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# SPECIALTY PHARMACY NEWS

**News and Strategies for Managing High-Cost Specialty Products**


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## Horizon Invests in Oncology Firm COTA To Help Docs Offer Patient-Centered Care

Horizon Blue Cross and Blue Shield of New Jersey is hoping that its recent investment in COTA, Inc., a technology company focused on oncology management, will help it transform the delivery of health care. The deal, says the Blues plan, will help it to assist physicians in providing patient-centered care that's focused on value and not volume.

The firm shares its name with its product, a cloud-based data platform that offers real-time clinical outcomes and cost-analysis data for cancer care. More than 100 practicing oncologists and national leaders in cancer biostatistics and reimbursement contributed data to it. The offering is able to sort patients according to very specific subsets of information and provide outcomes tracking in areas such as overall survival, progression-free survival and costs. When providers enter detailed information on their patients, they are able to see how that experience compares with other similar ones, which in turn allows them to make better treatment decisions by narrowing down the most effective approaches.

COTA — which stands for "Cancer Outcomes Tracking and Analysis" — "provides oncologists a number of actionable clinical and financial reports for the patients they are caring for," explains Kelly Choi, M.D., the firm's chief operating officer. "The key is that COTA can parse down to the finest of patient subtypes within a particular type of cancer. As an example, for a particular subtype of breast cancer, an oncologist

*continued on p. 11*

## Walgreens Reportedly Is Looking for Buyer To Purchase Majority Stake in Infusion Unit

Walgreen Co. allegedly is looking for an investor to purchase a majority stake in its infusion unit, according to a Sept. 23 Reuters article that cited four anonymous people who were familiar with the situation.

Walgreens Infusion Services, the largest infusion provider in the country, has annual earnings before interest, taxes, depreciation and amortization of about $1.5 billion, said one of those sources. The purchaser would receive slightly more than 50% of the company, said the article, which added that Walgreens has retained Bank of America Corp. to manage the potential transaction. Walgreens' website says the unit employs more than 1,400 clinicians. According to Michael Polzin, a Walgreens spokesperson, the unit has 89 infusion and respiratory services facilities.

Polzin tells *SPN* that "regarding the Reuters story, I'd only say that we don't comment on rumors or speculation involving any of our businesses."

Walgreens has built up the infusion unit over the years, with perhaps the most significant deal being its 2010 purchase of Omnicare, Inc.'s home infusion business in exchange for Walgreens' long-term care pharmacy business *(SPN 10/10, p. 1)*. More recently it acquired Crescent Healthcare, Inc. in February 2012 for about $73 million *(SPN 3/12, p. 1)*.

*continued*

Asked whether it's likely that such a deal happens, an industry expert who declines to be identified tells *SPN*, "I think so." He points to CVS Caremark Corp.'s purchase of Coram Healthcare Corp. for about $2.1 billion earlier this year *(SPN 12/13, p. 1)*. The Walgreens deal would follow "the most comparable transaction being pulled off earlier this year" in that Coram was the No. 2 player in the infusion industry. "This deal has legs."

"I doubt that it would have gone public if there wasn't the likelihood of cutting a deal," Bill Sullivan, principal consultant with Specialty Pharmacy Solutions LLC, tells *SPN*. "Some exposure would bring out bidders and create a more active bidding process."

### Private-Equity Interest Is 'Most Likely'

The Reuters article said that the potential transaction "has already attracted interest from" private-equity companies. "Given what we've seen happen in the infusion sector, a [financial] sponsor is most likely" as the potential buyer, particularly one that is "looking to get into the sector or has already" got some experience there, says the source. He tells *SPN* that private-equity firm Harvest Partners, LP "has been one of the more acquisitive partners" recently.

That company tells *SPN* that it has no comment on speculation that it is eyeing Walgreens.

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As far as a buyer being a specialty pharmacy/PBM/specialty infusion company, the source says that BioScrip, Inc. is the No. 3 player in the infusion industry, but "this acquisition may be too big for them to swallow," particularly after a fairly active last few years *(SPN 11/13, p. 10)*. According to Seeking Alpha, in a November 2013 conference call to discuss third-quarter 2013 earnings, Chief Financial Officer Hai Tran said that "I don't expect for us to go out there and do another acquisition with the size of even an InfuScience, which is the smallest of the 3 acquisitions, right? If we do an acquisition, it'll be probably a single mom-and-pop that is in a strategic location that we can bring volume to immediately because they are national contracts, for a change, okay? That's the type of acquisition we'll do, if any." The comments came shortly after the company closed on its purchase of CarePoint Partners Holdings LLC for $223 million, which was the last of BioScrip's recent transactions *(SPN 7/13, p. 1)*.

Sullivan says he doubts that BioScrip would be the purchaser. "My gut tells me that Walgreens can attract high quality partners simply because of who they are, so why settle for chicken liver when you can afford goose?"

BioScrip did not respond to a request for comment on whether it was a potential Walgreens suitor.

And perhaps BioScrip executives may not be looking to buy another firm but rather are thinking about selling their own company (see box, p. 3).

### Home Infusion Is Valuable Segment

The sale of a majority stake in Walgreens' infusion unit represents "the recognition of the value that home infusion brings," the source maintains. He explains that when companies sell a partial stake in their business, "typically a little bit of a discount would be applied." But because Walgreens would be ceding control of the infusion unit, the company is looking to get a "multiple north of 14 times" earnings before interest, taxes, depreciation and amortization — a "full valuation" of the unit and a "premium to Coram.…We're seeing very robust multiples being paid for infusion assets."

"Scale is very important in this segment," contends Sullivan. "Walgreens isn't selling out a full stake so they want an active partner that can manage the business more effectively/efficiently. Walgreens would still have skin in the game to see their asset grow and expand their plans, especially with in-store infusion chairs (already previously announced) and free-standing infusion suites (part of their partnering strategy with hospitals and ACOs)."

Nick Opalich, managing partner for Strategica Health Care Partners, LLC, says the rumored deal indicates that "Walgreens will retain a stake for investment purposes with a future opportunity to capitalize on the

investment, as well as possibly repurchasing the unit at a later date."

Having Walgreens continue to be involved with the company would be "very attractive" to a potential buyer considering its industry expertise, says the anonymous source. Walgreens has 30 years of infusion experience, according to its website.

Another Walgreens deal could be influencing this rumored sale in a couple of ways. "Last month Walgreens announced that it would buy the remaining 55% it does not already own of Alliance Boots for $5.3 billion in cash and 144.3 million shares for a total deal of about $15 billion," points out Opalich. "The cash portion of the deal is significant as it relates to Walgreens' current balance sheet."

Opalich explains that "Walgreens reports a cash balance of $2.65 billion, operating cash flow of $3.89 billion and levered free cash flow of $2.44 billion. Thus, if Walgreens is going to pay out $5.3 billion…for the cash portion to Alliance Boots," that could mean that Walgreens wants "to raise additional cash via a strategic maneuver to help offset the Boots purchase."

The anonymous *SPN* source agrees that this is the likely strategy. That Walgreens is looking for a company to purchase a majority stake in the unit rather than selling it outright would seem to indicate that "they are looking to raise some capital for the upcoming phase two buyout of Alliance Boots" *(SPN 4/13, p. 9)*. "This is one way to monetize assets."

And perhaps that impending deal with Alliance Boots is having an additional impact on the infusion unit. The source tells *SPN* that he's "heard the infusion segment is not getting too much internal attention from corporate" because of Walgreens' focus on the Alliance Boots transaction, although that's "not to say it was a management distraction," he adds.

"I believe this is a highly valued strategic decision that allows Walgreens to focus on its core retail pharmacy business and continue to work on correcting their generic issues," says Opalich, referring to the company's $1.1 billion reduction in projected pharmacy-unit earnings for

## *Is BioScrip a Walgreens Infusion Suitor or Another M&A Market Entrant?*

With the news that Walgreen Co. reportedly is looking for a company to purchase a majority stake in Walgreens Infusion Services, many industry observers may think of BioScrip, Inc. as a possible purchaser. After all, the company is one of the top infusion services providers in the country, aided in large part by multiple acquisitions over the past several years *(SPN 7/13, p. 1)*.

But perhaps BioScrip is not a contender because it may be preparing to sell its own company. The company did not respond to an *SPN* request for comment on the issue. But the firm has been building up its infusion services business through acquisitions, including the purchase of CarePoint Partners Holdings LLC for $223 million earlier this year; InfuScience, Inc. in 2012 for $38 million *(SPN 9/12, p. 12)*; and Critical Homecare Solutions in 2010 for about $347 million *(SPN 2/10, p. 1)*. BioScrip also sold its community specialty pharmacies and centralized specialty and mail-service pharmacy businesses to Walgreens in 2012 *(SPN 3/12, p. 1)*.

In addition, BioScrip CEO Rick Smith has a track record of selling companies. He was president of OptionCare, Inc. when Walgreens bought the company *(SPN 8/07, p. 1)*, chief financial officer and then president and CEO of Coram Healthcare Corp. when Apria Healthcare Group Inc. purchased it *(SPN 11/07, p. 1)* and CEO of Byram Healthcare, a disposable medical supply provider, when it was purchased by a European-based firm.

Nick Opalich, managing partner for Strategica Health Care Partners, LLC, tells *SPN* that he hasn't heard anything about a potential BioScrip sale, "but it would not surprise me as it is so long overdue."

But "BioScrip is still stumbling,…[and] have some operational issues that are not very appealing," maintains Sullivan, pointing to a Zachs.com analyst blog that cites "near-term revenue dis-synergies from acquisitions," margins that "continue to be under pressure,…reimbursement issues,…[and] the competitive landscape."

He adds that the company's $15 million settlement with the Department of Justice to resolve allegations of False Claims Act violations concerning Novartis Pharmaceuticals Corp. and its drug Exjade (deferasirox) *(SPN 2/14, p. 1)* "also puts a blight on their image."

"BioScrip needs to do some fence mending before they can restore their market valuation, so I don't see them selling out prematurely," says Sullivan.

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fiscal year 2016, which starts Sept. 1, 2015. In an August conference call with investors, Walgreens President and CEO Greg Wasson said his company had experienced problems in reimbursement negotiations for dispensing drugs under Medicare Part D and didn't "fully anticipate" the rapid increase in pricing for generic drugs.

"The timing [of the infusion unit sale] does not surprise me," says the anonymous source. "Given that Coram has traded hands,…Walgreens has had the opportunity to be acquisitive." For example, the company purchased BioScrip's community specialty pharmacies and centralized specialty and mail-service pharmacy businesses in 2012 *(SPN 3/12, p. 1)*, but "Walgreens didn't go after other deals," such as BioScrip's infusion unit. And with Coram's sale, "I don't know if Walgreens was a player," but the company obviously wasn't the winner of that deal, says the source. "They are not in the acquisition game right now."

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## Catamaran Plans to Buy Salveo, Giving It 14 Specialty Pharmacies

Catamaran Corp. will continue to boost its specialty pharmacy presence with the planned purchase of Salveo Specialty Pharmacy, unveiled Oct. 8 and expected to close by the end of the year. Catamaran will pay $260 million for the St. Petersburg, Fla.-headquartered firm, which operates as Echo Salveo Specialty Pharmacy in New York and Mission Road Pharmacy in California. Salveo manages about $400 million in drug spend annually, and it will be combined with Catamaran's specialty pharmacy, BriovaRx.

According to Mike Zeglinski, Catamaran's vice president, specialty pharmacy operations, "Salveo is entirely complementary to Catamaran's specialty offering, providing a local market presence on the East and the West Coasts." The deal will give the company 14 specialty pharmacies across the country.

BriovaRx launched in October 2012 *(SPN 10/12, p. 6)*, after SXC Health Solutions Corp. purchased Catalyst Health Solutions, Inc. earlier that year and rebranded as Catamaran *(SPN 5/12, p. 3)*. Catalyst did not have an in-house specialty pharmacy and was working with vendors, mainly Walgreen Co. SXC, on the other hand, had acquired Ascend Specialty Pharmacy through its 2008 merger with National Medical Health Card Systems and then expanded its specialty focus through the late 2010 purchase of MedfusionRx, LLC *(SPN 1/11, p. 12)*.

"Salveo's core focus on oncology, HIV, rheumatoid arthritis, organ transplant, hepatitis C and gastrointestinal diseases augments Catamaran's expertise in a number of rapidly growing therapies and provides access to additional limited-distribution drugs," Zeglinski says. Those therapies, he adds, are in five therapeutic categories, primarily oncology.

He tells *SPN* that Catamaran expects integrating Salveo into BriovaRx "will take approximately 18 months and will allow the best practices from each organization to be recognized and leveraged. We will retain the existing pharmacies in New York and California and expect to leverage Salveo's talent and expertise."

Zeglinski maintains that "Nothing will change with regard to operations or Briova's approach to patient care. Clients and patients will continue to experience the high-touch, personalized service that Briova brings to the table. Over time, we will look to integrate certain aspects of the business with the ultimate goal of providing the very best level of support and care for our patients."

The timing for the deal is appropriate because "specialty is the fastest growing segment of pharmaceutical spending, projected to outpace traditional spend by 2018," says Zeglinski. "Catamaran is committed to investing in the resources necessary to effectively manage specialty."

Contact Zeglinski through Lauren Denz at lauren.denz@catamaranrx.com. ✧

## Sovaldi Compliance Rates Show Room for Improved Management

After Gilead Sciences, Inc.'s hepatitis C therapy Sovaldi (sofosbuvir) launched in December, much of the attention on the drug has focused on its $1,000-per-day price. But in clinical trials, the drug had sustained virologic response rates of more than 90%, making it much more effective than any previous therapy. However, a drug can be effective only if someone adheres to the proper treatment regimen, and early results are showing a mix of compliance rates among patient populations.

The CVS Health Research Institute released an analysis of its patient population in mid-September that showed a plateau and downward trend in Sovaldi use from May through August. That's perhaps not surprising considering that two new hepatitis C therapies are expected to hit the market by the end of the year — with approval for Gilead's combination Sovaldi plus ledipasvir given Oct. 10 (see brief, p. 10) — and four more are in the near pipeline. "All of them offer cure rates exceeding 90%," noted Renee Rayburgh, senior director of clinical consulting for Artemetrx Specialty Drug Solutions, during an Oct. 3 webinar titled *The Brewing Hepatitis C Storm*

— *Are You Ready?* And they will be the first all-oral regimens indicated for genotype 1 infection.

In clinical trials, Sovaldi showed discontinuation rates of about 2%. That's in line with what Burman's Specialty Pharmacy is seeing with its Sovaldi population, says CEO Steve Burman. He tells *SPN* that out of its first 135 patients, 2.2% were noncompliant with their regimen. But the CVS analysis of almost 2,000 people managed by CVS/caremark showed an overall discontinuation rate of 8.1%, with a 5.3% rate among people who previously had been treated and an 8.7% rate among people who were treatment-naïve.

The company distinguished between the two patient populations based on whether people had a claim for a hepatitis C drug between Jan. 1, 2011, and Nov. 30, 2013. Burman says this may not be a clear snapshot of patients because they could have gotten treatment prior to the survey period or from a company other than CVS.

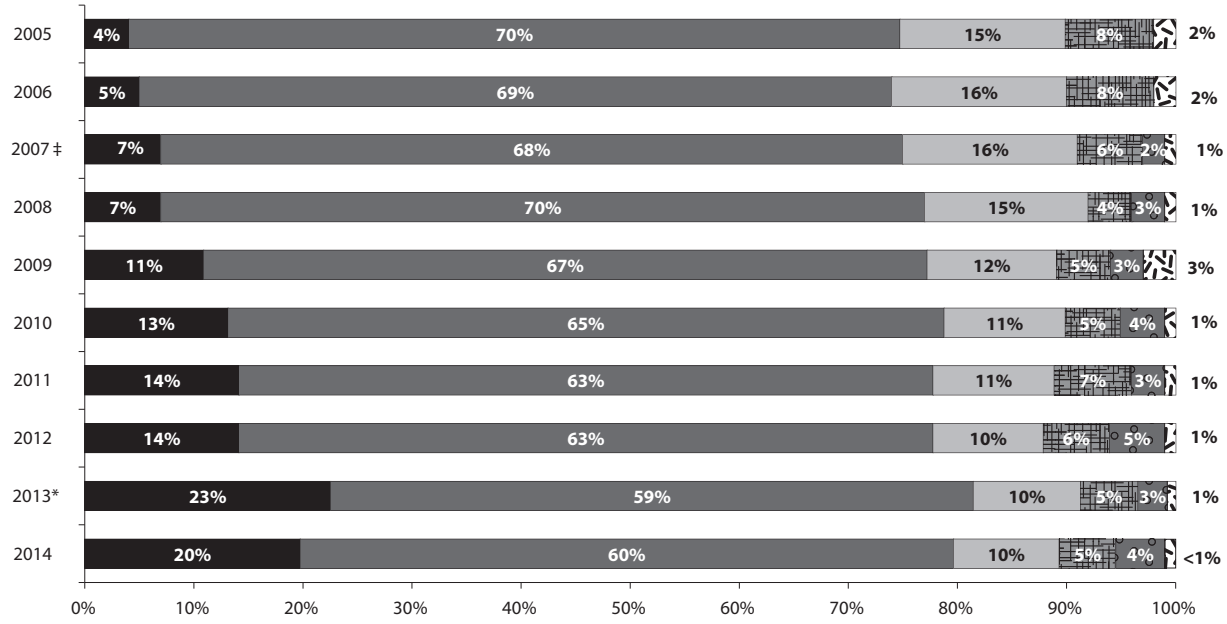
*continued*

## *Percentage of Workers in Plans With At Least Four Tiers Drops Slightly*

According to the *2014 Employer Health Benefits Survey* released Sept. 10 by the Kaiser Family Foundation and the Health Research & Educational Trust, 20% of employees are now in a plan with four or more cost-sharing tiers. By comparison, only 4% of covered workers were in a plan with four or more cost-sharing tiers in 2005, and that has continued to rise every year until 2013, observes the 16th annual survey of more than 2,000 small and large employers conducted this year from January to May.

Among plans with at least three tiers, copayments are much more common than coinsurance in the first three tiers, while coinsurance is more common in the fourth. Drugs in that tier have an average coinsurance of 29% for 2014, down from 32% in 2012 and 2013.

**Distribution of Covered Workers Facing Different Cost-Sharing Formulas for Prescription Drug Benefits, 2005–2014**




* Distribution is statistically different from distribution for the previous year shown ($p<.05$).

‡ No statistical tests are conducted between 2006 and 2007 due to the addition of a new category.

SOURCE: *2014 Employer Health Benefits Survey*, The Henry J. Kaiser Family Foundation and the Health Research & Educational Trust, published Sept. 10, 2014. View the report at http://kff.org/health-costs/report/2014-employer-health-benefits-survey.

Getting "real information from patients or physicians" would give a clearer picture, he says.

"Without detailed history you will miss previously treated patients, and a critical determination of what treatment you should go on is determined by your actual response to the previous treatment," Burman explains. "It takes work."

Similar to CVS's results, an Artemetrx study of almost 1,000 people found the following results:

◆ ***12% discontinuation rate for a regimen of Sovaldi plus peg-interferon and ribavirin***

◆ ***10% discontinuation rate for people taking Sovaldi plus Olysio (simeprevir)***

◆ ***6% discontinuation rate for a Sovaldi-plus-ribavirin regimen***

The CVS study showed that where Sovaldi was delivered made a difference in adherence as well, although the Artemetrx report did not. CVS showed discontinuation rates of 5.9% among people who filled their prescriptions at either CVS/pharmacy retail stores or CVS/caremark specialty pharmacies compared with rates of 8.5% at non-CVS sites. Artemetrx's analysis found that people who received their first fills at retail pharmacies had a 9% discontinuation rate, and those who initially filled their prescriptions at a specialty pharmacy actually had an 11% discontinuation rate. "We were surprised we didn't see a difference," said Corey Belken, Pharm.D., vice president of business development for Artemetrx, during the webinar.

The Artemetrx study also found that "inappropriate use of Sovaldi is significant," said Belken. More specifically, 8% of patients used Sovaldi by itself, which is "off-label and ineffective," and 31% used a combination of Sovaldi and Olysio, a percentage that "should be closer to 15%," he explained.

Interestingly, across CVS's book of business, 23% of its members being treated for hepatitis C were on a Sovaldi-plus-Olysio regimen, 34% were taking Sovaldi with ribavirin and pegylated interferon, and 43% were taking Sovaldi with ribavirin. "The analysis grouped patients by 'treatment' regimens, which may infer the genotype based on the treatment regimen but did not review medical claims to identify the specific genotype," a CVS spokesperson tells *SPN*.

"The rate of use for the combination of Sovaldi plus Olysio is higher than what we would expect based on known rates of interferon ineligibility," Belken tells *SPN*. "The financial implications are enormous. Better enforcement of the PA [i.e., prior-authorization] criteria for interferon ineligibility is needed."

Artemetrx found that there was "$18 million in potential Sovaldi waste and $9 million in potential Olysio waste, equaling a total of $33,000 per member in potential waste" among the studied population, noted Belken.

His company recommends having clinicians review PAs, adhering to specific criteria during PA reviews and requiring some kind of clinical documentation to support a requested therapy.

"Improved models are needed to address nonadherence given the clinical and financial implications for hep C patients," Belken says.

It's important to note that when someone is nonadherent, notes Burman, this could be due to reasons other than the patient was just not compliant with the regimen. For example, discontinuation could be due to early lab results showing patients were not responding to therapy, so it was discontinued, cutting down on potential waste.

The CVS spokesperson tells *SPN* that "This analysis was intended to provide a snapshot of overall adherence to treatment with the new HCV regimens, and we did not interview patients on reasons for discontinuation." The company did not review lab work as part of the data set.

During the webinar, Belken outlined the following "action plan" for managing hepatitis C:

◆ ***"Understand the challenge."*** Plans need to understand their challenges because "new agents could make the problems bigger."

◆ ***"Plan now."*** Follow the specialty pipeline, and prepare strategies now, before the new products hit the market.

◆ ***"Ensure appropriate use."*** Not only should plans "develop evidence-based PA criteria, quantity and treatment-duration limits," but they also should make sure they adhere to the PA guidelines and benefit designs.

◆ ***"Protect your investment."*** Plans should "manage compliance and adherence for all patients and all regimen therapies, and provide the necessary tools to achieve treatment success. Monitor the effectiveness of the PA, benefit design and adherence programs on a routine basis."

"There's no question that adherence is a challenge," said Belken. But it's important to remember that "no adherence equals no cure and potential wasted spend" of therapy.

"It is critical that plan sponsors look at their adherence in their population and monitor it on a routine basis to ensure that the value of these new medications is actually realized," he tells *SPN*.

For more information, contact Belken at cbelken@artemetrx.com, Burman at s.burman@burmansmedical.com and CVS through Christine Cramer at christine.cramer@cvscaremark.com. ✧

## PhRMA Reports Show Promise, Challenges of Oncology Therapies

Pharmaceutical manufacturers are maintaining their research-and-development focus on oncology, with 771 therapies, including vaccines, in the pipeline, according to a new report from the Pharmaceutical Research and Manufacturers of America (PhRMA), released Oct. 7. And while many innovative products are coming onto the U.S. market, there are many more that fail during clinical trials. But it's those failures that help researchers gain a better understanding of how cancer works — and how best to attack it — said PhRMA in a second report released the same day.

*Medicines in Development for Cancer, 2014 Report* notes that solid tumors have the most treatments in the pipeline, with 213 (see chart, below). Among the noteworthy therapies overall that are in development are ones for colorectal, liver, lung, pancreatic and stomach cancer, according to the report.

The second PhRMA report, *Researching Cancer Medicines: Setbacks and Stepping Stones,* notes that an average of 80% of therapies in the pipeline could be first-in-class treatments, including in the following areas:

- ***91% of the products for melanoma***
- ***81% of the colorectal cancer therapies***
- ***77% of blood cancer products***
- ***76% of breast cancer treatments***
- ***75% of therapies for bladder, lung and prostate cancer***

"However, researching and developing new medicines remains a risky investment and a lengthy process," says the pipeline report. "On average, it costs $1.2 billion and takes between 10–15 years to bring a new, effective medicine to patients."

And that effectiveness can be seen in survival rates. The pipeline report cites data from the American Cancer Society (ACS) showing that the death rate from cancer has continued to decline since the 1970s, with a decline of more than 15% from 2000 to 2011. In addition, five-year survival rates have increased almost 40% across all cancers since 1975, "with 2 out of 3 people diagnosed with cancer surviving at least five years." The ACS attributes 83% of survival gains to new therapies.

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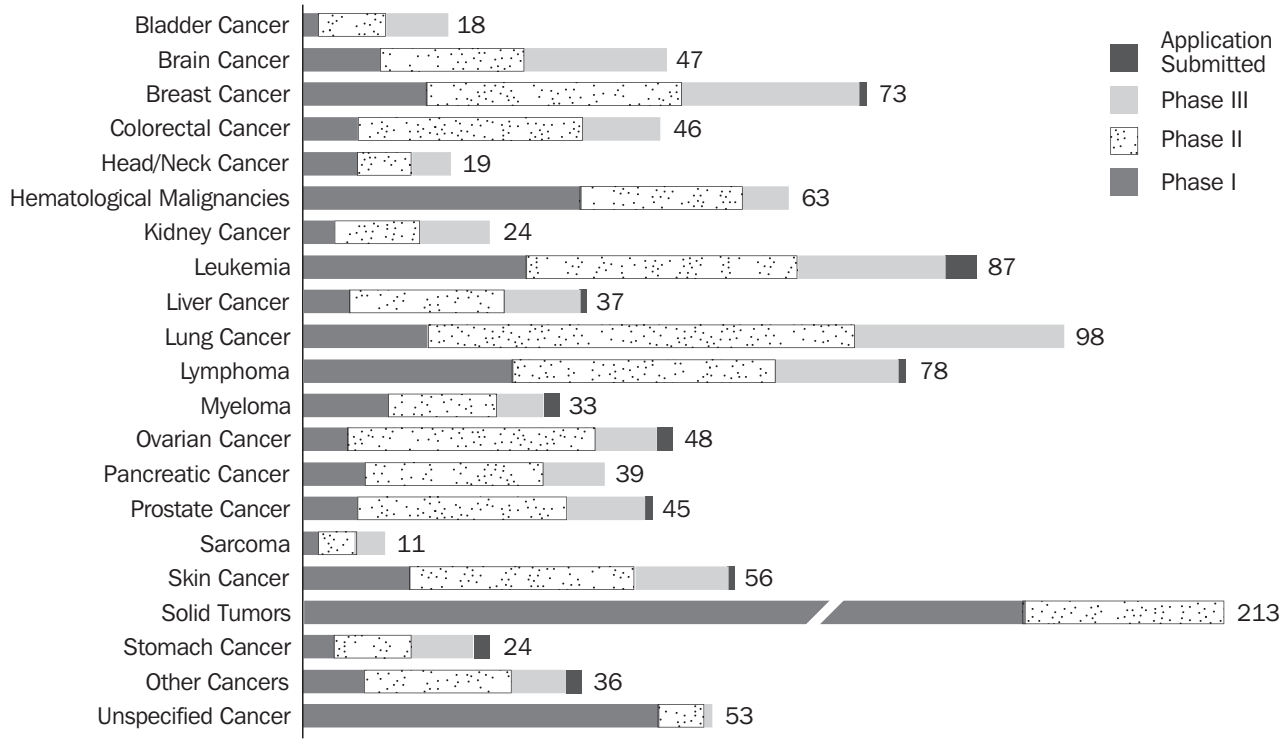
### Cancer Medicines in Development by Disease and Phase

Some medicines are listed in more than one category.




SOURCE: *Medicines in Development for Cancer, 2014 Report,* Pharmaceutical Research and Manufacturers of America. View the report at http://www.phrma.org/sites/default/files/pdf/2014-cancer-report.pdf.

PhRMA maintains that the progress seen in developing oncology drugs "could echo the success we have seen in HIV/AIDS treatment." Innovative therapies in that condition have lowered the death rate by more than 80% since 1981. And antiretroviral treatments, first developed in 1995, have made HIV "a chronic condition with manageable costs, and patients are able to reach nearly full life expectancy," says the pipeline report.

Challenges still exist, though, says the second report. As an illustration, it points to melanoma, lung cancer and brain cancer, which are challenging to treat. "Since 1998, there have been 96 unsuccessful attempts to develop drugs to treat melanoma, 167 for lung cancer, and 75 for brain cancer. In the same period we also saw medicines that beat the odds and advanced care: 7 new drugs to treat melanoma, 10 for lung cancer, and 3 for brain cancer were approved by the Food and Drug Administration."

View *Medicines in Development for Cancer, 2014 Report* at http://tinyurl.com/nx3gsaa. View *Researching Cancer Medicines: Setbacks and Stepping Stones* at http://tinyurl.com/o33do6h.

Contact PhRMA at newsroom@phrma.org and (202) 835-3460. ✧

## PhRMA Files Second Lawsuit on Orphan Drugs in 340B Program

The Pharmaceutical Research and Manufacturers Association (PhRMA) filed another lawsuit challenging the Health Resources and Services Administration's (HRSA) ability to force manufacturers to offer orphan drugs used for nonorphan indications at discounted rates to certain entities in the 340B program.

The move is the latest in a longstanding battle that was sparked by the Affordable Care Act, which made changes to the program, including expanding the list of health care entities able to participate and thus purchase drugs at discounted rates in order to serve a broader range of patients. It also said that those entities would not have access to 340B pricing for orphan drugs when used for a rare condition. The scope of this aspect was unclear, so HRSA issued a final rule (78 Fed. Reg. 44016) in July 2013 clarifying that the exclusion was limited to any indication receiving an orphan drug designation, rather than more broadly limiting access to any drugs with an orphan designation, regardless of what they were used for *(SPN 8/13, p. 7)*.

PhRMA filed 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), in September 2013 contending that (1) HHS lacked the statutory authority to issue such a rule, and (2) language in the ACA made it "clear that Congress intended the orphan drug exclusion to apply to any orphan drug sold to one of the newly covered entities, regardless of whether the covered entity uses the drug for an orphan indication" *(SPN 10/13, p. 6)*.

### Court Vacated Final Rule in May

On May 23, 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. It did, however, invite HHS to present additional information for its "half-hearted" argument that it issued an "interpretive" rule rather than a "legislative" one and gave a June 13 deadline.

In response to the ruling, HHS said on June 12 that it "respectfully declines the Court's invitation to submit further briefing defending the challenged regulation as an interpretive rule. HHS is currently evaluating its options as to how to respond to the Court's decision.…HHS does not interpret the Court's decision as precluding it from issuing an interpretive rule or other type of interpretive guidance, even if that rule or guidance sets forth the same interpretation previously embodied in the challenged regulation."

That same day, HRSA noted on its website that while the ruling "vacated the orphan drug regulation on the grounds that HHS lacks the statutory authority to engage in such ruling," the agency maintained that the "Court did not invalidate HRSA's interpretation of the statute. HHS/HRSA continues to stand by the interpretation described in its published final rule, which allows the 340B covered entities affected by the orphan drug exclusion to purchase orphan drugs at 340B prices when orphan drugs are used for any indication other than treating the rare disease or condition for which the drug received an orphan designation." On July 23, HRSA set forth its contention in an interpretive rule.

PhRMA appealed, and in August, the court "declined to address the validity of the agency's underlying interpretation." In addition, it said that PhRMA could challenge the interpretive rule in a new lawsuit — which is exactly what it did Oct. 9, when it filed the most recent case (*Pharmaceutical Research and Manufacturers of America v. United States Department of Health and Human Services,* No. 1:14-cv-01685).

PhRMA maintains that HRSA's interpretive rule "violates the plain language of the statutory orphan drug exclusion." It asks the court to "invalidate the July 2014 Rule as final agency action that is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'"

The Safety Net Hospitals for Pharmaceutical Access, the trade group for 340B hospitals, says it "is disappointed that brand-name drug manufacturers have gone back to court to try and quash a federal regulation that significantly lowers the cost of orphan drugs for rural and cancer hospitals and their patients. The Health Resources and Services Administration's 340B orphan drug 'interpretative' rule is well-reasoned and legally valid."

According to an Oct. 9 Pharmalot blog in *The Wall Street Journal*, HRSA says that only five manufacturers are complying with the rule to provide discounts.

View the new lawsuit at http://freepdfhosting.com/d55574efbd.pdf. ✧

*In Their Own Words*

## PerformRx Executive Discusses New Specialty Pharmacy Launch

*The following interview is part of an occasional series by* Specialty Pharmacy News *that examines pertinent issues through the words of the industry's leading executives. To suggest a topic and commentator, contact Angela Maas at amaas@aishealth.com.*

With more than a decade in the industry under its belt, PBM PerformRx has launched a new specialty pharmacy known as PerformSpecialty. The company is headquartered in Orlando, Fla., and is expected to create more than 80 jobs. But PerformRx isn't a novice when it comes to specialty drug management. President Mesfin Tegenu explains how the specialty pharmacy will complement PerformRx's offering.

**SPN:** ***Why did you create PerformSpecialty?***

***Tegenu:*** For more than a decade, PerformRx has had an extremely robust specialty drug utilization management program that manages provider-administered and pharmacy-dispensed products. The concept for developing a specialty pharmacy distribution capability is a natural extension of our utilization management program. The dramatic increase in specialty drug expenditures over the past few years, culminating with the release of Incivek, as well as Victrelis and Sovaldi, for the treatment of hepatitis C, and drugs like Kalydeco for cystic fibrosis, emphasized the need to move forward with this solution.

**SPN:** ***How is the company different from/similar to the specialty pharmacy management services you provided previously?***

***Tegenu:*** The services provided by PerformRx and PerformSpecialty will be complementary. With the addition of PerformSpecialty, we now provide the distribution of specialty drugs, in addition to the products we are known for, which include PerformPA, our online prior authorization software; our award-winning drug therapy management programs; and PerformMAX, an integrated drug warehouse and Web-based portal.

PerformSpecialty enables us to build upon our protocols to make sure the patient is properly screened and follows his or her medication regimen as prescribed. We verify and confirm orders with the patient before anything is shipped. Also, at that time, our clinicians speak to the patient to assess their understanding and help with any concerns. After we ship the medications, we use a proactive tracking service to alert us if delivery is not made or will be delayed, and we reach out to patients accordingly. Depending on the therapy a patient is undergoing, our clinical team will reach out at specific times to support the patient with best practice education and interventions to ensure successful health outcomes for the chronically ill.

**SPN:** ***What have you learned from operating PerformRx that will translate into this new specialty pharmacy?***

***Tegenu:*** The main lesson learned is the need for integrated care. Providing integrated and well-coordinated pharmaceutical care is essential to the effective delivery of quality, cost-effective care. The explosion of expensive specialty drugs makes this even more important today than ever.

**SPN:** ***Will this company impact the services offered by PerformRx? If so, how?***

***Tegenu:*** PerformSpecialty will significantly enhance PerformRx's product offerings. PerformSpecialty's capabilities will be dynamic and a step ahead in the industry. We have a state-of-the-art facility and experienced staff focused on integrated comprehensive patient care to provide well-coordinated and integrated pharmaceutical care. Our real "difference" is in our approach to utilization management. Therefore, our focus has always been on creating and implementing the most cost-effective utilization management strategies. As our specialty drug management programs are developed and piloted with the collaboration of our client health plans, we will continue our focus on improved clinical and financial outcomes. With the addition of PerformSpecialty, we have the ability to bridge the information gap among medical, pharmacy and finance. We have the capability to centralize all pharmacy, medical and financial data. To provide real-time data improves the integration of care [and] health outcomes, and reduces administrative costs.

*continued*

**SPN:** ***Could you describe how you'll leverage technology to help care for patients?***

***Tegenu:*** We have technologies currently in different phases in a variety of pilot programs. Our mobile technology, Pill Station, tablets and Memotext will play significant roles in improving patient adherence and compliance. In addition, PerformSpecialty care coordinators will utilize these technologies to interface with health care providers' medical management systems to help achieve optimal patient outcomes. For example, care coordinators will work with providers to send reminders to patients about appointments or to make sure they are

## *NEW FDA SPECIALTY APPROVALS*

◆ ***September 14:*** **The FDA approved Baxter International Inc. and Halozyme Therapeutics, Inc.'s Hyqvia (immune globulin infusion 10% [human] with recombinant human hyaluronidase) for the treatment of adults with primary immunodeficiency (PI).** This is the first subcutaneous treatment for PI, and it is dosed up to once per month at one injection site. Most patients with PI receive infusions weekly or biweekly and have multiple infusion sites per treatment. Visit www.hyqvia.com.

◆ ***September 15:*** **The FDA expanded the approval of Rixubis (coagulation factor IX [recombinant]) for routine prophylactic treatment, control and prevention of bleeding episodes and for perioperative management in children with hemophilia B.** The agency initially approved the Baxter product in June 2013 for use in adults (*SPN 7/13, p. 10*). Visit www.rixubis.com.

◆ ***September 23:*** **The FDA gave an additional indication to Otezla (apremilast) for the treatment of moderate to severe plaque psoriasis in people for whom phototherapy or systemic therapy is appropriate.** The agency initially approved Celgene Corp.'s oral drug to treat adults with active psoriatic arthritis (*SPN 4/14, p. 6*). Visit www.otezla.com.

◆ ***September 24:*** **The FDA approved Gilead Sciences, Inc.'s Tybost (cobicistat) in combination with either atazanavir or darunavir for the treatment of HIV-1 infection.** The CYP3A inhibitor is recommended as a 150 mg daily oral dose. It works as a boosting agent to raise the levels of the other two drugs, and it joins Norvir (ritonavir) as the two such products with FDA approval. Visit www.tybost.com.

◆ ***September 24:*** **The FDA approved Gilead's Vitekta (elvitegravir) in a variety of combination regimens for the treatment of HIV-1 infection in people who have received antiretroviral treatment.** The agency approved 85 mg and 150 mg tablets of the integrase strand transfer inhibitor, which is taken once daily. Visit www.gilead.com.

◆ ***September 29:*** **The FDA approved Alimera Sciences, Inc.'s Iluvien (fluocinolone acetonide intravitreal implant) 0.19 mg for the treatment of diabetic macular edema (DME) in people who did not have a clinically significant rise in intraocular pressure after treatment with corticosteroids.** The company says it expects to launch the sustained-release implant in first-quarter 2015. Visit www.iluvien.com.

◆ ***September 29:*** **The FDA expanded the approval for Ozurdex (dexamethasone intravitreal implant) 0.7 mg to treat all people with DME.** The agency first approved the Allergan, Inc. biodegradable steroid implant in June for the treatment of DME in adults with an artificial lens implant or who are scheduled for cataract surgery (*SPN 7/14, p. 4*). Visit www.ozurdex.com.

◆ ***October 10:*** **The FDA approved Eisai Inc.'s Akynzeo (netupitant and palonosetron) for the treatment of nausea and vomiting in people undergoing chemotherapy.** The capsule is composed of two drugs: the new product netupitant and the oral formulation of palonosetron, which initially was approved in August 2008 (*SPN 9/08, p. 7*). Visit www.eisai.com.

◆ ***October 10:*** **The FDA granted an additional indication to Velcade (bortezomib) for the treatment of mantle cell lymphoma in people who have not been treated.** The FDA initially approved the Takeda Pharmaceutical Company Ltd. injectable in 2006 for the treatment of relapsed or refractory mantle cell lymphoma. Visit www.velcade.com.

◆ ***October 10:*** **The FDA approved Gilead's Harvoni (ledipasvir and sofosbuvir) to treat chronic hepatitis C in people with genotype 1 infection.** It is the first combination pill for this indication, as well as the first hepatitis C regimen to not require interferon or ribavirin. Harvoni has treatment durations of 8, 12 and 24 weeks depending on the patient population. Visit www.gilead.com.

taking their medications to optimize the medication regimens of high-risk patients with chronic diseases. These care coordinators will provide educational information and encouragement to ensure patients are engaged, take their medications as prescribed and effectively manage their chronic conditions.

**SPN:** ***Are there particular therapies and/or conditions that you plan to focus on?***

***Tegenu:*** Our program will focus on all specialty drugs, with special concentration on core disease states such as multiple sclerosis, cystic fibrosis, hepatitis C, hemophilia, rheumatoid arthritis and cancer.

**SPN:** ***With so many specialty drugs available through limited distribution, how do you plan on making sure PerformSpecialty is included in these networks?***

***Tegenu:*** Our pharmacy is designed to handle the needs of the specialty drugs that our members will be utilizing. When Risk Evaluation and Mitigation Strategies are part of the management of those therapies, we are well-equipped to meet the demands of those programs. As we work closely with drug manufacturers on limited-distribution arrangements, we are prepared to develop programs to support their individual requests and develop related services.

PerformSpecialty will actively collaborate with drug manufacturers to participate in exclusive-distribution programs. We're confident that our program exceeds the administrative, operational and clinical support and expertise mandated by manufacturers.

**SPN:** ***Will companies that contract with PerformRx automatically be working with PerformSpecialty, or will those be separate relationships?***

***Tegenu:*** PerformRx will offer the services of PerformSpecialty to all clients who choose to use it. PerformSpecialty will also develop working relationships with other patients and providers as well.

Contact Tegenu through C.J. Arnold at carnold@performrx.com. ✧

## Horizon Supports Data Platform

*continued from p. 1*

who is running a practice of multiple oncologists can see if all of their oncologists are consistently using NCCN [i.e., National Comprehensive Cancer Network]-approved regimens as well as see his/her operational efficiency and margins for the services provided for that particular subtype of breast cancer patient. The specific actions of course are unique to the practice depending on what the data shows."

The company was founded in 2011 by hematologist/oncologist Andrew Pecora, M.D., who also serves as executive chairman. Pecora, who is vice president, cancer services, and chief innovation officer for the John Theurer Cancer Center in Hackensack, N.J., formed the company "when he saw the major gap in data tracking and analysis, particularly within oncology," says Choi.

In late September, COTA closed $3.7 million in a planned $7 million Series A funding round in which Horizon "was the lead investor," Choi tells *SPN*. "While we have been active in the oncology space working with oncologists as well as other customers and partners, our recent Series A funding will allow us to further expand the COTA platform." Prior to that, private sources and Regional Cancer Care Associates, a group with more than 100 oncologists, provided COTA with a seed round of funding.

Thomas Vincz, spokesperson for Horizon, tells *SPN* that his health plan "made a significant investment in COTA's business. Horizon is leading the effort to change the delivery of health care in New Jersey through patient-centered based practices that are focused on quality versus quantity of care." Horizon now has more than 500,000 of its 3.7 million members in patient-centered programs, with more than 3,700 participating physicians at 900 practice locations.

"This investment is a way that Horizon can assist companies with the development of software, data analytics and information services to further this effort," maintains Vincz.

Glenn Pomerantz, M.D., vice president and chief medical officer of Horizon, will serve on COTA's board of directors, as will a second Horizon person who will be named later.

### Data Will Help Transition to Value-Based Care

Amidst growing concerns over skyrocketing health care costs that may not provide comparable returns on investment, more stakeholders within the industry are implementing value-based care models. COTA, contends the company, will help oncologists transition from fee-for-service care to these value-based approaches.

"COTA's technology provides clinical data and information services to enable real-time care management and comparison of quality outcomes between patients with specific types of cancer," says Vincz. "This technology will help improve the tracking of outcome data, quality and care coordination, and standardization of the highest quality care for patients with oncologic conditions. This will allow for very specific quality and outcomes metrics to be tracked, which will support bundled payment arrangements, which are focused on reimbursement for improved quality."

"In the new value-based reimbursement world, oncologists will need to understand the population of

patients they are managing to a very specific level in order to track progress, change treatment plans as needed, and understand and manage their costs at a much more granular level," Choi tells *SPN*. "COTA empowers users with the ability to sort cancer patients to the highest degree of specificity. Oncologists can thus glean a level of actionable and insightful analysis that no other system today can do."

Choi explains that COTA "is purely an outcomes and cost-tracking database. We do not publish guidelines nor make any clinical recommendations like the NCCN. We are completely compatible with guidelines and pathways since we do not tell an oncologist what to do — we merely show him/her the consequences of their actions."

Pricing for use of the platform "remains confidential at the moment," says Choi. "We charge the oncologists a nominal fee to use COTA, mainly to cover operating costs. We do not want to be a financial burden for the oncologists. We believe the payers have the most to gain from improved quality and lowering unnecessary costs, and we are pricing for health plans accordingly." She tells *SPN* that COTA has "several pending" contracts with health plans. "We can't share any specific details at the moment, but [they] will be made public in the coming weeks," she adds.

COTA also is looking to broaden its data. At this point, "New Jersey is the primary geographical area represented in our data, but we do have a few pilots in the Southeast and a soon-to-be pilot in the West," Choi says. "We absolutely expect there will be differences given we are seeing some big variance even in the state of New Jersey. However, we are waiting for a bit more data before we make any specific statements."

According to Choi, "We are focused right now on scaling our company. Our goal is for COTA at a national level to enable higher quality care while reducing unnecessary expenditures so that patients now and in future generations will get the care they need."

Contact Vincz at Thomas_Vincz@horizonblue.com and Choi through Victoria Khamsombath at vkhamsombath@shiftcomm.com. ✧

## *NEWS BRIEFS*

◆ **AxelaCare Health Solutions acquired Advanced Care, a provider of home intravenous therapy.** AxelaCare, a specialty home infusion service provider owned by private-equity group Harvest Partners, LP, did not reveal details of the deal, which it unveiled Oct. 2. The company now has 18 pharmacies across the country, and the transaction expands its home intravenous therapy network into the metro New York-New Jersey area. Contact AxelaCare via Chuck Weber at (262) 473-3018.

◆ **PharMerica Corp. acquired Millennium Pharmacy Systems, a pharmacy services provider to the long-term care industry.** PharMerica says it expects the deal will increase its annual revenue by about $120 million but did not reveal other details of the transaction. Contact PharMerica's David Froesel at (502) 627-7950.

◆ **Diplomat priced its initial public offering of 13.3 million shares of common stock at $13 per share.** Renaissance Capital noted that this was below the expected $14-to-$16 range. Contact Diplomat through Bob East of Westwicke Partners at (443) 213-0500.

◆ **PEOPLE ON THE MOVE:** The Burchfield Group, Inc. named **Craig Caldwell** national account executive across all lines of business. He was previously with Remedy Rx. The company also named **Kevin Waite** managing consultant. He was previously with Pharmaceutical Strategies Group.…Cardinal Health named **Michael Kaufmann** chief financial officer effective Nov. 11. He is CEO of the pharmaceutical segment, a role that will be filled by **Jon Giacomin,** who is president of U.S. pharmaceutical distribution.…CareCore National appointed **Debbie Stern** senior vice president of strategy and business development. She has been president of managed care consulting firm Rxperts, Inc., where she will continue work under contract through this month, as well as maintain her role in the production of the *EMD Serono Specialty Digest*.…The National Association of Specialty Pharmacy appointed **Gaurang Gandhi, Pharm.D.,** vice president of industry relations. He worked as the senior director of specialty pharmacy compliance and clinical operations at Express Scripts Holding Co.…New Century Health named **Andrew Hertler, M.D.,** chief medical officer. He was previously was the medical director for physician practices at Maine General Medical Center.…Specialty pharmacy QmedRx, Inc. appointed **Scott Karolchyk** vice president of formulations. He previously was the owner of Pharmacy Creations, a compounding and nutritional pharmacy, and is an adjunct professor of pharmaceutics for the College of Pharmacy at Rutgers University.

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