilities</td>
</tr>
<tr>
<td>Staff-model HMO</td>
</tr>
<tr>
<td>Home health care</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

*Retail pharmacies include licensed retail pharmacies including standalone chain and independent stores, as well as mass merchandisers and food and convenience stores with a pharmacy. Mail-order pharmacies include licensed mail service pharmacies, including both private-sector and federal facilities. Clinics include physician offices and outpatient clinics, including general, family medicine, and specialty clinics covering oncology, nephrology, dialysis, family planning, orthopedics, and urgent care centers. Nonfederal hospitals include all nonfederally owned facilities licensed as hospitals, including inpatient treatment and rehabilitation facilities, in addition to general and specialty acute care institutions. Long-term care includes nursing homes and residential care facilities, including Department of Veterans Affairs (VA) institutions. Federal facilities include VA, Public Health Service, and other federal hospitals; VA clinics and pharmacies; and U.S. ships at sea. Staff-model HMO (health maintenance organization) includes closed-panel HMO pharmacies and hospitals, union clinics and pharmacies, and workers’ compensation clinics. Home health care includes licensed home health organizations and visiting nurse entities. Other covers a variety of otherwise unclassified government accounts, as well as entities such as jails, prisons, and veterinary hospitals and clinics.


*Percent increase in expenditures compared with previous 12 months.
in mail-order pharmacies (5.5%), followed by federal facilities (4.1%). Clinics experienced 3.1% growth. Sectors with decreased expenditures were long-term-care facilities (−4.7%), retail pharmacies (−0.8%), and nonfederal hospitals (−0.4%). While retail pharmacies experienced a slight decrease in drug expenditures, this was offset by increases in mail-order pharmacies and reflects an ongoing shift between these channels.

A pattern of increased expenditures due to greater use of new products and increased prices of existing products, combined with decreased expenditures from reduced overall volume and mix, was consistent across all sectors except clinics. While clinics experienced an overall 3.1% increase in expenditures, there were major shifts in the use of generics in this setting. Expenditures for generic injectables decreased 22.7%, primarily because of decreased prices, and expenditures for generic noninjectables increased 28.8%, primarily because of new products and volume and mix.

Figure 1 shows trends in growth (increase or decrease) of prescription drug expenditures in the United States from 1998–99 through 2011–12 in clinics, nonfederal hospitals, and all sectors. The values for 2011–12 represent the first nine months (year to date) of 2012 compared with the same period in 2011. Growth in total prescription drug expenditures generally declined over the past 15 years, with a high of 19.7% between 1998 and 1999 to a low of 1.8% between 2007 and 2008, but has somewhat leveled off since. Between 2010 and 2011, total prescription expenditures grew 4.0%; for the nine months ending September 2012, total prescription expenditures grew 2.7% (compared with the same period in 2011). Note that this growth is different than that shown in Table 1 (and discussed above) because it represents a different (shorter) time period. In most years, growth in expenditures for clinic-administered drugs outpaced growth in total expenditures, but clinic expenditures have leveled off in the past five years. Between 2010 and 2011, expenditures for clinic-administered drugs grew by 5.7%; for the first nine months of 2012, they grew by 3.4% (compared with the same period in 2011). Conversely, growth in prescription drug expenditures in nonfederal hospitals
Special feature projecting future drug expenditures

The largest increase in expenditures for agents in the top 15 were for duloxetine (28.7%), insulin glargine (24.9%), adalimumab (21.9%), and etanercept (21.7%).

The top 15 drug products based on expenditures in 2012 (nine months through September 30, 2012) in the clinic setting are listed in Table 3. Rankings based on expenditures were largely unchanged compared with 2011. Pegfilgrastim, epoetin alfa, and infliximab top the list. Among the top 15, the drugs with the biggest change in expenditures from 2011 to 2012 were denosumab (119.0% increase), varicella vaccine (28.9% increase), and epoetin alfa (21.2% decrease). Expenditures for cetuximab and trastuzumab increased greatly (16.6% and 11.1%, respectively), while those for zoledronic acid and pneumococcal vaccine decreased (–11.0% and –9.1% respectively).

Oncology products accounted for 32.2% of drug expenditures in the clinic setting in the first nine months of 2012. The top 20 clinic-administered antineoplastic agents are highlighted in Table 4. Oncology drug expenditures in clinics have continued to moderate, growing just 1.4% in the first nine months of 2012 (compared with the same time period in 2011) and down from 4.4% in 2011. Rituximab, bevacizumab, and trastuzumab represent the top 3 oncology drugs based on expenditures for clinic-administered drugs in the first nine months of 2012, just as they did in 2011 and 2010. Of the top 20 clinic-administered oncology drugs on the list, the agent with the largest growth in 2012 was ipilimumab (80.0%), while cabazitaxel saw the largest decrease (–25.1%).

Over the past five years, there has been a considerable shift in the distribution of spending for oral oncology agents by setting (Figure 2). In the 12 months ending in September 2007, 28% of spending on oral oncology agents was through mail-order pharmacies, while 58% was through

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Table 2.
Top 15 Drugs by Expenditures Overall in 2012

<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Esomeprazole (Nexium)</td>
<td>6,387,854</td>
<td>0.4</td>
<td>4,504,844</td>
<td>–3.8</td>
</tr>
<tr>
<td>Aripiprazole (Abilify)</td>
<td>5,269,477</td>
<td>15.7</td>
<td>4,329,396</td>
<td>12.0</td>
</tr>
<tr>
<td>Atorvastatin (Lipitor)</td>
<td>8,701,659</td>
<td>20.0</td>
<td>3,915,301</td>
<td>–34.9</td>
</tr>
<tr>
<td>Fluticasone–salmetrol (Advair Diskus, Advair HFA)</td>
<td>5,101,695</td>
<td>2.6</td>
<td>3,903,586</td>
<td>5.5</td>
</tr>
<tr>
<td>Rosuvastatin (Crestor)</td>
<td>4,634,147</td>
<td>23.2</td>
<td>3,765,940</td>
<td>15.0</td>
</tr>
<tr>
<td>Duloxetine (Cymbalta)</td>
<td>3,776,913</td>
<td>19.7</td>
<td>3,443,695</td>
<td>28.7</td>
</tr>
<tr>
<td>Montelukast (Singulair)</td>
<td>4,752,029</td>
<td>16.7</td>
<td>3,376,185</td>
<td>–1.1</td>
</tr>
<tr>
<td>Adalimumab (Humira)</td>
<td>3,743,275</td>
<td>21.7</td>
<td>3,355,731</td>
<td>21.9</td>
</tr>
<tr>
<td>Insulin glargine (Lantus, Lantus Solostar)</td>
<td>3,661,623</td>
<td>20.3</td>
<td>3,269,934</td>
<td>24.9</td>
</tr>
<tr>
<td>Etanercept (Enbrel)</td>
<td>3,769,454</td>
<td>14.5</td>
<td>3,170,952</td>
<td>21.7</td>
</tr>
<tr>
<td>Clopidogrel (Plavix)</td>
<td>7,063,187</td>
<td>15.1</td>
<td>3,054,467</td>
<td>–40.6</td>
</tr>
<tr>
<td>Infliximab (Remicade)</td>
<td>3,491,199</td>
<td>5.7</td>
<td>2,904,964</td>
<td>10.5</td>
</tr>
<tr>
<td>Glatiramer (Copaxone)</td>
<td>3,161,957</td>
<td>31.8</td>
<td>2,635,364</td>
<td>11.1</td>
</tr>
<tr>
<td>Pegfilgrastim (Neulasta)</td>
<td>3,326,838</td>
<td>10.2</td>
<td>2,627,821</td>
<td>6.2</td>
</tr>
<tr>
<td>Quetiapine (Seroquel, Seroquel XR)</td>
<td>5,741,781</td>
<td>10.9</td>
<td>2,589,222</td>
<td>–39.0</td>
</tr>
<tr>
<td>All others</td>
<td>255,456,892</td>
<td>4.7</td>
<td>194,014,245</td>
<td>4.4</td>
</tr>
<tr>
<td>Total</td>
<td>328,044,980</td>
<td>6.7</td>
<td>244,861,647</td>
<td>2.7</td>
</tr>
</tbody>
</table>

*Based on data collected between January 1 and September 30, 2012.

†Percent change compared with same period in 2011 (data not shown in table).

‡Available from one or more manufacturers, distributors, or repackagers by generic name.
Projecting future drug expenditures

retail pharmacies. However, for the 12 months ending in September 2012, 57% of the spending for oral oncology agents was through mail-order pharmacies, while only 27% was through retail pharmacies. There was no such shift in spending observed for injectable oncology agents. In both 2007 and 2012, 72% of the spending for injectable oncology drugs was incurred in the clinic setting, and 23% of the spending was incurred in the hospital setting.

The top 15 products based on expenditures during the first nine months of 2012 in the nonfederal hospital setting are listed in Table 5. For the nine-month period ending September 30, 2012, the top 3 hospital drugs in terms of expenditures were immune globulin, infliximab, and rituximab. Immune globulin maintained the top spot on the list despite a 20.5% decrease in expenditures compared with the same period in 2011. Of the agents included in this list, enoxaparin experienced the largest decline in expenditures (–36.6%), continuing a downward trend that began in 2010. Of note, generic enoxaparin accounted for 36.7% of the enoxaparin market in nonfederal hospitals in 2012, compared with 25.2% in 2011. Expenditures for piperacillin–tazobactam also had a double-digit decrease (–18.1%), as did those for epoetin alfa (–13.5%). Drugs included in the list that had the largest increases in expenditures in nonfederal hospitals were alteplase (20.8%), trastuzumab (19.6%), rituximab (14.0%), infliximab (12.1%), and oxaliplatin (10.4%).

Beyond the top 15 drugs listed in Table 5, other agents used in nonfederal hospitals had major decreases in expenditures in the nine-month period ending September 30, 2012, compared with the same period in 2011. These included olanzapine (–67.5%, $137.8 million decrease), quetiapine (–41.3%, $63.1 million decrease), coagulation factor VIIa (–79.1%, $61.5 million decrease), levofloxacin (–65.5%, $95.6 million decrease), and cetuximab (–31.0%, $46.9 million decrease). Four iodinated contrast medium agents, which combined represented $592.8 million in expenditures in the first nine months of 2011, experienced a decrease (–13.5%, $79.8 million decrease) in expenditures over the same period in 2012. Iohexol, iodixanol, and ioversol experienced significant decreases in expenditures (–10.4%, –22.1%, and –26.5%, respectively) when compared with the first nine months of 2011 to those of 2012, although iopamidol expenditures experienced a smaller change (–0.76%).

Table 3.
Top 15 Drugs by Expenditures in Clinics in 2012

<table>
<thead>
<tr>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Pegfilgrastim (Neulasta)</td>
<td>2,411,397</td>
<td>11.4</td>
<td>1,919,238</td>
<td>7.2</td>
</tr>
<tr>
<td>Epoetin alfa (Procrit, Epogen)</td>
<td>3,119,524</td>
<td>–16.5</td>
<td>1,870,309</td>
<td>–21.2</td>
</tr>
<tr>
<td>Infliximab (Remicade)</td>
<td>2,255,393</td>
<td>3.2</td>
<td>1,865,160</td>
<td>8.5</td>
</tr>
<tr>
<td>Rituximab (Rituxan)</td>
<td>2,119,656</td>
<td>7.6</td>
<td>1,633,746</td>
<td>5.2</td>
</tr>
<tr>
<td>Bevacizumab (Avastin)</td>
<td>2,092,741</td>
<td>–14.8</td>
<td>1,533,918</td>
<td>–2.1</td>
</tr>
<tr>
<td>Ranibizumab (Lucentis)</td>
<td>1,592,326</td>
<td>23.3</td>
<td>1,101,816</td>
<td>–6.1</td>
</tr>
<tr>
<td>Trastuzumab (Herceptin)</td>
<td>1,328,336</td>
<td>6.8</td>
<td>1,082,530</td>
<td>11.1</td>
</tr>
<tr>
<td>Oxaliplatin (Eloxatin)</td>
<td>840,706</td>
<td>26.3</td>
<td>862,309</td>
<td>6.9</td>
</tr>
<tr>
<td>Varicella vaccine (Varivax, Zostavax)</td>
<td>771,031</td>
<td>10.1</td>
<td>652,645</td>
<td>28.9</td>
</tr>
<tr>
<td>Pemetrexed (Alimta)</td>
<td>804,033</td>
<td>5.5</td>
<td>639,058</td>
<td>7.5</td>
</tr>
<tr>
<td>Denosumab (Xgeva, Prolia)</td>
<td>382,903</td>
<td>1873.0</td>
<td>525,098</td>
<td>119.0</td>
</tr>
<tr>
<td>Zoledronic acid (Zometa, Reclast)</td>
<td>758,485</td>
<td>–9.3</td>
<td>512,328</td>
<td>–11.0</td>
</tr>
<tr>
<td>Pneumococcal vaccine (Prevnar, Prevnar 13)</td>
<td>637,880</td>
<td>–2.6</td>
<td>443,686</td>
<td>–9.1</td>
</tr>
<tr>
<td>Bortezomib (Velcade)</td>
<td>526,431</td>
<td>17.6</td>
<td>400,255</td>
<td>3.9</td>
</tr>
<tr>
<td>Cetuximab (Erbitux)</td>
<td>455,628</td>
<td>4.0</td>
<td>390,627</td>
<td>16.6</td>
</tr>
<tr>
<td>All others</td>
<td>18,715,804</td>
<td>9.0</td>
<td>14,187,464</td>
<td>4.5</td>
</tr>
<tr>
<td>Total</td>
<td>38,812,274</td>
<td>5.7</td>
<td>29,620,187</td>
<td>3.4</td>
</tr>
</tbody>
</table>

*Based on data collected between January 1 and September 30, 2012.

Percent change compared with same period in 2011 (data not shown in table).

Available from one or more manufacturers, distributors, or repackagers by generic name.
expenditures. Antineoplastics were followed by hemostatic modifiers (11.5% of total) and antinefectives (9.2% of total). The class with the largest change from 2011 to 2012 was hospital solutions, declining 13.4%, followed by hemostatic modifiers which decreased by 10.6%. Gastrointestinal agents grew the most (9.7% compared with 2011).

Recent drug approvals. Select novel agents that may receive FDA approval in the United States by the end of 2013 are listed in Table 7, along with FDA review deadlines under the PDUFA. The PDUFA date is the deadline by which FDA must make a decision on a drug’s application (this may be a decision to approve or not approve a drug) after a defined period of review.

Table 4.
Top 20 Antineoplastic Drug Expenditures in Clinics in 2012

<table>
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<tr>
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<td>3.9</td>
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<tr>
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<td>455,628</td>
<td>4.0</td>
<td>390,627</td>
<td>16.6</td>
</tr>
<tr>
<td>Bendamustine (Treanda)</td>
<td>372,628</td>
<td>29.8</td>
<td>324,763</td>
<td>18.2</td>
</tr>
<tr>
<td>Docetaxel (Taxotere)</td>
<td>695,997</td>
<td>−23.0</td>
<td>307,622</td>
<td>−45.9</td>
</tr>
<tr>
<td>Ipilimumab (Yervoy)</td>
<td>225,066</td>
<td>...</td>
<td>253,551</td>
<td>80.0</td>
</tr>
<tr>
<td>Paclitaxel–albumin (Abraxane)</td>
<td>307,197</td>
<td>−1.5</td>
<td>233,666</td>
<td>4.6</td>
</tr>
<tr>
<td>Leuprolide acetate</td>
<td>299,245</td>
<td>1.4</td>
<td>218,014</td>
<td>−2.6</td>
</tr>
<tr>
<td>Fulvestrant (Faslodex)</td>
<td>216,934</td>
<td>76.4</td>
<td>183,718</td>
<td>16.6</td>
</tr>
<tr>
<td>Azacitadine (Vidaza)</td>
<td>225,460</td>
<td>11.9</td>
<td>182,149</td>
<td>8.6</td>
</tr>
<tr>
<td>Decitabine (Dacogen)</td>
<td>143,991</td>
<td>15.7</td>
<td>117,451</td>
<td>11.7</td>
</tr>
<tr>
<td>Cyclophosphamide</td>
<td>74,064</td>
<td>94.7</td>
<td>92,833</td>
<td>74.8</td>
</tr>
<tr>
<td>Cabazitaxel (Jevtana)</td>
<td>146,763</td>
<td>87.2</td>
<td>88,859</td>
<td>−25.1</td>
</tr>
<tr>
<td>Eribulin (Halaven)</td>
<td>87,769</td>
<td>5044.7</td>
<td>82,864</td>
<td>35.8</td>
</tr>
<tr>
<td>Liposomal doxorubicin (Lipodox, Lipodox 50, Doxil)</td>
<td>106,894</td>
<td>−39.1</td>
<td>79,106</td>
<td>−19.6</td>
</tr>
<tr>
<td>Panitumumab (Vectibix)</td>
<td>99,543</td>
<td>5.6</td>
<td>75,185</td>
<td>2.0</td>
</tr>
<tr>
<td>All other antineoplastic drugs</td>
<td>1,200,418</td>
<td>−20.2</td>
<td>760,407</td>
<td>−18.0</td>
</tr>
<tr>
<td>Total</td>
<td>12,656,309</td>
<td>4.4</td>
<td>9,542,631</td>
<td>1.4</td>
</tr>
</tbody>
</table>

*aBased on data collected between January 1 and September 30, 2012.
*bPercent change compared with same period in 2011 (data not shown in table).
*cNot available in 2010.
*dLeuprolide acetate includes the following formulations: Lupron, Lupron Depot, Lupron Depot-3 Month, Lupron Depot-4 Month, Lupron Depot-6 Month, Lupron Depot-Ped, and Lupron Dep-Ped 3 Month.

As in the past, many new oncology agents are oral dosage forms (e.g., axitinib, bosutinib, caboza- tinib, enzalutamide, ponatinib, regorafenib, vismodegib); thus, they are unlikely to significantly impact hospital or clinic expenditures because they are not usually initiated during a patient’s hospital stay or administered by a practitioner in the outpatient clinic setting. Health systems with a modest-to-large oncology service line should plan for an increase in expenditures from the use of both ziv-aflibercept and pertuzumab. These agents are considered additions to existing therapeutic options for the treatment of high-incidence cancers. Institutions may see higher usage rates of pertuzumab, because...
it is an add-on to established first-line options for patients with metastatic, human epidermal receptor-2-positive breast cancer.

The impact of the other novel injectable antineoplastic agents on an institution’s expenditures will depend on the volume of patients being treated for multiple myeloma (carfilzomib), chronic myeloid leukemia (omacetaxine), and acute lymphocytic leukemia (liposomal vincristine). Larger tertiary institutions that routinely use high-dose methotrexate should prepare for the use of glucarpidase to increase inpatient drug expenditures, but the use of this therapy is unpredictable.

**Patent expirations.** The growing availability and subsequent rapid use of generic drugs continue to have a substantial moderating influence on prescription drug expenditures. Compared with 2012, fewer blockbuster drugs (annual sales of more than $1 billion) are expected to lose patent protection in 2013. Key products that may face generic competition in the coming year based on various sources are listed in Table 9.5.

Several agents that were blockbuster drugs or those that occupy therapeutic niches have recently lost patent protection: atorvastatin, clopidogrel, escitalopram, montelukast, pioglitazone, quetiapine, and oral vancomycin. These newly available generic agents are expected to have a significant impact on expenditures in the outpatient setting, though some savings may be realized by hospitals as well. Expenditures on generic non-injectables (not including branded generics) in the retail pharmacy setting increased by 19.7% for the year through September 2012, with volume and mix (3.0% increase) and use of newly available products (22.1% increase) contributing to the increase, despite a reduction in price of 5.4% during that time. A similar increase (21.9%) in the sale of these agents occurred in nonfederal hospitals; however, noninjectable agents accounted for only 28.6% of expenditures in this setting compared with 91.7% of expenditures in the retail setting.3

While a generic version of the sildenafil formulation used to treat pulmonary hypertension (Revatio, Pfizer) became available in 2012, a key patent for the formulation used to treat erectile dysfunction was upheld, and generic availability of this agent is not expected until 2020.

Two blockbuster drugs, fenofibrate and duloxetine, are projected to lose patent exclusivity in 2013 (Table 9).5 Several additional high-cost agents (e.g., extended-release niacin, rabeprazole) are also expected to lose patent protection during that time. While this is fewer than the number of blockbuster agents that lost exclusivity during 2012, significant savings are expected to be realized through the reduced price of these agents. The release of generic fenofibrate is especially interesting due to changes made by the manufacturer of brand-name fenofibrate, who has reformulated the product multiple times and gained additional patent protection.

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**Figure 2.** Distribution of expenditures for oral oncology agents by setting, 2007–12.3 HMO = health maintenance organization.
protection, making generic substitution not possible. Despite previous approval of fenofibrate products by FDA beginning in 2002, these reformulations have limited diffusion of generic fenofibrate products until now. Teva, Impax Labs, Mylan, Ranbaxy, Valeant, and Lupin have received approval from FDA to market fenofibrate. Numerous manufacturers have received tentative approval to market duloxetine, including Torrent Pharmaceuticals, Impax Labs, Lupin, Dr. Reddy’s Labs, Zydus Pharmaceuticals (and Zydus Healthcare), Sun Pharmaceuticals, Wockhardt, Sandoz, Aurobindo Pharma, and Teva.

Table 5.
Top 15 Drugs by Expenditures in Nonfederal Hospitals in 2012

<table>
<thead>
<tr>
<th>Drug</th>
<th>2011 Expenditures ($ Thousands)</th>
<th>Percent Change from 2010</th>
<th>2012 Expenditures ($ Thousands)a</th>
<th>Percent Change from 2011b</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immune globulinc</td>
<td>1,255,739</td>
<td>9.3</td>
<td>750,520</td>
<td>–20.5</td>
</tr>
<tr>
<td>Infliximab (Remicade)</td>
<td>794,024</td>
<td>8.3</td>
<td>659,503</td>
<td>12.1</td>
</tr>
<tr>
<td>Rituximab (Rituxan)</td>
<td>743,312</td>
<td>10.2</td>
<td>627,233</td>
<td>14.0</td>
</tr>
<tr>
<td>Pegfilgrastim (Neulasta)</td>
<td>660,328</td>
<td>7.5</td>
<td>513,923</td>
<td>4.5</td>
</tr>
<tr>
<td>Enoxaparin (Lovenox)d</td>
<td>833,752</td>
<td>–20.2</td>
<td>415,666</td>
<td>–36.6</td>
</tr>
<tr>
<td>Bevacizumab (Avastin)</td>
<td>465,513</td>
<td>–13.1</td>
<td>378,433</td>
<td>7.4</td>
</tr>
<tr>
<td>Daptomycin (Cubicin)</td>
<td>417,002</td>
<td>23.2</td>
<td>332,929</td>
<td>8.9</td>
</tr>
<tr>
<td>Alteplase (Activase, Cathflo Activase)</td>
<td>369,425</td>
<td>22.6</td>
<td>327,622</td>
<td>20.8</td>
</tr>
<tr>
<td>Bivalrudin (Angiomax)</td>
<td>380,687</td>
<td>3.0</td>
<td>292,933</td>
<td>10.1</td>
</tr>
<tr>
<td>Pipercillin–tazobactam (Zosyn)d</td>
<td>448,824</td>
<td>–31.3</td>
<td>286,957</td>
<td>–18.1</td>
</tr>
<tr>
<td>Filgrastim (Neupogen)</td>
<td>370,370</td>
<td>0.7</td>
<td>283,239</td>
<td>1.7</td>
</tr>
<tr>
<td>Linezolid (Zyvox)</td>
<td>369,534</td>
<td>3.1</td>
<td>272,499</td>
<td>–2.6</td>
</tr>
<tr>
<td>Epoetin alfa (Procrit, Epogen)</td>
<td>388,806</td>
<td>–21.7</td>
<td>258,550</td>
<td>–13.5</td>
</tr>
<tr>
<td>Trastuzumab (Herceptin)</td>
<td>280,449</td>
<td>9.8</td>
<td>247,968</td>
<td>19.6</td>
</tr>
<tr>
<td>Oxaliplatin (Eloxatin)d</td>
<td>306,976</td>
<td>43.9</td>
<td>246,401</td>
<td>10.4</td>
</tr>
<tr>
<td>All others</td>
<td>20,199,075</td>
<td>1.2</td>
<td>15,107,444</td>
<td>0.9</td>
</tr>
<tr>
<td>Total</td>
<td>28,283,816</td>
<td>0.8</td>
<td>21,001,820</td>
<td>–0.2</td>
</tr>
</tbody>
</table>

aBased on data collected between January 1 and September 30, 2012.
bPercent change compared with same period in 2011 (data not shown in table).
cImmune globulin includes the following products: Baygam, Carimune NF, Flebogamma, Flebogamma DIF, Gamastan S/D, Gamimune N, Gammagard Liquid, Gammagard S.D., Gamunex, Gamunex-C, Privigen, Vivaglobin.
dAvailable from one or more manufacturers, distributors, or repackagers by generic name.

Table 6.
Top 10 Therapeutic Classes in Nonfederal Hospitals in 2012

<table>
<thead>
<tr>
<th>Therapeutic Class</th>
<th>2011 Expenditures ($ Thousands)</th>
<th>Percent Change from 2010</th>
<th>2012 Expenditures ($ Thousands)a</th>
<th>Percent Change from 2011b</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antineoplastic agents</td>
<td>3,965,460</td>
<td>4.2</td>
<td>3,166,745</td>
<td>5.8</td>
</tr>
<tr>
<td>Hemostatic modifiers</td>
<td>3,527,441</td>
<td>–10.3</td>
<td>2,415,081</td>
<td>–10.6</td>
</tr>
<tr>
<td>Antiinfectives, systemic</td>
<td>2,821,727</td>
<td>–8.4</td>
<td>1,942,031</td>
<td>–9.8</td>
</tr>
<tr>
<td>Blood growth factors</td>
<td>1,983,557</td>
<td>–3.3</td>
<td>1,443,666</td>
<td>–3.3</td>
</tr>
<tr>
<td>Hospital solutions</td>
<td>1,782,160</td>
<td>5.3</td>
<td>1,160,435</td>
<td>–13.4</td>
</tr>
<tr>
<td>Gastrointestinal agents</td>
<td>1,286,800</td>
<td>4.1</td>
<td>1,047,530</td>
<td>9.7</td>
</tr>
<tr>
<td>Respiratory therapy agents</td>
<td>1,189,049</td>
<td>8.1</td>
<td>919,811</td>
<td>4.2</td>
</tr>
<tr>
<td>Biologicals</td>
<td>1,112,541</td>
<td>6.3</td>
<td>916,949</td>
<td>6.6</td>
</tr>
<tr>
<td>Diagnostic aids</td>
<td>1,234,994</td>
<td>–5.8</td>
<td>854,497</td>
<td>–8.7</td>
</tr>
<tr>
<td>Anesthetics</td>
<td>853,041</td>
<td>3.0</td>
<td>676,762</td>
<td>9.8</td>
</tr>
<tr>
<td>All others</td>
<td>8,527,088</td>
<td>6.7</td>
<td>6,458,311</td>
<td>5.8</td>
</tr>
<tr>
<td>Total</td>
<td>28,283,858</td>
<td>0.8</td>
<td>21,001,820</td>
<td>–0.2</td>
</tr>
</tbody>
</table>

aBased on data collected between January 1 and September 30, 2012.
bPercent change compared with same period in 2011 (data not shown in table).
Although the majority of expenditures for these four agents (fenofibrate, duloxetine, extended-release niacin, and rabeprazole) occur in the community setting, these agents were responsible for $67.4 million in expenses for nonfederal hospitals in the first nine months of 2012. The majority of these expenditures were for duloxetine ($51.0 million). The availability of numerous generic-producing competitors could result in significant reductions in expenditures across all settings, though limited impact is expected in 2013 due to the 180-day exclusivity period provided to the first generic competitor.

In addition, generic availability of two angiotensin II receptor blockers—candesartan and valsartan—as well as rizatriptan for migraines, was anticipated by the end of 2012; however, all have been delayed. The patent for brand-name valsartan expired in September 2012; however, at the time of writing, Ranbaxy has yet to release its generic valsartan product.

**Drug expenditure forecast for 2013.** Several groups provide analysis and projections of trends in drug expenditures, and a comparison of these projections is provided in Table 10. As with our forecast, these estimates were generated through both qualitative analysis of current and future drivers of pharmaceutical expenditures and quantitative analysis of past and current expenditure patterns. It is important to note differences in the projections provided by various sources. The Centers for

<table>
<thead>
<tr>
<th>Drug</th>
<th>Manufacturer</th>
<th>Indication</th>
<th>Route</th>
<th>PDUFA Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerol phenylbutyrate</td>
<td>Hyperion Therapeutics</td>
<td>Urea cycle disorders</td>
<td>Oral</td>
<td>January 23, 2013</td>
</tr>
<tr>
<td>Alogliptin</td>
<td>Furiex Pharmaceuticals</td>
<td>Type 2 diabetes mellitus</td>
<td>Oral</td>
<td>January 27, 2013</td>
</tr>
<tr>
<td>Mipomersen</td>
<td>Genzyme</td>
<td>Homozygous and severe heterozygous familial hypercholesterolemia</td>
<td>Subcutaneous</td>
<td>January 29, 2013</td>
</tr>
<tr>
<td>Rintatolimod</td>
<td>Hemispherex Biopharma</td>
<td>Chronic fatigue syndrome</td>
<td>Oral</td>
<td>February 2, 2013</td>
</tr>
<tr>
<td>Trastuzumab emtansine</td>
<td>Genentech</td>
<td>Breast cancer</td>
<td>I.V.</td>
<td>February 26, 2013</td>
</tr>
<tr>
<td>Apixaban</td>
<td>Bristol-Myers Squibb/Pfizer</td>
<td>Prevention of stroke and systemic embolism in patients with nonvalvular atrial fibrillation</td>
<td>Oral</td>
<td>March 17, 2013</td>
</tr>
<tr>
<td>Granisetron, long acting</td>
<td>A.P. Pharma</td>
<td>Chemotherapy-induced nausea and vomiting</td>
<td>Oral</td>
<td>March 27, 2013</td>
</tr>
<tr>
<td>Cysteamine bitartrate</td>
<td>Raptor Pharmaceutical</td>
<td>Nephropathic cystinosis</td>
<td>Oral</td>
<td>April 13, 2013</td>
</tr>
<tr>
<td>Buprenorphine hydrochloride implant</td>
<td>Titan Pharmaceuticals</td>
<td>Opioid dependence</td>
<td>Subdermal implant</td>
<td>April 29, 2013</td>
</tr>
<tr>
<td>Technetium Tc 99m tilmancept</td>
<td>Navidea Biopharmaceuticals</td>
<td>Lymphatic mapping</td>
<td>Injection at tumor site</td>
<td>April 30, 2013</td>
</tr>
<tr>
<td>Fluticasone furoate-vilanterol</td>
<td>GSK and Theravance</td>
<td>Chronic obstructive pulmonary disease</td>
<td>Inhalation</td>
<td>May 12, 2013</td>
</tr>
<tr>
<td>Gabapentin extended release</td>
<td>Depomed</td>
<td>Menopausal hot flashes</td>
<td>Oral</td>
<td>May 31, 2013</td>
</tr>
<tr>
<td>Melphalan chemosaturation system</td>
<td>Delcath Systems</td>
<td>Unresectable metastatic melanoma in the liver</td>
<td>Percutaneous hepatic perfusion</td>
<td>June 15, 2013</td>
</tr>
<tr>
<td>Tivozainib</td>
<td>AVEO Oncology and Astellas Pharma</td>
<td>Renal cell carcinoma</td>
<td>Oral</td>
<td>July 28, 2013</td>
</tr>
<tr>
<td>Dihydroergotamine inhalation</td>
<td>MAP Pharmaceuticals</td>
<td>Migraine</td>
<td>Inhalation</td>
<td>August 16, 2013</td>
</tr>
</tbody>
</table>

*aFDA = Food and Drug Administration, PDUFA = Prescription Drug User Fee Act, HIV = human immunodeficiency virus, AIDS = acquired immune deficiency syndrome.
bPDUFA date extrapolated based on new drug application submission date and review status (i.e., 10 months for standard review and 6 months for priority review) or specified data provided when available.
Medicare and Medicaid Services reports and projects overall expenditures for all settings. Medco–Express Scripts reports trends and projections in traditional and specialty medications, not the sector in which those medications are purchased.

We developed qualitative estimates of growth in nonfederal hospitals, clinics, and all sectors combined for 2013, considering a number of factors that will influence future drug expenditures. First, as described above, recent expenditure trends have shown significantly lower growth than in previous decades. In all sectors combined and in the hospital sector, continued generic competition for widely used drugs should moderate expenditure increases. Although fewer blockbuster agents will lose patent protection in 2013 than in 2011 and 2012, 2013 will represent the first full year of widespread generic competition (i.e., after the expiration of the 180-day exclusivity period) for many of the agents approved in 2011 and 2012.

While significant changes resulting from the Patient Protection and Affordable Care Act may be noted in the future, the only element expected to affect pharmaceutical expenditures in the coming year is the mandate to cover contraceptive prescription drugs, which is not expected to have a significant effect on drug expenditures. In 2014, coverage of preexisting conditions will be expanded, and the individual mandate to carry a minimum level of health insurance will be required. This is likely to influence prescription drug expenditures in 2014 and beyond.

Based on the expenditure trends, new drug approvals, and patent expirations described above, we estimate an increase of 1–3% in expenditures overall (all sectors combined). We expect that expenditures for clinic-administered drugs will increase by 2–4%. For the hospital setting, we project a decrease of –0.5% to an increase of 1.5% for 2013.

Discussion

Emerging health care trends, including the continued implementation of health care reform, expansion of accountable care organization development, efforts to reimburse providers on the basis of improving performance, and the growing consolidation of health care into integrated health systems, are rapidly changing health care delivery in the United States. These substantial and fundamental changes make it essential for health-system pharmacy

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**Table 8. Oncology Agents That Received FDA-Approved Labeling in 2012**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Manufacturer</th>
<th>Indication</th>
<th>Route</th>
<th>Approximate Price for 28 Days of Therapy ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Axitinib (Inlyta)</td>
<td>Pfizer</td>
<td>Renal cell carcinoma</td>
<td>Oral</td>
<td>9,900</td>
</tr>
<tr>
<td>Bosutinib (Bosulif)</td>
<td>Pfizer</td>
<td>Chronic myeloid leukemia</td>
<td>Oral</td>
<td>9,200</td>
</tr>
<tr>
<td>Cabozantinib (Cometriq)</td>
<td>Exelixis</td>
<td>Thyroid cancer</td>
<td>Oral</td>
<td>. . . b</td>
</tr>
<tr>
<td>Carfilzomib (Kyprolis)</td>
<td>Onyx Pharmaceuticals</td>
<td>Multiple myeloma</td>
<td>Injection</td>
<td>9,300 c</td>
</tr>
<tr>
<td>Enzalutamide (Xtandi)</td>
<td>Medivation and</td>
<td>Prostate cancer</td>
<td>Oral</td>
<td>8,300</td>
</tr>
<tr>
<td></td>
<td>Astellas Pharma US</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glucarpidase (Voraxaze)</td>
<td>BTG International</td>
<td>Toxic plasma methotrexate</td>
<td>Injection</td>
<td>94,500 d</td>
</tr>
<tr>
<td>Omacetaxine mepesuccinate (Synribo)</td>
<td>Teva Pharmaceutical Industries</td>
<td>Chronic myeloid leukemia</td>
<td>Injection</td>
<td>8,700 e</td>
</tr>
<tr>
<td>Pertuzumab (Perjeta)</td>
<td>Genentech</td>
<td>Breast cancer</td>
<td>Injection</td>
<td>4,900 f</td>
</tr>
<tr>
<td>Ponatinib (Iclusig)</td>
<td>Ariad Pharmaceuticals</td>
<td>Chronic myeloid leukemia and acute lymphoblastic leukemia</td>
<td>Oral</td>
<td>. . .</td>
</tr>
<tr>
<td>Regorafenib (Stivarga)</td>
<td>Bayer HealthCare Pharmaceuticals</td>
<td>Colorectal cancer</td>
<td>Oral</td>
<td>11,200</td>
</tr>
<tr>
<td>Vincristine sulfate liposome injection (Marqibo)</td>
<td>Talon Therapeutics</td>
<td>Acute lymphoblastic leukemia</td>
<td>Injection</td>
<td>. . .</td>
</tr>
<tr>
<td>Vismodegib (Erivedge)</td>
<td>Genentech</td>
<td>Basal cell carcinoma</td>
<td>Oral</td>
<td>9,000</td>
</tr>
<tr>
<td>Ziv-aflibercept (Zaltrap)</td>
<td>Sanofi U.S.</td>
<td>Colorectal cancer</td>
<td>Injection</td>
<td>10,800</td>
</tr>
</tbody>
</table>

*aApproximate cost calculated based on average wholesale price (AWP) listed in Redbook Online. For drugs that are dosed by weight or body surface area, standards of 70 kg and 1.73 m², respectively, were used. FDA = Food and Drug Administration.
*bPrice after dosage adjustment.
*cAWP not available.
*dPrice for one-time bolus dose.
*ePrice for maintenance therapy.
executives and other leaders to develop financial plans and budgets for prescription drug expenditures as accurately as possible. Over the past several years, we have cautioned readers to not use our financial projections as “multipliers” to calculate future expenditure levels in their health systems. Instead, as described previously and in ASHP guidelines, local data must be carefully and systematically incorporated into an organization’s drug expenditure forecast, as well as the external trends relevant to drug expenditures described in this article. This advice has never been more important than it is today.

As health systems expand and become more highly integrated, health-system pharmacy leaders must embrace the pharmacy enterprise concept to improve patient care, align with health care reform, and effectively manage prescription drug expenditures. Leaders who take the pharmacy enterprise approach will be positioned to manage medication use and expenditures across the continuum of care. The data presented in Figure 2 that show the dramatic shift in spending on oral oncology agents over five years from the retail pharmacies to the mail-order setting illustrate how essential it is to monitor shifts in drug expenditures. Because IMS Health does not have a separately defined and maintained channel for drugs from specialty pharmacies, the mail-order pharmacy category also reflects anticancer agents mailed from specialty pharmacies. Therefore, the growth of specialty pharmacy may be the cause of this channel shift, and pharmacy leaders must proactively monitor and plan a strategy for specialty pharmaceuticals for cancer and patients with other diseases.

Beyond drug use and expenditures, pharmacy leaders must take a proactive approach to staying aware of developments in health policy, health finance, technology,
and practice in order to respond to new phenomena in a confident and thoughtful manner. Even the most assiduously developed, strategic, tactical, and financial plans must remain flexible to accommodate unexpected events; changes that are known to be on the horizon must be considered in order to be responsive to unexpected events.

Besides broader trends in health care and pharmacy, this article includes key information to help guide planning for pharmaceuticals. Another resource that has recently been published and that provides additional guidance must also be read and understood by health-system pharmacy leaders: "Pharmacy Forecast 2013–2017: Strategic Planning Advice for Pharmacy Departments in Hospitals and Health Systems." The report summarizes the results of a survey exploring eight domains in which emerging trends are likely to challenge pharmacy practice leaders. It also includes recommendations to guide planning in pharmacy departments. We strongly urge readers to review and use this report in financial and strategic planning. The complete report is freely available at www.ashpfoundation.org/pharmacyforecast.

Our projections focus on factors likely to influence prescription drug expenditures in 2013, but pharmacy leaders should carefully monitor other developments that are expected to influence prescription drug expenditures beyond 2013, including the continuing implementation of the approval pathway for biosimilars and actions to facilitate the introduction of generic drugs.

Biological agents are essential but often expensive therapies; they are well represented on the list of top clinic (oncology and non-oncology) expenditures. An opportunity for decreasing hospital and health-system costs exists with biosimilars, which are copies of biological agents (not manufactured by the original, innovator company) and are approved through an abbreviated pathway. The legal framework for approval of biosimilars was established through the Biologics Price Competition and Innovation (BPCI) Act of 2009, which became law in March 2010. Although a number of unresolved issues remain, further details of the regulatory process to implement approval of biosimilars through the BPCI Act became available when FDA released a series of draft guidances on biosimilars in early 2012. These guidances provide information related to scientific considerations when demonstrating biosimilarity and on quality considerations when developing biosimilars. These documents also state that a biosimilar agent’s label will contain information explicitly stating whether the product is deemed to be interchangeable with the reference product.

Because biosimilars are not a new concept in Europe, the processes proposed by FDA can be compared with regulations established by the European Medicines Agency. Legislation first established a European biosimilar approval pathway in 2004, and the first biosimilar product was approved in 2006. Future development of the biosimilar pathway in the United States is expected to continue to draw on the European biosimilar experience.

An alternative pathway for noninnovator biological products to reach the market is through completing a full development program and submitting a new BLA. This approach has been taken for a new granulocyte colony-stimulating factor product, tbo-filgrastim (Teva), which was approved by FDA in 2012. Because the product was approved through a full BLA, this product is not bio-
similar to the innovator filgrastim product (Neupogen, Amgen), and when approval of the product was announced, FDA made it clear that the product is not a biosimilar. The manufacturer of tbo-filgrastim announced that the earliest the product will be available is November 2013; therefore, the product does not represent a significant opportunity for cost savings in 2013. Approval of this noninnovator biological agent and release of the draft FDA guidance for biosimilars represent substantive progress toward competition and subsequent savings for expensive biological products. Pharmacy leaders should continue to carefully monitor biosimilar developments over the next several years.

The introduction of generic medications can be slowed when the innovator company pays generic manufacturers to delay introduction of their generic product (“pay to delay”). While legislation barring such

### Table 10. Projections of Changes in Drug Expenditures

<table>
<thead>
<tr>
<th>Projection Source and Type of Expenditure</th>
<th>Projected Expenditure Increase (%) from 2012 to 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Centers for Medicare and Medicaid Services</td>
<td></td>
</tr>
<tr>
<td>Total national health</td>
<td>3.8</td>
</tr>
<tr>
<td>Total drug</td>
<td>2.4</td>
</tr>
<tr>
<td>Express Scripts–Medco</td>
<td></td>
</tr>
<tr>
<td>Traditional drug</td>
<td>1.6</td>
</tr>
<tr>
<td>Specialty drug</td>
<td>19.0</td>
</tr>
<tr>
<td>Authors</td>
<td></td>
</tr>
<tr>
<td>Total drug</td>
<td>1 to 3</td>
</tr>
<tr>
<td>Nonfederal hospital drug</td>
<td>–0.5 to 1.5</td>
</tr>
<tr>
<td>Clinic drug</td>
<td>2 to 4</td>
</tr>
</tbody>
</table>
arrangements has not progressed through Congress, significant action related to pay-for-delay agreements has occurred over the past year. The U.S. Court of Appeals for the Third Circuit ruled in July 2012 that pay-for-delay agreements between pharmaceutical manufacturers are anticompetitive.\textsuperscript{51} The Federal Trade Commission has requested that the Supreme Court review a different case regarding a pay-for-delay arrangement between Abbott Laboratories and three generic manufacturers.\textsuperscript{52} Final action in these cases will influence the speed at which first-time generic products become available.

Our forecast has several limitations. The primary source of our drug expenditure trend data was IMS Health NSP data through the end of September 2012, but expenditure patterns may change in the last quarter of 2012. This may be especially important for drugs that have seasonal fluctuations in utilization, like antimicrobials. IMS Health has a robust process to review, verify, and update data; therefore, data may be revised in the future, which could influence trend data and our projections. Empirical computation of the expected change in expenditures is limited, and the forecast projections were decided after carefully analyzing key trends. Further, we relied on reviews of key trends from various sources, but some important trends may have been missed. Due to these limitations, our forecasts are expressed in ranges, reflecting our uncertainty of the data analyzed.

Conclusion
For 2013, we project a 1–3\% increase in total drug expenditures across all settings, a 2–4\% increase in expenditures for clinic-administered drugs, and a 0.5\% decline to 1.5\% increase in hospital drug expenditures. Health-system pharmacy leaders should carefully examine their own local drug-utilization patterns to determine their own organization's drug expenditure forecast.

References
3. IMS Health National Sales Perspectives. Analysis conducted by the authors. Analysis conducted November 2012.


