Walgreens’ Sale of Majority Stake in Its Infusion Unit Stresses Sector’s Importance

Almost four months to the day from when a news report suggested that Walgreen Co. was looking for a buyer to purchase a majority stake in its infusion business, the company now known as Walgreens Boots Alliance Inc. has unveiled its plans to restructure. Private-equity group Madison Dearborn Partners, LLC (MDP) has agreed to purchase a majority stake in Walgreens Infusion Services.

The companies did not disclose any financial information. But the Sept. 23 Reuters article that broke the news that Walgreens was seeking a buyer said that “a deal could value that division at around $1.5 billion.”

Much of the motivation behind the deal, say various sources, was Walgreens’ plan to purchase the remaining 55% it didn’t already own of Alliance Boots GmbH, a transaction that was completed shortly after the beginning of the year. By selling a majority stake in the unit, Walgreens could raise some funds to help offset that buyout.

According to Walgreens, the infusion unit has more than 30 years of experience and “is one of the nation’s largest providers of home and alternate treatment site infusion services.” It has “89 infusion pharmacies and 110 alternate treatment sites in 40 states, approximately 4,700 employees and the ability to serve more than 90 percent of the U.S. population. Its clinical personnel, including nurses, pharmacists, technicians and dieticians, treat patients who are managing a broad range of acute and chronic conditions.”

continued on p. 10

High Specialty Drug Prices, PAs Will Cause Some Angst; Biosimilars May Help

The drug industry focus on specialty pharmaceuticals will continue in 2015, spurred by issues including high prices, biosimilars, personalized medicine and prior authorization (PA).

Specialty drug prices will continue to garner a lot of attention. Jon Hamrick, executive vice president, biotech and specialty services for Therigy, tells SPN that “Everyone will be watching closely to see how Express Scripts’ preference for AbbVie’s Viekira Pak plays in the market. To the degree they are successful in moving share to the new market entrant, pricing strategies in competitive specialty categories will be influenced.”

According to Debbie Stern, senior vice president, strategy and business development oncology and specialty drugs at CareCore National, “Based on the recent activity by Express Scripts and CVS Health on their formulary selection, it looks like payers may have the upper hand in addressing some of the costs. Pharma should expect more of this activity, and payers need to be willing to flex their muscle, assuming they can support their decisions with clinical efficacy and minimal safety issues.”

“Not only the cost of new drugs, but the significant price increases that are not tied to anything will continue to encourage discussion,” says Sean Karbowicz, Pharm.D.,
The path towards viable biosimilars in the U.S. market will continue forward, though several key regula-

Biosimilars Could Finally Arrive in U.S.

With the FDA’s Oncologic Drugs Advisory Committee unanimously voting for approval of the first drug to go through the biosimilar pathway, 2015 could finally see the launch of these therapies (SPN 1/15, p. 1). Payers are hoping these products will offer some price relief, but there are issues they should consider now. According to Hamrick, “There will be fundamental differences between the biosimilar and generic business models. For example, manufacturers of biosimilars are recognizing that they will need to provide product support services, and in some cases manage distribution strategy, in a fashion similar to the originator branded products.”

And Russel Allinson, Therigy CEO and chief clinical officer, maintains that “The key will be how far the FDA goes with their guidance — will these products be simply ‘biosimilar,’ or will they be ‘interchangeable’? It seems unlikely now that there will be an ‘interchangeable’ designation from FDA.” If that happens, chief pharmacy officers and chief medical officers “at PBMs, health plans and health systems will need to decide on interchangeable. Will prescribers accept that products are interchangeable, or will they resist the designation without FDA approval? Will Medicare and Medicaid plans be more likely to assume interchangeable to get some cost savings vs. other health plans?”

director, Rx policy and clinical business development for OmedaRx Pharmacy Services. He tells SPN that the pharma industry “insists that the prices are necessary to support development of new products, but it’s hard to identify any other industry where that’s sustainable for any length of time. The uproar will get louder and louder. That being said, we can’t underestimate the impact of accountable health care organizations and how honest, transparent discussions with patients, doctors and payers about the value of these costly medications will influence medication use. As providers are incentivized to improve real, meaningful outcomes (and many of these costly new products have no data they deliver significant value), we may start to see trends shift a bit.”

“Manufacturers cannot continue the pattern of ratcheting up drug cost per course somewhat above the most recently launched drug in its class,” maintains Elan Rubinstein, Pharm.D., founder and principal of EB Rubinstein Associates. “While that has worked to date, the frog in the increasingly hot water is beginning to notice. Don’t expect the frog to wait until it’s almost boiled alive, when it can no longer jump.”

Stephen Cichy, founder and managing director at Monarch Specialty Group, LLC, tells SPN that “we’re seeing a multitude of challenges that are putting pressure on the specialty pharmacy industry as we move into 2015. Pricing and economic pressure is by far the most pressing issue for most stakeholders, as upfront costs to patients and payers for accessing specialty biologics continues to grow, and operating margins for service providers continues to narrow.”

Cichy adds that the current hepatitis C environment “relating to drug pricing illustrates just how difficult it is for health plans to control for cost, accessibility and affordability with innovative new biologics. In this case, while the average cost of the new Sovaldi treatment is $86,000, it’s also possible that hep C results in a liver transplant which could cost upwards of $580,000. Going forward, a more complete picture of pharmaceutical pricing and value will be needed in order to help better guide payer management strategies.”

And the hepatitis C category will continue to be hot in terms of the pipeline. Lily P. Doung, Pharm.D., vice president, clinical programs for Therigy, says that “2014 was an exciting year, as a few new all-oral drug regimens were approved for the treatment of chronic hepatitis C. Following the 2014 projection, new HCV [i.e., hepatitis C virus] treatment options will continue to come to market in 2015 that offer more suitable treatment choices to different patients with this chronic disease state.”

tory and legislative issues have yet to be resolved," notes Cichy. "Apart from the still uncertain regulatory pathway, we continue to have many unknowns regarding product naming, nomenclature, and interchangeability. On the legal front, we’re seeing significant defense tactics by originator manufacturers, including IP and patent extension, which complicates the timeframe for new market development. There’s also a whole host of downstream market issues such as uncertain pricing models, physician adoption and patient utilization should biosimilars be approved.”

Gillian Woollett, senior vice president at Avalere Health LLC, tells SPN that “the payer community, with Express Scripts and Aetna in the lead, has been more aggressive in tying the future of biosimilars to the broader debate regarding the price of specialty products. The outcome of these discussions will also shape biosimilar sponsors’ commercial strategy on pricing and contracting and the level of investment needed for prescriber detailing. Savings in other markets from biosimilars have varied extensively. The savings depend on the therapeutic area, pricing strategy of the innovator, who makes the decisions and how payments are administered (e.g., Germany is a fast adopter as there are financial incentives; others get big savings through tenders). Also some countries are prepared to switch patients between the biosimilar and the reference repeatedly, which is winnertake-all for the whole market (e.g., Poland); others only recommend change for new patients (e.g., France). Others have expanded the markets as a result of the savings (e.g., UK). In the U.S., the potential for savings will not only be based on the price set by the sponsor, but also how aggressively the payer and provider community is able to establish programs and policies to encourage initiating or switching patients on a biosimilar and engaging the prescribing community.”

**Personalized Medicine Continues to Grow**

With respect to genetic testing and companion diagnostics, “2015 will bring more companion diagnostics and personalized medicine in oncology, and we also expect to see targeted therapies in other areas, such as cardiovascular and diabetes,” says Lakshman Ramamurthy, director at Avalere. “Importantly, many of these companion diagnostics will use panel-based testing — for example, a solid-tumor panel which will look at a variety of mutations, and therefore will be applicable as a companion diagnostic for more than one personalized drug regimen. This is a variation from the current trend, where typically one diagnostic has been linked to one drug.”

“We’ll see new payment arrangements emerge” within this area, Karbowicz says, and “as fee for service changes to a focus on outcomes, patterns in testing will support that.”

In addition, says Ramamurthy, “Regulatory oversight of laboratory developed tests is a big topic to watch this year. What is left to be decided is the regulatory status of laboratory developed tests and how this policy impasse is resolved. This will also have an impact on reimbursement, as payers may begin to use UDI [i.e., Unique Device Identifier], which is only available for FDA-approved tests.”

**Prior Authorization Will Be Issue**

Prior authorization likely will continue to be an issue for some stakeholders. According to Joseph Morse, president and chief operating officer of Therigly, “The administrative challenges related to submission and timely approval of prior authorizations continues to rank as one of the highest issues for prescribers and pharmacies. Some states have mandated timelines for payers to provide responses to prescribers for prior authorization requests and appeals. These regulatory changes are expected to greatly affect key metrics such as a pharmacy’s ‘time-to-fill.’ With that said, technology advancements are still needed to reduce the manual work for prescribers and pharmacies. We see a greater trend for solutions designed for specific specialties (e.g., oncology) rather than use of a single prior-auth platform, due to each specialty having distinct data requirements and operational use cases. Continued progress towards standardization of a true ‘e-prior auth’ is expected but appears limited to cooperative initiatives among subsets of payers.”

Stern tells SPN that she has “concerns about state level regulations that are coming to the forefront related to the use of mandatory PA forms. These forms do not allow for the clinical decision support tools that are being developed to streamline the PA process directly from the doctor’s office. I am most familiar with the California form, which most payers have determined will be required for both pharmacy and medical benefit drugs. This form does not work with pathway programs or other advanced ePA tools.” Stern says she’s “heard anecdotally that [similar legislation] is also active or proposed in at least 12 other states.”

“We understand the intent of the Uniform Prior Authorization Form in California to make the process simpler,” Aetna spokesperson Tammy Arnold tells SPN. “However, we have seen a continued issue with information submitted from providers on the incorrect form, which unfortunately results in an initial denial and additional time required to resubmit the correct form. Additionally, clinical questions cannot be included on the uniform prior authorization form, which slows the process. For example, where allowed, we use a form that is populated to include the relevant clinical questions for the requested medication based on the specific coverage requirements for that medication. This results in a
more efficient process, as the treating provider is aware of the specific clinical information that will be needed and averts additional administrative follow up. We continue to work closely with providers to ensure the most streamlined and effective process possible so that our members have seamless and timely access to the medications they need.”

Contact Therigy through Sara Wilson at sara.wilson@therigy.com, Ramamurthy and Woollett at (202) 207-1300, Stern at dstern@carecorenational.com, Arnold at arnoldtd@aetna.com, Rubinstein at ebra@pacbell.net and Cichy at scichy@monarchsp.com.

**CMS Will Launch Five-Year Oncology Care Initiative in 2016**

On Feb. 12, CMS unveiled a multipayer initiative aimed at providing better oncology care and care coordination for Medicare fee-for-service beneficiaries but at a lower cost to the program.

Developed by the CMS Innovation Center, the Oncology Care Model (OCM) will reimburse providers for episodes of care in the administration of chemotherapy. “Nearly all cancers” will be included in the initiative, which also will allow beneficiaries to have 24-hour access to providers.

Payments to providers will “include financial and performance accountability,” and OCM has a two-part payment system: (1) a per-beneficiary per-month payment of $160 for an episode’s duration for “effectively managing and coordinating care,” and (2) a possible performance-based payment for episodes of care that “will incentivize practices to lower the total cost of care and improve care for beneficiaries during treatment episodes.” The latter payment will be available only for providers who care for people with “high-volume cancers for which it is possible to calculate reliable benchmarks.” CMS estimates that these cancers cover about 90% of Medicare fee-for-service beneficiaries who are getting chemotherapy, and the agency says it will publicize a list of these conditions before participation agreements are made.

Episodes of care are for six months starting with chemotherapy administration per a Part B claim or an initial chemotherapy claim under Part D and will include all Parts A and B services a beneficiary receives during that period of time, as well as some Part D costs. Subsequent episodes beyond the initial six months are possible as well when beneficiaries continue treatment beyond that period of time.

The initiative will focus on three main areas:

(1) “Linking payment to quality of care”;

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**Anthem’s Cancer Care Quality Program: A Blueprint to Improve Care and Reduce Costs**

- What was the motivation behind the Anthem program?
- What was the original plan, and how have the pathways already expanded since the program started?
- What are the specifics of how the program works? For example, how do providers know if a treatment regimen is on-pathway?
- How does the program incorporate biomarkers indicating that patients are appropriate candidates for certain drugs?
- What role do providers play in the pathways?
- How has Anthem communicated with providers as it rolls out the program? What has been the response from the provider community?
- How does this program compare with other pathways programs? What does Anthem see as the pros and cons of different models?

Feb. 18 Webinar Featuring Jennifer Malin, M.D., Ph.D., Medical Director for Oncology at Anthem, Inc. — Listen On-Demand or Get a CD!

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and

(3) “Sharing information more broadly to providers, consumers, and others to support better decisions while maintaining privacy.”

Group practices and sole practitioners who provide chemotherapy for cancer treatment and are enrolled in Medicare may apply to participate in the program. If a group practice participates, all of its physicians who prescribe chemotherapy must participate.

CMS also says it is “seeking the participation of other payers in the model,” including “commercial insurers, Medicare Advantage plans, state programs, and Medicaid managed care plans.” This participation, it says, will “create broader incentives for care transformation at the physician practice level. Aligned financial incentives that result from engaging multiple payers will leverage the opportunity to transform care for oncology patients across a broader population. Other payers would also benefit from savings, better outcomes for their beneficiaries, and information gathered about care quality. Payers who participate will have the flexibility to design their own payment incentives to support their beneficiaries, while aligning with the Innovation Center’s goals for care improvement and cost reduction.”

**Initiative Will Start in Spring 2016**

OCM will start next spring and run for five years. In the first two years, participants will have one-sided risk arrangements, under which they will not be responsible for the difference between the target price and expenditures exceeding it. Starting in the third year, participants may switch to a two-sided risk arrangement on a semianual basis.

Payers that wish to participate must submit letters of intent by March 19 at 5 p.m. Eastern time. Providers have until April 23 at 5 p.m. Eastern to submit letters of intent. All letters of intent should be submitted to Oncology-CareModel@cms.hhs.gov. CMS then will provide a Web link and password by which electronic applications can be submitted. Those are due by 5 p.m. Eastern on June 18. The agency will contact those parties selected for participation within six months of that submission date.

CMS will hold a webinar on the core concepts of the model, including information on how to apply to participate, on Feb. 19 from 12 to 1 p.m. Eastern time. Participants do not need to register in advance. Visit http://innovation.cms.gov/resources/OCMintro.html for more information on the webinar.

For more information on OCM, including letters of intent and application templates, visit http://innovation.cms.gov/initiatives/Oncology-Care.

**Lawmakers Again Introduce Home Infusion Coverage Bills**

The home infusion industry is hoping that the fifth time’s the charm for bills recently proposed in the U.S. Senate and the House that seek to offer comprehensive Medicare coverage for home infusion. The Medicare Home Infusion Site of Care Act of 2015 seeks to amend the Social Security Act to allow the home to be a covered infusion site of care for Medicare beneficiaries. If passed, it would apply to home infusion provided as of Jan. 1, 2016.

When Part D began in 2006, only the drug that was infused was covered under that benefit. The nursing visit and per-diem cost — which includes all services, supplies, equipment and other related costs — were not covered. The situation is the same for Parts A and B. Only if patients meet strict criteria to be considered homebound would those additional costs be covered. So if beneficiaries do not have supplemental insurance to cover these services and cannot cover the costs themselves, then these people would have to be infused in potentially more costly settings such as hospitals, outpatient departments or skilled nursing facilities through which the service would be covered. With most commercial plans, as well as state Medicaid programs, Medicare Advantage plans and federal government plans such as TRICARE, covering comprehensive home infusion care, Medicare’s stance has resulted in a two-tier system.

**Patient Access, Costs Are Issues**

The situation is particularly problematic when frequent visits to outpatient infusion clinics are difficult, such as for patients who live in rural areas, the elderly and the infirm, or patients who require multiple infusions per day. The result is patient-access issues, as well as higher costs from patients being treated in hospitals and nursing homes as opposed to the home setting, contends many throughout the home infusion industry. In addition, patients with compromised immune systems are more likely to be exposed to hospital-acquired infections, boosting the chances that the treatment will be ineffective, meaning additional care and potential hospitalization — as well as additional costs for this care — may be needed.

An Avalere Health LLC analysis commissioned by the National Home Infusion Association (NHIA) and released last summer showed the cost savings inherent in home infusion. Avalere found that Medicare comprehensive coverage of home infusion would produce 10-year savings of $80 million. The analysis assumes the NHIA-proposed $120 Part B per-diem payment for administration services for each day home infusion is provided.

continued
Rep. Eliot Engel (D-N.Y.) introduced H.R.605 on Jan. 28; co-sponsors were Reps. Patrick Tiberi (R-Ohio), Gregg Harper (R-Miss.), Chellie Pingree (D-Maine), John Larson (D-Conn.) and Collin Peterson (D-Minn). It was referred to the Energy and Commerce and Ways and Means committees.

Sen. Johnny Isakson (R-Ga.) introduced S.275 the same day; co-sponsors were Sens. Mark Warner (D-Va.), Kirsten Gillibrand (D-N.Y.), Rob Portman (R-Ohio), Benjamin Cardin (D-Md.) and Sherrod Brown (D-Ohio). The bill was referred to the Committee on Finance.

This is the fifth time since 2006 that lawmakers have introduced legislation to close the coverage gap (SPN 7/11, p. 3) The most recent bill was in 2011.

“Home infusion therapy has been the accepted standard of care within the private sector for more than three decades, providing patients with high-quality infusion care in a setting that is often cheaper and more comfortable than a hospital or doctor’s office — their homes,” said Warner when the bill was introduced. “Medicare should allow physicians, in consultation with their patients, to judge where infusion services are best provided, whether that is at home or another facility.”

The legislation, contended Isakson, “is good for the patient and good for Medicare’s bottom line.”

An industry expert who declines to be identified tells SPN that although similar legislation has been proposed before, “this time it’s a little different,” in part due to the Avalere analysis. “There’s more teeth this time around, and it will be beneficial to the industry if it’s passed.”

And with so many payers stretched to the limit due to ever-rising health care costs, the legislation likely will receive careful consideration this time.


**Merck Will Pull Victrelis From U.S. Market at End of December**

Although hype around the hepatitis C space really geared up in late 2013 with the approval of Gilead Sciences, Inc.’s Sovaldi (sofosbuvir), it was actually two FDA approvals in 2011 that initially brought renewed attention to that therapeutic class. The June 2011 approvals of Vertex Pharmaceuticals Inc.’s Incivek (telaprevir) and Merck & Co., Inc.’s Victrelis (boceprevir) had been widely anticipated, as they were the first oral therapies to treat hepatitis C, and they provided a higher cure rate than the previous regimen of pegylated interferon and ribavirin. But while these protease inhibitors had a tre-

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**Coverage of Incivek and Victrelis by Selected 2015 Health Plans**

<table>
<thead>
<tr>
<th>Health Insurer</th>
<th>State</th>
<th>Health Plan</th>
<th>Drug</th>
<th>Covered</th>
<th>Tier</th>
<th>Rx Cost Share/Limitations</th>
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<td>Specialty</td>
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<td></td>
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</tr>
</tbody>
</table>

*Call 800-521-4323 to receive free copies of other AIS newsletters, including Health Plan Week, ACO Business News, Drug Benefit News and Medicare Advantage News.*
mendous impact when they first launched, by the end of this year, neither will be available in the U.S.

In January, Merck notified the FDA that it would discontinue U.S. availability of Victrelis after December 2015. It clarified that the “discontinuation is not related to product safety or efficacy.” The move follows Vertex’s August announcement that it would stop the sale and distribution of Incivek in the U.S. in October 2014 (SPN 9/14, p. 1).

Sovaldi’s approval came shortly after that of Janssen Therapeutics and Medivir AB’s Olysio (simeprevir), also a protease inhibitor. Those approvals were followed by ones for Gilead’s Harvoni (ledipasvir/sofosbuvir) in October 2014 (SPN 10/14, p. 10) and AbbVie Inc.’s Viekira Pak in December (SPN 1/15, p. 6), prompting a rush from payers to strike deals preferring some of the newer therapies (SPN 1/15, p. 1).

Incivek and Victrelis also suffered from recommendations on hepatitis C treatment released last January by the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America, in collaboration with the International Antiviral Society-USA (SPN 2/14, p. 3). The recommendations supported the use of Sovaldi first for treatment-naïve patients with genotype 1 infection, with an Olysio-based regimen as an alternative. Regimens that include Victrelis and Incivek were deemed “markedly inferior to the preferred and alternative regimens” due to “their higher rates of serious adverse events (eg, anemia and rash), longer treatment duration, high pill burden, numerous drug-drug interactions, frequency of dosing, intensity of monitoring for continuation and stopping of therapy, and the requirement to be taken with food or with high-fat meals.”

When Merck reported fourth-quarter 2014 and full-year earnings Feb. 4, the company said Victrelis revenues had declined each quarter of the past year. In 2013, the drug had total revenues of $428 million, but that dropped to $153 million in 2014, a 64% decline.

Still, according to Gilead, most of the treatment regimens with Incivek and Victrelis were less expensive than those of the newer drugs (SPN 9/14, p. 5). And considering how much pushback the newer drugs have gotten in terms of their prices, perhaps the older therapies may have been an option for payers balking at paying $1,000 per day or more for treatment. In fact, an analysis of a random sample of data from health plans in AIS’s new RxB database shows that most of the sampled plans still cover Incivek and Victrelis (see table, p. 6).

But the bad news, at least in terms of hepatitis C, kept coming for Merck. The company has another hepatitis C drug, grazoprevir/elbasvir (MK-5172/MK-8742), in clinical development, and the FDA had granted it breakthrough therapy designation. That distinction, which companies must apply for, allows drugs representing significant medical advances to potentially gain approval faster.

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### Coverage of Incivek and Victrelis by Selected 2015 Health Plans (continued)

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<th>Tier</th>
<th>Rx Cost-Share/Limitations</th>
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<tr>
<td>MVP Health Care</td>
<td>VT</td>
<td>MVP VT Vitality Bronze HMO 3500 (FRVT-HMO-B-001-S)</td>
<td>Incivek</td>
<td>No</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Oregon's Health CO-OP</td>
<td>OR</td>
<td>SiMPLEsilver HSA Broad Network</td>
<td>Incivek</td>
<td>Yes</td>
<td>Specialty</td>
<td>No charge after $3,000 annual deductible; PA</td>
</tr>
<tr>
<td>Prominence Health Plan</td>
<td>NV</td>
<td>Gold 1 ChoicePlus</td>
<td>Incivek</td>
<td>Yes</td>
<td>Specialty</td>
<td>20% coinsurance; PA</td>
</tr>
<tr>
<td>UnitedHealthcare</td>
<td>MS</td>
<td>UnitedHealthcare Bronze Compass HSA 6275</td>
<td>Incivek</td>
<td>Yes</td>
<td>Non-Preferred</td>
<td>$80 copay after $6,275 annual deductible; QL</td>
</tr>
<tr>
<td>WinHealth Partners</td>
<td>WY</td>
<td>WinHealth Gold HSA with Child Dental</td>
<td>Incivek</td>
<td>Yes</td>
<td>Non-Preferred</td>
<td>10% coinsurance after $1,500 annual deductible</td>
</tr>
</tbody>
</table>

Note: PA = Prior Authorization; QL = Quantity Limit; ST = Step Therapy.

**SOURCE/METHODOLOGY:** RxB: Rx Benefit Design Data, AIS’s new online subscription database of prescription benefit design parameters; formulary status researched online using RxB formulary links. Plans are a collection of individual and small-group plans and were selected randomly for a variety of metal tiers and geographic locations. Visit http://aishealthdata.com/nb for more information, or view demo at http://aishealthdata.com/dashboard/nb/demo.
However, when Merck reported its most recent earnings, the manufacturer also disclosed that the FDA had notified it on Jan. 30 “of its intent to rescind Breakthrough Therapy Designation status for this combination treatment regimen, citing the availability of other recently approved treatments for Genotype 1 patients.” Merck says it “expects to discuss this matter with the FDA and does not expect that it will impact its ability to file an NDA [i.e., New Drug Application] for this combination regimen or the timing of that filing.”

Steve Burman, CEO of specialty pharmacy Burmans, tells SPN that the FDA’s move “kind of makes sense because while it may be a great choice for hep C treatment, it is not a breakthrough treatment. I believe it delays the launch no more than three to six months.” He adds, “The hepatitis C market will be strong for the next seven to 10 years, so depending on its advantages, it will still enter the market in the early stages.” However, he notes that the “Gilead agents are tough to beat,” and Viekira Pak “is about 2% market share at our pharmacy.”

Contact Burman at s.burman@burmansmedical.com and Merck at (800) 444-2080. 

### NEW FDA SPECIALTY APPROVALS

**January 9:** The FDA granted an additional approval to the cobas TaqScreen MPX Test, v2.0 to simultaneously detect and identify HIV and the hepatitis B and C viruses in donations of human whole blood and blood components. F. Hoffmann-La Roche Ltd says its assay is the only FDA-approved test with this capability. Visit http://tinyurl.com/k3hvjlh.

**January 21:** The FDA approved Novartis Pharmaceuticals Corp.’s Cosentyx (secukinumab) to treat moderate-to-severe plaque psoriasis in adults eligible for systemic therapy, phototherapy or a combination of them. The first-in-class injectable is the first interleukin-17A inhibitor approved for the condition and works by binding to IL-17A, which is a trigger for inflammation. Visit www.cosentyx.com.

**January 23:** The FDA approved NPS Pharmaceuticals, Inc.’s Natpara (parathyroid hormone) for the treatment of hypoparathyroidism that is not controlled with calcium and vitamin D. The once-daily injectable should be available in second-quarter 2015, says NPS, which is being acquired by Shire plc in a deal expected to close in the first quarter. NPS has not revealed pricing for the drug. Visit www.natpara.com.

**January 26:** The FDA approved Rockwell Medical, Inc.’s Triferic (soluble ferric pyrophosphate) as an iron replacement product to maintain hemoglobin in adults with chronic kidney disease who require dialysis. The drug can be administered through dialysate directly to the bone marrow during dialysis, ensuring that target hemoglobin levels can be met without iron overload, which can happen when iron is administered intravenously, says the manufacturer. For more information, visit http://tinyurl.com/p64mgm7.

**January 29:** The FDA gave an additional approval to Imbruvica (ibrutinib) for the treatment of Waldenstrom’s macroglobulinemia (WM). The decision makes the capsule the first drug with FDA approval for this rare form of non-Hodgkin lymphoma; this is also Imbruvica’s fourth approval by the agency. Developed and commercialized by Pharmacyclics, Inc. and Janssen Biotech Inc., the drug received breakthrough-therapy, priority-review and orphan-drug designations for this indication. Dosing for WM is three 140 mg capsules once daily. According to website GoodRx, one month of this regimen costs around $9,000 with a coupon. Visit www.imbruvica.com.

### 340B Battle Continues, as HHS Asks For PhRMA Lawsuit’s Dismissal

HHS asked a district court judge on Jan. 27 to dismiss the most recent lawsuit (Pharmaceutical Research and Manufacturers of America v. United States Department of Health and Human Services, Civil Action No. 1:14-cv-01685-RC) over the 340B discount drug program, which PhRMA brought against it in early October. The request was followed by early February filings of amicus curiae briefs by the American Hospital Association and the Safety Net Hospitals for Pharmaceutical Access.

The battle between the entities was started by the Affordable Care Act’s (ACA) expansion of the program, which offers outpatient drugs at discounted rates to certain hospitals. At issue is pricing for orphan drugs, which previously were not subject to 340B pricing. HHS contends that the ACA expanded discount pricing to these drugs but only for non-orphan uses, a stance that the Health Resources and Services Administration (HRSA) set out in a final rule in July 2013 (SPN 8/13, p. 7).
PhRMA initially challenged HRSA’s ability to issue such a rule as well as its interpretation of the ACA’s orphan drug exclusion in a lawsuit (Pharmaceutical Research and Manufacturers of America v. United States Department of Health and Human Services, Civil Action No. 1:13-cv-1501-RC) filed in September 2013 (SPN 10/13, p. 6).

In May 2014, the U.S. District Court for the District of Columbia agreed with PhRMA’s first argument, vacating the final rule (SPN 6/14, p. 12). It did not issue an opinion on the second one. HRSA responded by maintaining that it had issued an interpretive rule as opposed to a legislative one, which it has the ability to do. PhRMA appealed, but the court declined to address HRSA’s interpretation and said the association could file a new lawsuit.

That’s exactly what PhRMA did in October 2014, maintaining that HRSA’s interpretive rule “violates the plain language of the statutory orphan drug exclusion” (SPN 10/14, p. 8). It asked the court to “invalid the July 2014 Rule as final agency action that is ‘arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.’” This second suit is the one HHS now is seeking to have dismissed.

**NEW FDA SPECIALTY APPROVALS (continued)**

**January 29:** The FDA approved Bristol-Myers Squibb Co.’s Evotaz (atazanavir 300 mg/cobicistat 150 mg) for the treatment of HIV in combination with other antiretroviral agents. The tablet combines atazanavir, which is marketed as Reyataz, and cobicistat, marketed as Tybost, and it is taken once daily. Visit www.evotaz.com.

**January 29:** The FDA approved Janssen’s Prezcobix (darunavir 800 mg/cobicistat 150 mg) for the treatment of HIV in combination with other antiretroviral drugs in treatment-naive and -experienced adults with no darunavir resistance-associated substitutions. The tablet combines darunavir, marketed as Prezista, and cobicistat, and it is dosed once per day. Visit www.prezcobix.com.

**February 2:** The FDA approved expanded administration options for Hizentra (immune globulin subcutaneous [human]) to include flexible dosing for people with primary immunodeficiency. The CSL Behring drug now can be self-administered anywhere from daily to biweekly. The FDA initially approved it in March 2010 for weekly dosing and then approved biweekly dosing in September 2013. Visit www.hizentra.com.

**February 3:** The FDA granted accelerated approval to Pfizer Inc.’s Ibrance (palbociclib) in combination with letrozole to treat postmenopausal women with estrogen receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer who have not been treated with an endocrine-based therapy. The agency gave the kinase inhibitor breakthrough-therapy and priority-review designations, as well as accelerated approval. The recommended starting dose is 125 mg once daily for 21 days, followed by seven days off the medication, with 2.5 mg of letrozole given daily for the 28-day cycle. Additional dosing is based on safety and tolerability. Visit www.ibrance.com.

**February 6:** The FDA gave an additional approval to Lucentis (ranibizumab) to treat diabetic retinopathy in people with diabetic macular edema (DME). The agency gave the Genentech, Inc. injectable breakthrough-therapy designation and priority review for this indication, which is the fourth one it has received since its initial approval in 2006. Dosing for this use is 0.3 mg. The Lucentis Direct program gives a 2.4% discount on the wholesale acquisition cost, for a price of $1,142 per 0.3 mg vial. Visit www.lucentis.com.

**Battle Likely Impacted Mega Reg**

The legal battle is widely seen as the reason why HRSA scrapped its planned “mega reg” late last year, withdrawing it from consideration by the Office of Management and Budget on Nov. 13 (SPN 12/14, p. 12). The mega reg was supposed to address the definition of an eligible 340B patient, hospital eligibility criteria and eligibility of off-site facilities. The proposed rule was also supposed to contain compliance requirements for contract pharmacy arrangements, which have rapidly expanded in recent years and could lead to duplicate manufacturer discounts being paid on the same prescriptions to commercial payers and 340B entities.

Instead, HRSA said it will issue a proposed guidance for notice and comment this year “that will address key policy issues raised by various stakeholders committed to the integrity of the 340B program.”

View the latest lawsuit at http://freepdfhosting.com/d55574efbd.pdf. For more information, visit www.hrsa.gov.
Analysis Shows Specialty Drug Prices Rose Almost 10% in 2014

Prices for commonly used specialty drugs increased almost 10% overall last year, and trends in the industry show no signs of inflation slowing any time soon. That’s the word from Truveris, a health information technology company that provides audit services as well as an online pharmacy benefit marketplace, based on its Truveris National Drug Index (NDI), a monthly indicator of the pricing changes taking place for brand, generic and specialty drugs in the U.S.

The company recently reported full-year figures for the first time. Included in the analysis were drugs available in December 2013, and those prices were compared with the drugs’ prices in December 2014. So drugs that launched in 2014 were not included in this analysis.

Rheumatoid Arthritis Category Led Price Hikes

Truveris found that specialty drug prices increased 9.7% during that time, while prices for nonspecialty brand drugs increased 14.8%, and generics’ prices rose 4.9%. According to the firm, the specialty therapeutic categories with the highest price increases were rheumatoid arthritis (11.9%), infertility (11.8%), hormone deficiency (9.25%) and immune disease (7.3%).

Prices are “the actual price paid by the payer or consumer at the point of sale,” explains Bryan Birch, president and CEO of Truveris. Because what payers consider specialty drugs can vary, “we take the basic composite of all lists and review them from a clinical nature” to determine what should be considered in the analysis.

While there is “discounting and a little bit of rebating going on” at the specialty level, “there will be continued escalation in these prices,” Birch tells SPN.

Contact Pete Ottaviano at pottaviano@lakpr.com.

Walgreens Gets Infusion Partner

continued from p. 1

The new company will be independent and privately held, and Walgreens Infusion Services Divisional Vice President Paul Mastrapa will be the CEO.

According to Bill Sullivan, principal consultant with Specialty Pharmacy Solutions LLC, this is a positive move for Walgreens, which “will still be steering the ship but separately from the strategic requirements that the new ‘global’ Walgreens may have.” For its part, MDP brings “cash and relationships that they can leverage to further the growth of the infusion line of business.”

The deal is “fairly consistent” with the rumored deal that Reuters first reported (SPN 10/14, p. 1), says an industry expert who declines to be identified. “We believed the deal would go to a large private-equity firm,…and Madison Dearborn certainly fits the list.” The company has “a track record of investing in health care,” explains the source, who points to MDP-owned VWR Corp., a laboratory distribution company that filed for an initial public offering last year.

“They’re not new to health care, but they’re not a health care-only firm,” the source notes. In addition to health care, MDP’s website lists five other sectors in which the company invests: “basic industries; business and government services; consumer; financial and transaction services; and telecom, media and technology services.”

“I don’t know what to read into” the fact that both companies are based in the Chicago area, says the source, quipping that “the Chicago mafia is still around.” But “I would not have been surprised” if another large private-equity group from outside the area had been the purchaser. Sullivan chalks up the geographic similarities to “coincidence [and] convenience.”

While neither Walgreens nor MDP have said how much the majority stake is, the source says he believes it’s 51%, which, if true, would allow “Walgreens to hold onto a large minimum stake.”

When the rumblings about a deal first surfaced, one source told SPN that by keeping a stake in the company, perhaps Walgreens would repurchase the infusion unit at a later date. This is possible, allows the anonymous source, and “it’s happened before with other companies. It depends on how the deal is structured.” A “more logical” approach would be that each company has the first right of refusal if the other one decides to sell its stake.

Deal Underscores Infusion’s Value

The deal is significant to the overall specialty and infusion services area because it “reiterates the value that home care will be increasingly important due to site-of-service issues and the need for payers to have partners to handle specialty infusion,” asserts Sullivan.

“Both providers and health plans view the infusion benefit as a way to take costs out of the health care system,” contends the anonymous source, who says this likely will lead to “a closer alliance between certain health plans and a narrow network of infusion providers” as “health plans start cracking down on the number of infusion providers” their members can use. But those providers would need to be of enough scale to make this feasible — for example, comparable to a Coram Healthcare Corp., Walgreens or BioScrip, Inc.

The arrangement signals multiple things, maintains the source, mainly that the companies “believe in the infusion segment” and that “the market is ripe for con-
and with Walgreens focused on its Alliance Boots initiative, this arrangement gives it “the opportunity to monetize the infusion unit asset.”

Mike Ellis, vice president, Walgreens specialty pharmacy and infusion services, said when the deal was unveiled that “This agreement will enable us to continue to strengthen the Walgreens infusion offering as part of our broad health care portfolio as we work closely with the new [infusion] company, which will have a dedicated focus on this $14 billion and growing U.S. market.”

The unnamed source tells SPN that estimates he’s seen for annual infusion space revenues have ranged between $9 million and $12 million, “so the market has grown… The market itself still continues to be robust.” One sign of this is the fact that bills recently were introduced in both the U.S. Senate and the House supporting Medicare coverage of the home infusion benefit (see story, p. 5). While similar legislation has been proposed before, “this time it’s a little different,” in part due to an Avalere Health LLC analysis commissioned by the National Home Infusion Association and released last summer showing the cost savings inherent in home infusion. “There’s more teeth this time around, and it will be beneficial to the industry if it’s passed.”

In the infusion segment, “within the last 18 to 24 months, there’s been a fair amount of [merger and acquisition] activity,” points out the source. During that time, a lot of private-equity groups were selling infusion firms, many of which were acquired in the 2007-2008 period. That’s about “the right time to harvest portfolios,” the source maintains (SPN 1/13, p. 9). And while there are “still a number of infusion firms out there, there are only a handful of scale” (SPN 1/15, p. 4).

But there also have been “a number of strategies that have been aggressive,” he notes. BioScrip has been leading the way with acquisitions including InfuScience, Inc. from private-equity firm Cressey & Co. (SPN 9/12, p. 12); CarePoint Partners Holdings LLC from Waud Capital Partners, another private-equity firm (SPN 7/13, p. 1); and HomeChoice Partners Inc. from DaVita HealthCare Partners Inc. (SPN 1/13, p. 5). In addition, “PharMerica is also active and growing within the space,” boosted by deals for Millennium Pharmacy Systems (SPN 10/14, p. 12) and Amerita (SPN 1/13, p. 12), as well as a “significant minority stake” in Onco360 (SPN 12/13, p. 12). And perhaps the most noteworthy agreement of all was CVS Caremark Corp.’s purchase of Coram (SPN 12/13, p. 1).

So with the deal done for Walgreens’ infusion unit, what might be some other companies of scale for potential buyers to consider? The source cites AxelaCare Holdings, Inc., owned by private-equity group Harvest Partners, LP, which itself is “one of the most acquisitive” firms right now…. AxelaCare itself is growing nicely, having done five or six deals under Harvest ownership.” Recent acquisitions include Ambient Healthcare (SPN 1/15, p. 12) and Advanced Care (SPN 10/14, p. 12).

If Harvest Partners were to sell AxelaCare, which it purchased in April 2013, that would make it a “relatively short holding period” compared with the seven or eight years that private-equity groups traditionally hold their acquisitions. However, continues the source, “given where the markets are now,” it may make sense to do just that. “A lot of [financial] sponsors are seeing robust multiples and want to take advantage of” this trend.

Contact Sullivan at wsullivan@specialtyrxsolutions.com and Walgreens’ Jim Cohn at (847) 315-2950.

**NEWS BRIEFS**

- Some exchange plans place all drugs available to treat certain conditions on the specialty tier of their formularies, according to an Avalere Health LLC analysis. The firm looked at 20 classes of specialty and primary care drugs, and found that in five classes, many plans put all the drugs in a class, including generics, on the specialty tier. Of the five, two have therapeutic categories with generics available, protease inhibitors and multiple sclerosis (MS) agents, and 29% of plans in 2015 have all the protease inhibitors in the highest tier, up from 16% last year. In the MS class, 51% of plans put all the drugs in the specialty tier, up from 42% last year. However, within the antiangiogenics class, 60% of plans this year placed all the drugs in the top tier, a drop from 67% last year. View the analysis at http://tinyurl.com/lyg3km3.

- Rite Aid Corp. said Feb. 11 that it will acquire Envision Pharmaceutical Services for $2 billion. Among PBMs EnvisionRx’s offerings is Orchard Pharmaceutical Services, which provides mail-order and specialty pharmacy services, and Design Rx, LLC, which provides fertility services. In a Drug Channels blog posted the morning the deal was announced, Adam Fein, Ph.D., maintained that “Rite Aid now has a legitimate specialty growth platform.” In addition, he says, EnvisionRx “mail and specialty pharmacies currently buy drugs from AmerisourceBergen. Once the deal closes, EnvisionRx...
NEWS BRIEFS (continued)

will purchase drugs via Rite Aid’s partnership with McKesson.” EnvisionRx’s projected 2015 revenues are approximately $5 billion. Both companies’ boards of directors unanimously approved the deal, which is expected to close by September. EnvisionRx will operate as a wholly owned subsidiary of Rite Aid, with its headquarters remaining in Twinsburg, Ohio, and will be led by current EnvisionRx CEO Frank Sheehy. Contact Rite Aid’s Matt Schroeder at (717) 214-8867.

◆ Amerita, Inc. acquired Coastal Pharmaceutical Services Corp., which operates as InfusionRx. The companies did not disclose financial details of the deal. InfusionRx offers home infusion and pharmacy services, including specialty pharmacy services, for people treated outside the hospital setting. Through the acquisition, Amerita, a subsidiary of PharMerica Corp., will expand its presence in Southern California. Contact PharMerica’s David W. Froesel, Jr., at (502) 627-7950.

◆ Artemetrx Specialty Drug Solutions, LLC launched a specialty drug consulting solution known as Specialty Drug Advisor. The offering helps plan sponsors manage their specialty drug spend in both the pharmacy and the medical benefits. The program is an expansion of Artemetrx’s Specialty Diagnostic solution. Features include claims reviews, pipeline oversight, health plan and PBM performance auditing and oversight, and monitoring of drug spend aspects such as reimbursement and site-of-care optimization. Contact Tina Payne Hunt at (615) 891-4993.

◆ Pharmaceutical wholesaler Rochester Drug Cooperative and Aureus Health Services launched a specialty pharmacy services program for RDC’s independent community pharmacy clients. The program will be known as Quality Care Specialty Pharmacy Program, and it is available now to RDC customers in southern Connecticut, New Jersey, New York, eastern Ohio and Pennsylvania, with plans to expand to other areas. Aureus, a national specialty pharmacy and health management company, will provide specialty pharmacy services to help RDC pharmacies support patients and physicians. RDC is owned by independent pharmacies and has about 250 shareholders. Contact RDC’s Lanny Doud at (800) 333-0538 or Aureus’ Portia Capuli at (412) 275-6786.

◆ CareCentrix will provide home care benefit management services for Horizon Healthcare Services, Inc. The five-year deal will cover home health services, including durable medical equipment and home infusion, for Horizon’s more than 3.7 million members. CareCentrix has a national network of home infusion, specialty pharmacies and nursing agencies, and the company manages medical and specialty pharmacy services, among other offerings. Contact CareCentrix through Aaron Moore at aaronmoore@hillenby.com.

◆ Catamaran Corp. launched a new clinical outcomes-based program to manage the treatment of hepatitis C. The company’s specialty pharmacy, BriovaRx, will monitor patients in order to increase their adherence to treatment. Catamaran also named the Gilead Sciences, Inc. hepatitis C therapies Harvoni (ledipasvir/sofosbuvir) and Sovaldi (sofosbuvir) exclusive options on its National and Value Formularies (SPN 1/15, p. 1). Commercial clients using one of these formularies can participate in the BriovaRx program, as can clients with a custom formulary that opt into the program. Contact Lauren Denz at lauren.denz@catamaranrx.com.

◆ PEOPLE ON THE MOVE: BioScrip, Inc. says Hai Tran, senior vice president, chief financial officer and treasurer, will resign March 27. The company has hired an executive search firm to find his replacement….Diplomat Pharmacy, Inc. named Susan O. Faust vice president of specialty infusion and market development. She previously was vice president of specialty services at Medco Health Solutions….Managed Health Care Associates, Inc. appointed John Campo vice president of trade relations and contracting for its specialty pharmacy solutions segment. He has more than 18 years of experience in specialty pharmacy, payer and consulting roles, as well as with pharma manufacturers….Onco360 Vice Chairman and Chief Strategy Officer Burt Zweigenhaft will retire May 8; he’s been with the company since 2007. He will continue to serve as co-chairman of the Association of Value Based Cancer Care and vice president of the National Specialty Pharmacy Association….ProCare Rx named Nick Opalich president and chief operating officer of Western PBM operations. He was previously managing partner for Strategica Health Care Partners, LLC.
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