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**ANNUAL REPORT:**

# lockbusters

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**ua Slatko** joshua.slatko@ubm.com

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main groups

2011 release ary endpoint the Phase III ssue or bone apy. , determined udy achieved 001) 28 per- compared to

placebo (hazard ratio = 0.72). Determination of median PFS for each arm of the trial demonstrated that ridaforolimus treatment resulted in a statistically significant 21 percent (3.1 week) improvement in median PFS (ridaforolimus, 17.7 weeks versus placebo, 14.6 weeks).

Based on the full analysis of PFS determined by the investigative sites, there also was a statistically significant ($p<0.0001$) 31 percent reduction by ridaforolimus in the risk of progression compared to placebo (hazard ratio = 0.69). Ridaforolimus treatment resulted in a statistically significant 52 percent (7.7 week) improvement in median PFS (ridaforolimus, 22.4 weeks versus placebo, 14.7 weeks). The most common side effects observed in the study were consistent with the known safety profile of ridaforolimus and included stomatitis (e.g., mouth sores), fatigue, diarrhea, and thrombocytopenia.

"Patients with metastatic soft-tissue and bone sarcomas have extremely limited treatment options available to them," says Harvey J. Berger, M.D., chairman and CEO of Ariad (ariad.com). "These top-line data illustrate how devastating metastatic sarcomas can be, even in patients who have responded favorably to conventional chemotherapy. We are very pleased with the positive outcome of the SUCCEED trial and the statistically significant improvement in progression-free survival in those patients treated with oral ridaforolimus."

Ridaforolimus is also in development for another cancer-related indication. In October 2010, interim results of a randomized, open-label, active-control multicenter Phase II study of the drug in patients with metastatic or recurrent endometrial cancer demonstrated a statistically significant improvement in the primary endpoint of median progression-free survival in patients receiving single-agent ridaforolimus compared to patients receiving standard-of-care treatment.

This past December, **Genentech** announced results from CLEOPATRA, the first randomized Phase III study of the investigational HER2-targeted

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## his month on PharmaLive.com

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**sumptions:** Pharmaceutical sales leaders may have formed certain assumptions regarding the current omotion, but a hard look at the data may force them to rethink their customer-facing roles and strategy.

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**IN THIS ISSUE:**






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## 12TH ANNUAL REPORT:

# Future blockbusters

Many of 2012's up-and-coming new products are in the cancer and cardiovascular fields, but opportunities are also brewing in HIV, multiple sclerosis, and diabetes as the next generation of blockbusters closes in on approval.

**By Joshua Slatko** joshua.slatko@ubm.com

The popular rumors of the blockbuster's death may be at least slightly exaggerated. A number of pharma innovators, both big and small, have high hopes for key products at the top of their pipelines in 2012, many of which are targeting the classic chronic disorders of blockbusters of yore, such as high cholesterol and diabetes. New targeted biotech therapeutics for specific types of cancers are creeping up too, as are innovations in underserved fields like multiple sclerosis. Although late 2011 and 2012 might be remembered as the time of the patent cliff, the drugs listed among *Med Ad News*' Future Blockbusters this year suggest that at least some relief may be on the way.


### CANCER

This past October, FDA accepted for filing and review the new drug application for **ridaforolimus**, an investigational oral mTOR inhibitor under development for the treatment of metastatic soft-tissue or bone sarcomas in patients who had a favorable response to chemotherapy. Ridaforolimus is being developed jointly by **Merck** & Co. and **Ariad** Pharmaceuticals. The drug was also accepted for review by the European Medicines Agency in August. Sarcomas are a group of cancers of connective tissue of the body for which there are currently limited treatment options. Sarcomas can arise anywhere in the body and are divided into two main groups – bone tumors and soft-tissue sarcomas.

The application for ridaforolimus followed the January 2011 release of top-line data showing that the drug had met the primary endpoint of improved progression-free survival compared to placebo in the Phase III SUCCEED trial conducted in patients with metastatic soft-tissue or bone sarcomas who previously had a favorable response to chemotherapy.

Based on the full analysis of 552 PFS events in 711 patients, determined by an independent review committee, the blinded prospective study achieved its primary endpoint, with a statistically significant (p=0.0001) 28 percent reduction by ridaforolimus in the risk of progression compared to placebo (hazard ratio = 0.72). Determination of median PFS for each arm of the trial demonstrated that ridaforolimus treatment resulted in a statistically significant 21 percent (3.1 week) improvement in median PFS (ridaforolimus, 17.7 weeks versus placebo, 14.6 weeks).

Based on the full analysis of PFS determined by the investigative sites, there also was a statistically significant (p<0.0001) 31 percent reduction by ridaforolimus in the risk of progression compared to placebo (hazard ratio = 0.69). Ridaforolimus treatment resulted in a statistically significant 52 percent (7.7 week) improvement in median PFS (ridaforolimus, 22.4 weeks versus placebo, 14.7 weeks). The most common side effects observed in the study were consistent with the known safety profile of ridaforolimus and included stomatitis (e.g., mouth sores), fatigue, diarrhea, and thrombocytopenia.

"Patients with metastatic soft-tissue and bone sarcomas have extremely limited treatment options available to them," says Harvey J. Berger, M.D., chairman and CEO of Ariad (ariad.com). "These top-line data illustrate how devastating metastatic sarcomas can be, even in patients who have responded favorably to conventional chemotherapy. We are very pleased with the positive outcome of the SUCCEED trial and the statistically significant improvement in progression-free survival in those patients treated with oral ridaforolimus."

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## This month on PharmaLive.com

- **The next generation:** *Med Ad News*' data team charts hundreds of new compounds in late-stage development or awaiting approval.
- **Challenging assumptions:** Pharmaceutical sales leaders may have formed certain assumptions regarding the current state of personal promotion, but a hard look at the data may force them to rethink their customer-facing roles and strategy.

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# tothepoint

**By Christiane Truelove** chris.truelove@ubm.com

**Change is** also coming to the Manny Awards in April. We're moving from the old location in midtown, the Sheraton Hotel and Towers, to Pier Sixty in Chelsea. We hope to speed the night along so we can properly celebrate afterwards in an area well known for its fashionable bars and clubs.

**Change happens.** This month, the corporate owners transferred the entire staff here to a facility the company had custom-built in what was an old toilet factory. No, I'm not making this up. The American Metro Center of Hamilton, N.J., is located in what used to be a manufacturing facility for the American Standard Company.

Back when I was a municipal reporter for the Times of Trenton, and one of the beat reporters covering the town of Hamilton, I was contacted by a group of concerned citizens in the neighborhood of the plant. The neighboring residents claimed that the company's spoil pits on the grounds, where toilets and sinks that did not make it through the manufacturing process were dumped, had been contaminating local wells. There was going to be a hearing about the pits, the leachate, and the groundwater testing results that week. So I went to talk with the plant manager, who kindly showed me around. The World War I-era buildings were mostly unused, as manufacturing had been moved to other locations; with many broken windows and a general rundown appearance, they would have made a great location shoot for some postapocalyptic movie or horror film. The lunar-looking grounds certainly held several spoil pits with the aforementioned broken toilets and sinks, which had stained the ground white with clay and old glaze.

I had spent about an hour at the location, talking and looking around, attended the municipal meeting that addressed the issues the citizens had raised (turned out that yes, there was some contamination), wrote my story, and never thought about the place again.

And then we got acquired by UBM, which looked at making everything as cost-efficient as possible, and there came the talk of a move. And more talk, and more talk. Then I got invited to look at two possible office facilities near the Pennsylvania location we were in, and found myself driving to a startlingly familiar place. But very much changed. Now there's the brand-new commuter train station next door; the buildings have mostly been renovated and leased into office spaces that take advantage of the exposed brick and big windows; and there is a new luxury condo development springing up next door. As for the spoil pits, they are long gone and the surrounding grounds have been landscaped (I was told that in many places, the ground was dug down to 20 feet and all new fill brought in).

We moved here about two weeks ago. The biggest change of all has been to an "open office" environment. To many of you, that probably is not an unfamiliar situation. Open offices are the trend, especially in Europe. Just about every healthcare advertising agency has adopted the open office format, it seems, at least among its creatives and graphic designers. But the majority still seem to have little offices for their copywriters to disappear into. The ones that don't, I've seen people with noise-canceling headphones. I may have to look into a pair of these for myself. It's taken me more than five hours to get to this point of writing, as I am seated next to the sales team for UBM's conference division, UBM Live. I now know more about conference pavilion dimensions and the sales team's prospect lists than I ever wanted to know.

But overall, the change to the new office has been pretty nice. The commute is shorter and I have a speedy back way to get here. The space is beautiful. There's lots of natural ambient light. There's a complimentary fitness room. Our Internet connection is incredibly fast, with lots of bandwidth. My Mac Mini is being phased out and replaced with a loaded iMac, which has all the writing and graphic arts programs I know and love.

Finally, when I need to visit editorial board members and clients in New York, the train station is just a brisk walk away from the office, and I don't have to worry about paying for garage parking. Another win.

So overall, there should be more wins than not-wins from the move and the new digs.

Change is also coming to the Manny Awards in April. We're moving from the old location in midtown, the Sheraton Hotel and Towers, to Pier Sixty in Chelsea. We hope to speed the night along so we can properly celebrate afterwards in an area well known for its fashionable bars and clubs. Again, we hope there a more wins than not-wins coming from this move. Looking forward to seeing everyone in a few months!




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## Top Biotechnology Companies

**REVENUE — TOP 100 BIOTECHNOLOGY COMPANIES**

| RANK IN 2009 | COMPANY | REVENUE IN 2009 |
|---|---|---|
| 1 | Roche | $23,340,147,000 (biotech estimate) |
| 2 | Amgen Inc. | 14,642,000,000 |
| 3 | Gilead Sciences Inc. | 7,011,383,000 |
| 4 | Genzyme Corp. | 4,515,525,000 |
| 5 | Biogen Idec Inc. | 4,377,348,000 |
| 6 | UCB SA | 4,342,146,000 |
| 7 | CSL Ltd. | 4,044,118,500 |
| 8 | Celgene Corp. | 2,689,893,000 |
| 9 | Cephalon Inc. | 2,192,308,000 |
| 10 | Actelion Ltd. | 1,632,195,212 |
| 11 | Talecris Biotherapeutics Holdings Corp. | 1,533,209,000 |
| 12 | Elan Corp. | 1,113,000,000 |
| 13 | Amylin Pharmaceuticals Inc. | 758,419,000 |
| 14 | Cubist Pharmaceuticals Inc. | 562,144,000 |
| 15 | Biocon Ltd. | 529,142,437 |
| 16 | Crucell NV | 471,230,141 |

- Experts analyze the current state of the industry, challenges, and expected outcomes
- Top biotech companies are ranked by revenue, R&D expenditure, and other performance data

## Top Medicines

**TOP 200 PRESCRIPTION MEDICINES BY SALES**

| Rank 2009 | Medicine | 2009 sales ($ in millions) |
|---|---|---|
| 1 | Lipitor | 12,535<br>Pfizer 11,434<br>Astellas Pharma 1,101 |
| 2 | Plavix/Iscover | 9,801<br>Bristol-Myers Squibb 6,146<br>Sanofi-Aventis 3,655 |
| 3 | Advair/Seretide | 7,794 |
| 4 | Remicade | 7,151<br>Johnson & Johnson 4,304<br>Schering-Plough 1,896<br>Mitsubishi Tanabe Pharma 520<br>Merck 431<br>Note: Merck and Schering-Plough merged effect |
| 5 | Enbrel<br><br>Note: Pfizer merged with Wyeth effective Oct. 15, 2009. | 6,575 (estimate)<br>Amgen 3,493 (actual)<br>Wyeth 2,348 (estimate)<br>Pfizer 378 (actual)<br>Takeda Pharmaceutical 356 (actual)<br>Notes: Wyeth reported 1H 2009 sales of 1,363<br>last two-and-a-half months of 2009 from Wyeth's<br>one-and-a-half months of 2009 from Wyeth's inte |
| 6 | Diovan and Diovan HCT/Co-Diovan | 6,013 |
| 7 | Avastin | 5,729<br>Note: Figure reported by Roche and includes sal<br>and Chugai Pharmaceutical (373) |
| 8 | Rituxan/MabThera | 5,605+<br>Roche 5,605 (includes Genentech N/A and Ch<br>Zenyaku Kogyo N/A<br>Note: Biogen Idec's share of Rituxan revenue tot<br>of the company's share of U.S. co-promotion pro |
| 9 | Humira | 5,561<br>Abbott 5,488<br>Eisai 73 |
| 10 | Seroquel | 5,126 |

- Medicine of the Year and other leading drugs are analyzed based on key performance metrics
- The top 200 prescription medicines are ranked by sales

## Top Pharmaceutical Companies

**TOP 50 COMPANIES RANKED BY HEALTHCARE REVENUE**

| Rank 2009 | Company | Healthcare Revenue 2009 |
|---|---|---|
| 1 | Johnson & Johnson | $61,897,000,000 |
| 2 | Pfizer Inc. | 50,009,000,000 |
| 3 | Roche | 45,166,666,667 |
| 4 | GlaxoSmithKline Plc. | 44,427,124,800 |
| 5 | Novartis | 44,267,000,000 |
| 6 | Sanofi-Aventis Group | 40,837,911,000 |
| 7 | AstraZeneca Plc. | 32,804,000,000 |
| 8 | Abbott Laboratories | 30,764,707,000 |
| 9 | Merck & Co. | 27,428,300,000 |
| 10 | Bayer AG | 22,279,278,000 |
| 11 | Eli Lilly and Co. | 21,836,000,000 |
| 12 | Bristol-Myers Squibb Co. | 18,808,000,000 |
| 13 | Boehringer Ingelheim GmbH | 17,726,713,500 |
| 14 | Takeda Pharmaceutical Co. | 15,173,502,829 (March 10) |
| 15 | Amgen Inc. | 14,642,000,000 |
| 16 | Teva Pharmaceutical Industries Ltd. | 13,899,000,000 |
| 17 | Baxter International Inc. | 12,562,000,000 |
| 18 | Otsuka Holdings Co. | 11,165,603,460 (March 10) |

- Top pharma companies are ranked by healthcare revenue, R&D expenditure, and other performance metrics
- Analyzes the strategic business actions and resulting performance of the top companies

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## FEATURES



## DEPARTMENTS



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## WHAT'S ONLINE

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### DESKBANG MOMENTS IN DIABETES
The recently launched and deliciously ironic diabetes partnership between chef Paula Deen and Novo Nordisk has our editor in chief, Chris Truelove, all a-Twitter.

### APPLE'S NEW IPAD TEXTBOOKS AUTHORING TOOLS PRESENT A POWERFUL E-DETAILING OPPORTUNITY FOR PHARMA
Geoff McCleary of Digitas Health explains why Apple's new interactive iPad textbook format may have applications outside the classroom – specifically, for pharma sales efforts.

### 42 PERCENT OF ONLINE CONSUMERS THINK PHARMA COMPANIES SHOULD BE INVOLVED IN ONLINE HEALTH COMMUNITIES
The latest data from Manhattan Research suggests that pharma companies need to step up their involvement in online health communities, with ADD caregivers, bipolar disorder caregivers, and rheumatoid arthritis patients among the most insistent on the subject.

### FDA'S NEW GUIDANCE CALLS FOR EXPERT SPEAKERS AND CAREFUL CONVERSATIONS
Leigh Householder of GSW Worldwide discusses the implications of FDA's first draft social media guidance, released in late December.

Go to pharmalive.com/dotpharma to read these stories

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### SALES FORCE EFFECTIVENESS • GETTING IN THE IPAD GROOVE
A top 50 pharmaceutical company and a small specialty pharma company both find the iPad a perfect fit with their sales forces. Go to page 12

### COMPLIANCE PACKAGING TECHNOLOGY
Ogilvy CommonHealth Worldwide has developed an adherence bracelet that uses communication technology to remind patients to take their medications, similar to the design of a Livestrong bracelet.
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### JUST CLICK HERE • USING THE WEB FOR TRIAL RECRUITMENT
Quintiles' ClinicalResearch.com Website is linked to the company's Facebook page and has some 165,000 registered users who receive various newsletters.
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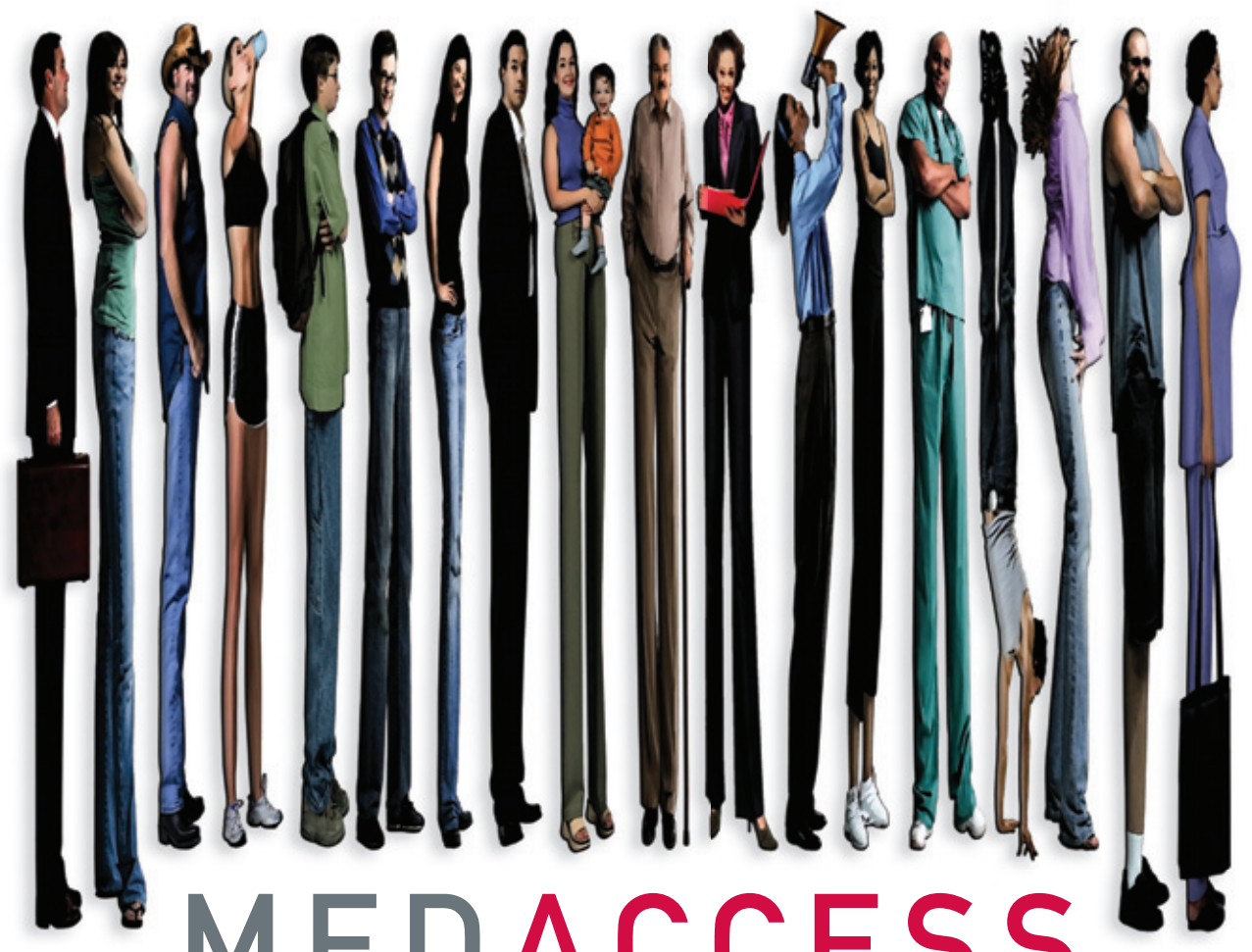
### FDA BREAKS SILENCE ON SOCIAL MEDIA
While not as specific as some industry professionals have expected, FDA has finally provided some guidance to pharmaceutical companies with respect to social media and other new, digital communication, including online forums and threads. Go to page 22



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*continued from page 1*

medicine **pertuzumab**. The study compared the combination of pertuzumab, **Herceptin** (trastuzumab), and docetaxel chemotherapy to Herceptin and docetaxel alone in people with previously untreated HER2-positive metastatic breast cancer. People who received pertuzumab in combination with Herceptin and chemotherapy experienced a 38 percent reduction in the risk of their disease worsening or death (progression-free survival, or PFS) (HR=0.62; p-value less than 0.0001). The median PFS improved by 6.1 months from 12.4 months for Herceptin and chemotherapy to 18.5 months for pertuzumab, Herceptin, and chemotherapy. Genentech has submitted a biologics license application for pertuzumab to FDA for people with previously untreated, HER2-positive mBC, and parent company **Roche** has submitted a marketing authorization application to the European Medicines Agency for pertuzumab in the same indication.

"We have been studying the HER2 pathway for 30 years to bring personalized medicines to people with HER2-positive breast cancer," says Hal Barron, M.D., chief medical officer and head, Global Product Development, Genentech (gene.com). "These results show we may soon improve on the current standard of care, Herceptin plus chemotherapy, to further help people with this advanced form of the disease."

The mechanisms of action of pertuzumab and Herceptin are believed to complement each other as both bind to the HER2 receptor but on different regions. This is believed to provide a more comprehensive blockade of HER signaling pathways.

In early December, FDA's Oncologic Drugs Advisory Committee voted 13 to 0 that data for **Pfizer** Inc.'s investigational agent **axitinib** support a favorable benefit/risk profile for the treatment of patients with advanced renal cell carcinoma after failure of a first-line systemic therapy. The company had filed for approval with FDA and European regulators in June.

"We are pleased with the panel's recommendation in support of axitinib for the treatment of previously treated advanced RCC, as additional therapeutic options are still needed for this patient population," says Dr. Mace Rothenberg, senior VP of clinical development and medical affairs, Pfizer Oncology Business Unit (pfizer.com). "We look forward to continued discussions with the FDA as we take the next steps in the regulatory process for axitinib."

The committee's decision was partially based on Phase III AXIS 1032 trial data, released in May 2011, showing that in patients with previously treated advanced renal cell carcinoma, axitinib significantly extended progression-free survival (HR=0.665, 95 percent CI; P<0.0001), with a median PFS of 6.7 months (95 percent CI, 6.3-8.6), compared with 4.7 months (4.6-5.6) for those treated with sorafenib, a standard of care for this patient population. PFS was significantly longer in axitinib-treated patients compared to those treated with sorafenib, regardless of prior therapy with Sutent or cytokines.

About 58,000 new cases of renal call carcinoma are diagnosed in the United States each year, and about 20 to 30 percent of these patients have advanced disease at the time of diagnosis. Around 13,000 individuals die of this tumor in the United States each year. Axitinib is an oral therapy that was designed to selectively inhibit vascular endothelial growth factor receptors 1, 2, and 3, receptors that can influence tumor growth, vascular angiogenesis, and progression of cancer.

Axitinib has been widely studied in a broad clinical development program, evaluating its efficacy and safety in more than 2,500 patients across several tumor types. The drug is also being investigated in a randomized Phase III clinical trial in patients with treatment-naïve as well as previously treated advanced RCC, and in a randomized Phase II clinical trial for the treatment of hepatocellular carcinoma.

In September, **Bayer** HealthCare Pharmaceuticals announced that the investigational drug radium-223 chloride, also called **Alpharadin**, showed positive data in the Phase III ALSYMPCA trial. The study met its primary endpoint by significantly improving overall survival by 44 percent (p=0.00185, HR=0.695) in patients with castration-resistant prostate cancer and symptomatic bone metastases. All of the main secondary efficacy endpoints analyzed to date were met, including delay in skeletal-related events. The data showed that patients who were treated with radium-223 chloride had a median overall survival of 14 months compared to 11.2 months for the placebo group, among other positive results. Radium-223 chloride was recently granted Fast Track designation by FDA.

"Radium-223 chloride is the first bone-targeted, alpha-emitting radiopharmaceutical to demonstrate a survival benefit in men with castration-resistant prostate cancer and symptomatic bone metastases," says Dr. Oliver Sartor of Tulane Medical School, New Orleans, and an ALSYMPCA trial investigator.

Another Bayer cancer compound, **regorafenib**, is also showing great promise. In October, the company announced results from its Phase III trial evaluating regorafenib for the treatment of patients with metastatic colorectal cancer whose disease has progressed after approved standard therapies. The trial met its primary endpoint of statistically significant improvement in overall survival. Bayer is continuing discussions with health authorities worldwide, including FDA and the European Medicines Agency, regarding next steps in filing for approval of regorafenib in the treatment of mCRC.

"These data are significant because they demonstrate that regorafenib increased overall survival in patients with heavily pretreated metastatic colorectal cancer, an area of high unmet medical need," says Kemal Malik, M.D., head of global development and member of the Bayer HealthCare (bayerhealthcare.com) executive committee.

Regorafenib is being studied for other indications as well. The drug was granted orphan drug status for the treatment of gastrointestinal stromal tumors by FDA in February 2011, and a fast track designation in May. It is also in Phase II trials in Europe for the treatment of renal cell carcinoma.

"There was a lot more skepticism in the HDL arena prior to the mid-phase trials of Merck and Roche ... Anacetrapib was first in this class to show it could raise HDL without associated increase in plaque and, even more so, without some of the other markers that would predict increased atherosclerosis in the coronary arteries."

## CARDIOVASCULAR

Merck's **anacetrapib** is a novel reversible and selective cholesteryl ester transfer protein inhibitor being investigated in a large Phase III outcomes study, the REVEAL study, for the treatment of atherosclerosis. The drug is anticipated to be filed after the results of the study become available; results from REVEAL are expected after 2015.

Another Phase III study of anacetrapib, DEFINE, already reported positive results at the end of 2010. In the trial of 1,623 patients with coronary heart disease or CHD risk equivalents, anacetrapib showed no significant differences from placebo in the primary safety measures studied. There were no significant differences in mean changes in blood pressure between the anacetrapib and placebo treatment groups, nor were there any significant differences in serum electrolytes or aldosterone levels. During the 76-week treatment phase, the pre-specified adjudicated cardiovascular endpoint (defined as cardiovascular death, myocardial infarction, unstable angina, or stroke) occurred in 16 anacetrapib-treated patients (2 percent) compared with 21 placebo-treated patients (2.6 percent) (p=0.40). At 24 weeks, anacetrapib decreased LDL-C by 40 percent (from 81 to 45 mg/dl versus 82 to 77 mg/dl for placebo, p<0.001) and increased HDL-C by 138 percent (from 40 to 101 mg/dl vs. 40 to 46 mg/dl for placebo, p<0.001) in patients already treated with a statin and at guideline-recommended LDL-C goal.

"These results are promising and serve as the basis for our decision to further develop anacetrapib," said Michael Mendelsohn, M.D., senior VP and franchise head, Cardiovascular, Merck Research Laboratories, on release of the DEFINE data. "We look forward to continuing to study anacetrapib in a large cardiovascular clinical outcomes trial."

In "Innovative Medicine Shaping the Cardiology Market," a report examining the latest breakthroughs in cardiovascular drugs, Dr. Leon Henderson of the inThought Research Group highlights anacetrapib as well as its two cousins, Roche's **dalcetrapib** and **Lilly**'s **evacetrapib**, as potential redefiners of the market.

"There was a lot more skepticism in the HDL arena prior to the mid-phase trials of Merck and Roche," Dr. Henderson says. "Anacetrapib was first in this class to show it could raise HDL without associated increase in plaque and, even more so, without some of

**FUTURE BLOCKBUSTERS**

| Product | Class of drug | U.S. pipeline status (latest stage only) | Companies |
|---|---|---|---|
| Alpharadin | Alpha-pharmaceutical | Phase III for the treatment of hormone-refractory prostate cancer in patients with skeletal metastases | Bayer and Algeta |
| AMR101 | Neuroprotectant | Awaiting approval for the treatment of very high triglycerides | Amarin Pharma |
| Anacetrapib | Cholesterol ester transfer protein inhibitor | Phase III for the treatment of atherosclerosis | Merck |
| Axitinib | Vascular endothelial growth factor receptor tyrosine kinase inhibitor | Awaiting approval for the treatment of advanced renal cell carcinoma | Pfizer |
| Bardoxolone | Synthetic triterpenoid | Phase III for the treatment of chronic kidney disease and for the treatment of type 2 diabetes | Abbott Laboratories and Reata Pharmaceuticals |
| BG-12 | Immunomodulator | Phase III for the treatment of relapsing-remitting multiple sclerosis | Biogen Idec |
| Bydureon (exenatide) | Glucagon-like peptide-1 receptor agonist | Awaiting approval for the treatment of type 2 diabetes | Amylin Pharmaceuticals and Alkermes |
| Dalcetrapib | Cholesteryl ester transfer protein inhibitor | Phase III for the treatment of atherosclerosis (cardiovascular risk reduction) | Roche |
| Eliquis (apixaban) | Factor Xa inhibitor | Awaiting approval for the prevention of stroke in patients with atrial fibrillation and for the prevention of systemic embolism in patients with atrial fibrillation | Pfizer and Bristol-Myers Squibb |
| Pertuzumab | HER2 dimerization inhibitor | Phase III in combination with Herceptin (trastuzumab) and docetaxel chemotherapy as first-line treatment of HER2-positive metastatic breast cancer | Roche |
| Quad | Integrase inhibitor | Awaiting approval for the treatment of HIV/AIDS infection | Gilead Sciences |
| Regorafenib | DAST inhibitor | Phase III for the treatment of patients with metastatic colorectal cancer who have progressed after standard therapies and for the treatment of gastrointestinal stromal tumors | Bayer |
| Ridaforolimus | Small-molecule inhibitor of the protein mTOR | Awaiting approval for the treatment of metastatic soft-tissue or bone sarcomas in patients who had a favorable response to chemotherapy | Merck and Ariad Pharmaceuticals |
| Tofacitinib | Janus kinase 3 inhibitor | Awaiting approval for the treatment of moderately to severely active rheumatoid arthritis | Pfizer |
| Vernakalant | Antiarrhythmic | Phase III for the treatment of atrial fibrillation | Merck |

*Source: eKnowledgeBase.com*

# If there's one thing I can't stomach, it's rotten data.

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the other markers that would predict increased atherosclerosis in the coronary arteries."

After being on the back burner following a failed attempt by Pfizer five years ago, HDL-raising is back in the spotlight, according to the inThought report. Heart attack prevention is always an important area of interest, and a growing body of evidence suggests that that raising HDL medically can help prevent heart attacks and other coronary events. All three of the HDL-raising cousins are emerging from trials looking like they lower HDL without increasing atherosclerosis or coronary plaque.

Roche's dalcetrapib, according to Dr. Henderson, appears to have more HDL-raising ability than Merck's anacetrapib, but whether that will be of clinical benefit remains unclear. The most recent data, presented in November, suggest that Lilly's evacetrapib also was associated with raising HDL while reducing coronary plaque.

Also in Merck's late-stage pipeline is the atrial fibrillation drug **vernakalant**, branded as **Brinavess** in Europe after its approval there in September 2010. In July 2011, Merck acquired the exclusive rights to develop and commercialize the investigational intravenous formulation of vernakalant in Canada, Mexico, and the United States from **Astellas** Pharma Inc.

"Atrial fibrillation represents a large and growing unmet medical need," Dr. Mendelsohn says. "With this agreement, Merck has secured worldwide rights to vernakalant i.v. This is an important step as we seek to expand access for patients in need."

Under the terms of the agreement, Merck paid Astellas an undisclosed upfront fee. In addition, Astellas will be eligible for milestone payments associated with development and regulatory approval as well as sales thresholds achieved in Canada, Mexico, and the United States.

In April 2009, Merck and **Cardiome** Pharma Corp. announced a collaboration and license agreement for the development and commercialization of vernakalant. The agreement provided Merck with exclusive global rights to vernakalant oral formulation for the maintenance of normal heart rhythm in patients with atrial fibrillation, and provides another Merck affiliate, Merck Sharp & Dohme (Switzerland) GmbH, with exclusive rights outside of the United States, Canada, and Mexico to vernakalant IV formulation for rapid conversion of recent onset atrial fibrillation to sinus rhythm in adults.

In October 2003, Astellas US LLC was granted an exclusive license to develop and commercialize vernakalant I.V. in Canada, Mexico, and the United States by Cardiome Pharma Corp. In April 2009, Merck, through a subsidiary, was granted exclusive rights to vernakalant I.V. outside of Canada, Mexico and the United States for rapid conversion of acute atrial fibrillation to normal heart rhythm.

In late November, **Bristol-Myers Squibb** and Pfizer announced that FDA had accepted for review and assigned a priority-review designation to the new drug application for **Eliquis**, an investigational compound for the prevention of stroke and systemic embolism in patients with atrial fibrillation.

The submission of the Eliquis NDA was based on the results of the ARISTOTLE and AVERROES studies, two Phase III trials that evaluated the efficacy and safety of the drug for the prevention of stroke or systemic embolism in patients with atrial fibrillation. These two trials, which included about 24,000 patients, comprise the largest completed clinical development program for stroke prevention in atrial fibrillation among novel oral anticoagulants, and included patients eligible for anticoagulant therapy based on current treatment guidelines, as well as patients expected or demonstrated to be unsuitable for vitamin K antagonist therapy. The drug was approved in May in the European Union for the prevention of venous thromboembolic events in adult patients who have undergone elective hip or knee replacement surgery. Eliquis is being investigated within the EXPANSE Clinical Trials Program, which is projected to include nearly 60,000 patients worldwide across multiple indications and patient populations and includes a total of nine completed or ongoing randomized, double-blind Phase III trials.

Also in November, the Eliquis partners announced the results of the Phase III ADOPT trial, which evaluated the drug versus enoxaparin in acutely ill medical patients, did not meet the primary efficacy outcome of superiority to enoxaparin for the endpoint of venous thromboembolism and VTE-related death at day 30. The Eliquis arm had a 13 percent lower rate of events than enoxaparin followed by placebo, which favored apixaban but was not statistically significant and thus no clinically directive conclusion can be drawn. The key safety outcome of major bleeding was low in both groups but occurred in more patients treated with apixaban than with enoxaparin (0.47 percent of patients in the apixaban group and 0.19 percent of patients in the enoxaparin group (P=0.04)).

"Solving the problem of VTE post-hospitalization remains a critical unmet need in preventing medically ill patients from developing deep vein thrombosis and pulmonary embolism," says Dr. Samuel Z. Goldhaber, senior cardiologist at Brigham and Women's Hospital, and professor of medicine, Harvard Medical School. "ADOPT provides important insights for clinical trialists designing studies of extended duration VTE prophylaxis among medically ill hospitalized patients."

**Amarin**'s **AMR101** is a prescription-grade omega-3 fatty acid that the company is developing as a potentially best-in-class prescription medicine for the treatment of patients with very high triglyceride levels (≥500 mg/dL) and as a potentially first-in-class therapy for patients with high triglyceride levels (≥200 and <500mg/dL) who are also on statin therapy for elevated LDL-cholesterol levels (also known as mixed dyslipidemia). The drug has completed Phase III clinical development for the treatment of hypertriglyceridemia in patients with very high triglycerides and for patients with high triglycerides who also have mixed dyslipidemia. Currently no omega-3 fatty acid based drugs are approved in the United States for patients with high triglycerides who also have mixed dyslipidemia, and only one U.S. prescription grade omega-3 fatty acid based drug (**GlaxoSmithKline**'s **Lovaza**) is approved for treatment of patients with very high triglycerides. FDA accepted Amarin's AMR101 NDA for review this past November.

"We are very pleased with the FDA's acceptance for filing of our AMR101 NDA submis-

## A CLOSER LOOK

### *Med Ad News'* top researcher focuses on three key future blockbusters.

**By Andrew Humphreys**

### Tofacitinib

**Analysis**: This new molecule is awaiting U.S., EU, and Japanese marketing approval for treating moderate-to-severe forms of active rheumatoid arthritis. Rheumatoid arthritis (RA) affects about 1.3 million Americans and one percent of the global population.

On track to gain FDA approval by August 2012, the janus kinase 3 inhibitor from **Pfizer** will go up against the stiffest of competition: **Abbott** and **Eisai**'s **Humira**. In addition to moderate-to-severe rheumatoid arthritis, Humira is FDA-approved for moderate-to-severe Crohn's disease, moderate-to-severe chronic plaque psoriasis, psoriatic arthritis, ankylosing spondylitis, and moderate-to-severe polyarticular juvenile idiopathic arthritis. The recombinant human IgG1 monoclonal antibody generated 2011 global sales of $7.93 billion for Abbott and is expected to become the world's top-selling prescription medicine, perhaps as soon as 2012. Humira's U.S. composition of matter patent is set to expire in December 2016.

The global rheumatoid arthritis market exceeds $20 billion. One favorable aspect of tofacitinib versus current blockbuster RA therapies is the drug's oral formulation, whereas Humira, **Remicade** (**Johnson & Johnson**, **Merck**, and **Mitsubishi**) and **Enbrel** (**Amgen**, **Pfizer**, and **Takeda**) are administered via injection. Studies indicate that tofacitinib is comparable to Humira in terms of efficacy data.

Tofacitinib has additionally been studied for psoriasis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, inflammatory bowel disease, ulcerative colitis, organ transplant rejection, and dry eye. Analysts have projected more than $1 billion in annual tofacitinib sales within four years of FDA approval of the RA indication. Potential peak sales for all approved indications could approach $3 billion, according to industry insiders.

Tofacitinib could represent the first blockbuster to emerge from Pfizer's laboratories since the likes of the schizophrenia medicine **Geodon** (launched in the United States during 2001) and the erectile-dysfunction drug **Viagra** (introduced in 1998). Other current billion-dollar brands marketed by the New York-based company came from M&A activity with Wyeth, Warner-Lambert, and Pharmacia.

Pfizer is in need of new blockbusters, as the company's cholesterol therapy **Lipitor** – the best-selling prescription medicine ever – lost U.S. patent protection at the end of November 2011.

### Anacetrapib

**Analysis**: One of the companies seeking to capitalize on the sales decline of Lipitor is Merck, which has a very promising cholesterol ester transfer protein (CETP) inhibitor in Phase III studies. Merck's potential atherosclerosis treatment **anacetrapib** is considered by company researchers to be one of two current pipeline compounds that could transform patient care.

Anacetrapib was the first drug in its class to demonstrate the ability to raise HDL without associated increase in plaque and minus some of the other markers that would predict increased atherosclerosis in coronary arteries. The compound has been praised for impressive lipid effects as demonstrated in clinical trials. At 24 weeks, anacetrapib treatment resulted in a placebo-subtracted 40 percent reduction in mean LDL-C and a 138 percent increase in mean HDL-C.

Another promising medicine in the CETP class was Pfizer's **torcetrapib**. At one point hailed as a potential replacement to the Lipitor franchise, the drug was pulled from development by Pfizer after being found to cause an excess of deaths and cardiovascular events.

Because of the unfortunate fate of torcetrapib, Merck and other companies such as **Roche** with **dalcetrapib** may take a few more years to reach the marketplace with their next-generation cholesterol therapies. Such medicines have the potential to exceed $10 billion in global yearly sales, as Lipitor did annually from 2004 through 2011.

In the near term, the cholesterol market will be lead by existing blockbusters such as **AstraZeneca** and **Shionogi**'s **Crestor**, Merck's **Zetia** and **Vytorin**,and prescription and generic versions of Lipitor.

### Bardoxolone

**Analysis**: Bardoxolone represents the lead molecule in **Reata** Pharmaceuticals' Antioxidant Inflammation Modulators (AIMs) portfolio. AIMs are potent inducers of the transcription factor Nrf2, a biological target that controls the production of many of the body's antioxidant and detoxification enzymes. Because oxidative stress and inflammation take place throughout the course of chronic kidney disease and are known to contribute to kidney function loss, agents that activate the Nrf2 pathway in individuals with chronic kidney disease may provide a novel method for preserving or improving kidney function.

During September 2010, Reata took on Abbott as a development and commercialization partner outside the United States, excluding certain Asian markets (**Kyowa Hakko Kirin** holds exclusive rights to develop and commercialize bardoxolone in Japan and other selected Asian markets). At that time, the oral, potential first-in-class antioxidant inflammation modulator was in Phase II trials for treating chronic kidney disease. Reata management previously had forecasted that the drug could generate up to $10 billion in peak yearly sales.

Since then, the drug has advanced into Phase III studies with the help of Abbott, and industry analysts recently projected peak annual sales of several billion dollars. Abbott leaders are excited about bardoxolone's market potential, as the product has the ability to significantly improve patient outcomes versus existing therapies that slow the progression of chronic kidney disease, a highly prevalent condition that affects 50-plus million adults globally.

The roughly $8 billion chronic kidney disease market is awaiting a blockbuster entrant and targeted therapy to take hold of it. The current marketplace is paced by generics and off-label medicines, which provide symptomatic relief.

Bardoxolone additionally is undergoing Phase III trials for the treatment of diabetes. Half of chronic kidney disease patients also have diabetes, and that percentage is expected to rise as diabetes rates grow.

Diabetes is the No. 1 cause of chronic kidney disease, with up to 40 percent of type 2 diabetics developing it. Currently marketed therapies modestly slow the progression of chronic kidney disease, and patients ultimately advance to dialysis.

A study announced in late 2011 suggests that bardoxolone may have the potential to boost the immune system's ability to detect and fight cancer. Bardoxolone was originally studied in cancer patients. In these studies, cancer patients with moderate-to-severe chronic kidney disease showed marked improvement in a key measure of kidney function. Based on those observations, Reata started development of bardoxolone in patients with advanced chronic kidney disease.

sion as it is a significant achievement in the development of what we believe is a next generation omega-3 based triglyceride lowering therapy," says Joseph S. Zakrzewski, chairman and CEO of Amarin.

Amarin has completed two pivotal Phase III clinical trials with AMR101 under Special Protocol Agreement with FDA. The first, the MARINE study, is a Phase III trial for the treatment of very high triglycerides. The second, the ANCHOR study, is a Phase III trial to treat high triglycerides in patients with mixed dyslipidemia who are on statins for elevated LDL-C levels. These two studies are designed to support the broadest label in this drug class. The company also previously investigated AMR101 in central nervous system disorders in several double-blind, placebo controlled studies, including Phase III trials in Huntington's disease. More than 900 patients have received AMR101 in these studies, with more than 100 receiving continuous treatment for a year or more. In all studies performed to date, AMR101 has shown a very good safety and tolerability profile.

## OTHER THERAPEUTIC AREAS

In late December, **Gilead** Sciences Inc. announced that the marketing authorization application for the **Quad** single-tablet regimen of elvitegravir, cobicistat, emtricitabine, and tenofovir disoproxil fumarate for the treatment of HIV-1 infection in adults, submitted in November, had been validated by the European Medicines Agency. Just a few days later, FDA accepted Gilead's Quad NDA for review.

"Based on the safety and efficacy data from the Phase III pivotal studies, we believe the Quad single-tablet regimen has the potential to be a convenient treatment option for patients new to HIV therapy," says Norbert Bischofberger, Ph.D., executive VP, Research and Development and chief scientific officer, Gilead Sciences. "We look forward to working with European regulatory authorities to bring this new single-tablet regimen to physicians and patients as quickly as possible."

The applications for the Quad are supported by results from two Phase III studies (Study 102 and Study 103). The MAA is also supported by clinical data for the individual components of the Quad and Chemistry, Manufacturing, and Controls information on the individual components of the Quad and the co-formulated single-tablet regimen.

Also in December, FDA accepted for review the new drug application for Pfizer's **tofacitinib**, an investigational novel oral JAK inhibitor being studied for the treatment of adult patients with moderately to severely active rheumatoid arthritis. Pfizer has also submitted an application for this indication for tofacitinib to regulatory authorities in Japan, and an application for tofacitinib for the treatment of adult patients with moderate-to-severe active RA is being reviewed by the European Medicines Agency.

"Pfizer is pleased to have achieved this regulatory milestone, which reflects our commitment to advancing treatments for inflammatory conditions, and constitutes a significant step toward bringing tofacitinib to RA patients who are in need of additional therapeutic options," says Geno Germano, president and general manager, Specialty Care and Oncology, Pfizer. "We are proud of the comprehensive Phase III clinical program that we have completed and believe that, if approved by the FDA, tofacitinib has the potential to improve the lives of people with RA."

> "As pioneers in the GLP-1 market, we are proud of the truly innovative diabetes products that our two companies have provided patients ... Amylin is excited to assume full responsibility for developing and commercializing exenatide."

In September, partner developers **Amylin** Pharmaceuticals Inc., Lilly, and **Alkermes** Inc. announced new analyses from the DURATION-3 and -4 trials demonstrating patients treated with the investigational medication **Bydureon** experienced significant improvements in select cardiovascular risk factors, in comparison to patients who received commonly prescribed diabetes treatments. The analyses showed that patients receiving Bydureon for the treatment of type 2 diabetes experienced improvements in composite endpoints related to body weight, abnormal blood pressure, and abnormal lipid levels.

"Patients with diabetes are at least twice as likely as people without the disease to have heart disease or a stroke," says James Malone, M.D., global exenatide medical director, Lilly Diabetes. "Having other chronic conditions including obesity, high blood pressure, or high cholesterol further increases this risk. These data underscore the need to consider not only glycemic control but also the important role played by other medical conditions that are common among patients with type 2 diabetes."

The Bydureon partners are no longer partners, though. In November, Amylin and Lilly agreed to terminate their alliance for the drug and resolve the outstanding litigation between the companies, transitioning full responsibility for the worldwide development and commercialization of Bydureon to Amylin.

"As pioneers in the GLP-1 market, we are proud of the truly innovative diabetes products that our two companies have provided patients," says Daniel M. Bradbury, president and CEO of Amylin. "Amylin is excited to assume full responsibility for developing and commercializing exenatide. We anticipate working with one or more partners outside the U.S. in order to maximize the global potential of this innovative molecule and achieve greater operational flexibility and efficiency. This clarity of focus will provide us with an enhanced opportunity to increase shareholder value."

Under the terms of the new global agreement, Amylin made a one-time, upfront payment to Lilly of $250 million. Amylin will also make future revenue sharing payments to Lilly in an amount equal to 15 percent of global net sales of exenatide products until Amylin has made aggregate payments to Lilly of $1.2 billion plus accrued interest. Amylin will issue a secured note in the amount of $1.2 billion to Lilly under which any revenue sharing payments made to Lilly will reduce amounts outstanding under the note. If Bydureon does not receive FDA approval prior to June 30, 2014, Amylin's revenue sharing obligations will terminate, and Amylin will thereafter pay Lilly 8 percent of global net sales of exenatide products. Amylin will also pay a $150 million milestone to Lilly contingent upon FDA approval of a once monthly suspension version of exenatide that is currently in Phase II. The companies have also agreed that the maturity date for the $165 million line of credit that Amylin drew from Lilly earlier in the year will be extended from the second quarter of 2014 to the second quarter of 2016.

Another diabetes drug, **bardoxolone**, is showing promise for its developers **Abbott** Laboratories and **Reata** Pharmaceuticals. In June, Phase II clinical trial data showed that patients with moderate-to-severe chronic kidney disease and type 2 diabetes receiving bardoxolone for 52 weeks experienced a sustained improvement in kidney function throughout the treatment period, as measured by estimated glomerular filtration rate. The Phase II dose-finding clinical trial, known as the BEAM study, showed that in patients with moderate to severe chronic kidney disease and type 2 diabetes, eGFR at 52 weeks was significantly improved with bardoxolone methyl treatment by up to 10.5 mL/min/1.73m$^2$ in patients receiving 75 milligrams ($p<0.001$).

"The published data for bardoxolone methyl suggest that it may have potential to delay kidney disease progression in patients with compromised kidney function," says Dr. David Warnock of the University of Alabama at Birmingham, the senior author of the study report article. "Further study to learn more about the clinical benefits of this drug candidate is warranted."

That additional study is already under way. Also in June, Reata and Abbott announced the initiation of a Phase III clinical trial to evaluate the safety and efficacy of bardoxolone in patients with chronic kidney disease and type 2 diabetes. The trial, known as BEACON, is the first multinational, double-blind, placebo-controlled study designed to assess the impact of bardoxolone on time to important clinical outcomes. About 1,600 patients at 300 sites worldwide – including in Austria, Australia, Belgium, Canada, the Czech Republic, France, Germany, Israel, Italy, Mexico, Spain, Sweden, the United Kingdom, and the United States – will be enrolled in the trial and randomized 1:1 to receive 20 milligrams of a reformulated version of bardoxolone or placebo once daily. Results are expected in 2013.

In October, **Biogen Idec** announced positive top-line results from CONFIRM, the second of two pivotal Phase III clinical trials designed to evaluate the investigational oral compound **BG-12** in people with relapsing-remitting multiple sclerosis. Results showed that 240 milligrams of BG-12, administered either twice a day or three times a day, demonstrated significant efficacy and favorable safety and tolerability profiles. In addition to significantly reducing annualized relapse rate, BG-12 met all secondary relapse and MRI endpoints for both dose regimens.

The results of CONFIRM came just a few days after Biogen Idec announced positive data from the Phase III DEFINE clinical trial of BG-12 in people with relapsing-remitting multiple sclerosis showing that 240 milligrams of BG-12, administered either twice a day or three times a day, significantly reduced the proportion of patients who relapsed by 49 percent and 50 percent, respectively, at two years compared with placebo.

"We now have strong positive results for BG-12 in two robust pivotal clinical trials with more than 2,600 patients," says Doug Williams, Ph.D., Biogen Idec's executive VP of research and development. "We are gratified by these strong efficacy and safety results, which, when combined with BG-12's oral route of administration, position it as a potentially important MS therapy. We are working aggressively to prepare our regulatory submissions with the goal of making BG-12 available to MS patients as quickly as possible." ■ MEDADNEWS

# Getting in the iPad groove

## A top 50 pharmaceutical company and a small specialty pharma company both find the iPad a perfect fit with their sales forces.

**by Christiane Truelove** chris.truelove@ubm.com

**When looking** for a sales force tool that would make promotional materials come alive, ties into closed loop and customer relationship marketing systems, and has a platform that allows quick updates of materials, **Depomed** Inc. and **Daiichi Sankyo** both turned to the iPad. Depomed, a small specialty pharmaceutical company, equipped its sales force with the iPad for the launch of **Gralise** in October. Daiichi Sankyo is using the iPad for its entire sales force across the company's whole product portfolio, rolling out the initiative in the beginning of the year. Executives from both companies agree that the iPad provides the portability, execution, and data to make their sales forces shine.

"When we realized we would have the opportunity to market Gralise ourselves, we had basically a greenfields opportunity to do whatever we chose in the technology arena," says Mark Howard, senior director of IT at Depomed (depomed.com). "From the get-go, we really wanted to focus on something that would be engaging for both our reps and our physicians. As a small pharmaceutical, we wanted to be very aggressive and very agile in this space. And after looking at a number of different platforms, including the Slate from HP and various and sundry tablet computers, we elected to pursue the iPad for ergonomic capability, development capability, and just general ease of use."

Daiichi Sankyo also viewed several options before settling on the iPad, including traditional tablet PCs, say Bill McClean, VP of sales, and Shawn O'Hagan, senior manager, marketing solutions, at Daiichi Sankyo (dsi.com).

"We did look at other tablet options, we piloted other tablet options, but the iPad was able to deliver – all of the options could deliver on the IVA [interactive visual aid] component, and some of the other tablets might have been able to do some of the other things, but not as efficiently and not as brilliant as what the iPad could deliver," Mr. McClean says.

Mr. O'Hagan says it was the iPad's light weight, ease of use, and very intuitive interface that made it stand out from tablet PCs.

David Rustum, director of marketing for Gralise for Depomed, agrees that the iPad's light weight was among the selling points that made it superior to tablet PCs. "When you consider the value of the iPad and its capabilities, portability, its ease of use, just from an ergonomic standpoint, if you've got a sales rep trying to hold a tablet computer up to the doctor's eye level, or shoulder-chest level, you better have a fairly strong rep, to hold four or five pounds that long," he says.

Three things attracted Depomed to the iPad, says Steve Greco, VP of sales.

"The first is the fact that we had to have a very strong customer impact, so it's really a test of our impact," he says. "The customers, physicians, healthcare providers, like to see something in this format, and we're able to then also do things with an iPad setting that you couldn't do on a non-iPad setting.

"The second part of it was a comprehensible approach. You're limited in what you can do on the traditional format; with an iPad, it gives you the breadth of material in a way that you can cover it quickly and succinctly, that you just can't do with other vehicles.

"And the third part of it, is the flexibility. With the flexibility piece, we're able to do changes much more quickly when normally you'd have to do a major meeting around it, we're able to have that downloaded and put into the system in such a way that we're responding to the market conditions much faster and much more efficiently than we would without it."

Daiichi Sankyo was impressed with the way an iPad visual aid can make the reps – and the physicians – stay on message, as opposed to a paper-based sales aid.

"Bottom line is, when you're showing the paper copy of something, and you're pointing at a piece of data on that piece of paper, the physician is potentially looking somewhere else and reading somewhere else, there's some distraction going on," Mr. O'Hagan says. "However, with the iPad, what we found out, it's only that piece of data that is being discussed. And it's interactive, and it really brings them in and keeps them laser-focused on the discussion point. That's really important because the messages resonate much better that way, and what we're finding out from feedback, with paper the physicians tend to get a little bit lost. So it gives us an opportunity to create a better dialog with them, and hopefully those messages resonate so that they could take those back to their patients."

Both companies say the initial feedback they have received from physicians and the sales forces has been overwhelmingly positive.

"They [sales representatives and physicians] absolutely love it," Mr. Greco says. "In fact the utilization of our visual aid is probably double what you would normally get based upon various surveys that you would get in a non-iPad system ... in the 75-plus percent range in terms of utilization, and as you know, normally you're in the 35 percent range, 35 to 40. It literally is double – physicians like it, the representatives like it, it's easy to use, it's easy to communicate from. You're able to go in the direction you need to go, and at the same time, you can have the same consistency of message"

### WORKING ON THE CUTTING EDGE

As one of the first companies to use the iPad as part of a product launch strategy, Depomed executives realized there were several challenges to overcome.

"For the launch of Gralise, we wanted to have consistency of message and utilization of a visual aid with that message, and those core messages are being delivered," Mr. Rustum says. "There's always a logistical nightmare to launching a product, both in getting a product available on the shelves and getting all the promotional material, nonpromotional materials ready, and the fact that we are entering a new realm of core visual, which is the cornerstone tool that the representatives use on a daily basis. That presented some challenges from a timing perspective in loading [the iPad] and getting it into the hands of the field. All in all, the No. 1 goal was making sure we had consistency of message, that the visual has been utilized, that's 101 in the launch of a product, and we felt that this tool could help us achieve that goal very effectively."

Although the iPad has many winning points, when the marketing solutions team first pitched the sales teams at Daiichi Sankyo about using the device, some reservations were expressed.

"I pushed back, I've got to be honest, because one of the things that I didn't want [the IVA] to be, was simply a passive visual aid on either a computer or an iPad or tablet or whatever it may be," Mr. McClean says.

To reassure Mr. McClean, Mr. O'Hagan's group formed a team to figure out exactly what the interactive visual aid would be, and not be.

"What resulted was a tool that really is achieving exactly what they were looking for, a tool that is actually making the experience between the sales representative and our customers a very engaging discussion," Mr. McClean says. "The makeup and the high-definition look of the iPad are fantastic, and the feedback we're getting from the field right now is great, to where we're actually seeing extended time with the physician as a result of it."

One thing Mr. McClean insisted on was that the iPad would be used by the entire sales force, and not just the team associated with one brand. "I didn't want it to be a one-off type thing," he says. "There had to be some sort of a strategy associated with this type of technology, and I think the team really came up with that strategy, so it goes beyond just the IVA, it goes on how we want to show up in front of our customer, how we want to create efficiencies for our organization, and so on."

Mr. O'Hagan says rollout of the iPad to the entire sales force was delayed until the platform could be standardized across the brands.

"The decision on that was to first standardize this on the platform, to really not do this as a one-off per brand, but really look at it from an enterprise perspective and use it across brands, and that really speaks to training too," he says. "We wanted to keep this as user-friendly as possible, to again gain buy-in from users, from the representatives, but also the interaction from the healthcare professional, and give that seamless approach, for instances when you're going to one brand to another, you're using that enterprise system to make that transition."

Although the sales force members were generally familiar with the iPad's functionality from consumer use, Daiichi Sankyo made sure that training was occuring before the devices were used in the field.

"I want people to not worry about what button they're pushing, I want it to be second nature to them," Mr. McClean says. "I don't want them fumbling around with the technology. One of the things that we required, is we did a 'train the trainer' for the district managers and we brought everyone together. We didn't feel comfortable in just having them out in the field. We brought people in specifically for this, and we basically certified the district managers on their ability to use the system, to do it right, and to transfer that knowledge to the representatives."


The Depomed Gralise team: from left, Jaime Nassar, senior director marketing; David Rustum, director, marketing; Mark Howard senior director, information technology; Kevin Weber, VP, marketing; Steve Greco, VP, sales; and Jeff Vengley, senior director, sales operations.

One aspect of the platform both companies appreciate is the ability to quickly change messaging as needed, and being able to disseminate the new materials through a corporate apps center.

"If we wanted to tweak a visual aid, now we'd have to go to production, and that takes time, then we'd have to ship it out, and that takes time, and then the reps have to be there to receive it," says Jaime Nassar, senior director of marketing for Depomed's gabapentin franchise. "This, we just send it through the app center, and they can get it right away and they're able to have it the next day as opposed to weeks down the road, so that allows us that speed to respond to the marketplace as well as the flexibility."

When it comes to deploying the iPad across brands, though, coordination of all the agencies providing materials is key, Mr. O'Hagan says.

"I can tell you from orchestrating an enterprise system, and my experience in the past with doing systems like this, you have a lot of folks playing in the sandbox together," he says. "And we are working with multiple agencies. You just have to make sure you have good governance and good business rules, the technology has to be laid out as well as it relates to standards, there's a compliance component early on with our MLR group, make sure they have early on feedback and buy-in. There's a lot of orchestration that goes on there, and we have it nailed down right now, even to the point of helpdesk, we have them fully enagaged. It's a lot of coordination, a lot of orchestration, but we have a system in place where agencies will create content, we'll package it up, and then we'll deploy it."

Some industry observers have expressed the view that if pharma companies focus only on the hardware, the novelty of the iPad will soon wear off. But leaders with both Depomed and Daiichi Sankyo are well aware that the iPad is just a tool, and it's the content that counts.

"The majority of physicians we talked to, it's really about the content you're serving up, that's important, as long as the content is good, the physician's going to get engaged, and I think that will translate to positive events," Mr. O'Hagan says. "We were talking to physicians

who had iPads for over a year and half who said they were very intrigued by the content that we were presenting, the educational materials we were presenting, the promotional messaging, they were intrigued by it, so that's something that speaks very positively on the future. As long as we can keep the content fresh and updated, we can keep the experience alive."

Still, there was a concern that certain sales reps would prefer to use the paper aids.

"My biggest fear was that if this was just a visual aid on a computer, I was concerned about that, because maybe the reps would then say, 'Why am I using this thing, I could simply use paper,'" Mr. McClean says. "What we're finding is that that's not the case, they don't want to go back and use the paper, because the way things are working right now, we're not running into any glitches, the reps feel very confident in utilizing the iPad."

Daiichi Sankyo also found that the appreciation of the iPad format was fairly universal.

"Some of the data that we saw early on going into this kind of led us down the path of thinking that physicians who were in practice for more than 12 years would have a tendency not to gravitate in this direction, that they'd want the paper," Mr. O'Hagan says. "Actually we found out, when we were interviewing physicians in practice more than 25 years, that they loved it. So it's a fair playing field throughout and it's not a specific audience or age that's leaning either way, paper versus iPad."

## IN THE (CLOSED) LOOP

When Depomed was looking at hardware, the company was also eyeing options for customer relationship management and closed loop marketing software. One company provided a software as a service program that was being developed for the iPad, and that's the one Depomed chose.

"We also developed a capability for a visual sales aid that has the ability to provide feedback back into the customer relationship management system, effectively giving us closed loop marketing," Mr. Howard says.

Depomed exeecutives say the goal of the combination of the iPad detailing program and the software-as-a-service cloosed loop marketing program was to give the sales forces a tool they could easily use – unlike traditional spreadsheet programs on laptops.

"In terms of entering their calls, we're using the CLM piece, it automatically puts the calls into the system, versus the rep having to do extra administrative work," Mr. Nassar says. "What that means is more time selling for the field sales representatives, versus more administrative time."

Depomed has been able to hook the CLM system into the interactive visual aid to track what the sales force is doing, knowing exactly what part of the aid has been used how many times and giving the company an idea of which messages have been well-received and which messages have not been.

Additionally, the program has cut down on paperwork for the sales force.

"There is little paperwork associated with samples when they do it on the iPad; we capture signatures via the screen itself, so there is no paperwork that the field has to send in on a weekly basis like companies that are still doing paper samples," Mr. Nassar says. "That also means fewer compliance issues, because we're putting this service in there that makes it easy to be compliant."

Daiichi Sankyo sales reps also appreciate the reduced paperwork aspect of the iPad, and physicians like the "green" aspect.

"Clearly, we're benefiting from signature on the iPad, because physicians can simply just sign the screen and then we can leave them samples, which cuts out all the paper, " Mr. McClean says. "When you take that paper and you bring it back to the home office, that paper has to go somewhere, we have to keep records. And we can't keep thousands and thousands and millions of documents, so we actually have to scan those documents and put them into a system, so we're going to eliminate that process. And I know a big piece of it, there's a lot of money spent on just simply paper and the production of massive visual aids, slimjims, all those types of things, where we'll be reducing that bigtime."

Unlike Depomed, however, Daiichi Sankyo chose not to have a CRM or CLM system built into the iPad detailing program.

"With a CLM, there's a lot of metrics and things like that, and we didn't want to burden the representatives with a lot of clutter, if you will, coming out of the gate," Mr. O'Hagan says. "We wanted to keep it as simple as possible. And the reason why I bring up phases is that downstream, we may consider choosing a CLM type of system, but at first, we really wanted them to get acclimated with it and feel comfortable with it."

According to Mr. McClean, the sales force needs to continue to train and give feedback on that training before a CLM component can be added in.

"If we start creating reports and making decisions based on what we're seeing from a utilization perspectives, that may send us in the wrong way because of the process of mastering this technology," he says. "We want to have insights, but we want to understand how the sales reps are using the tool and where we need to make changes, and if they're using a specific part of the tool a lot more than others, we need to find out why – why are they doing that and why are they not getting this part of the message. It's really going to be powerful information once we get it. We could do it now, but we made the decision not to because it wouldn't be the right time to do it for us." ■ MEDADNEWS

**Challenging assumptions**


Pharmaceutical sales leaders may have formed certain assumptions regarding the current state of personal promotion, but a hard look at the data may force them to rethink their customer-facing roles and strategy.

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# Compliance packaging:
# Incorporating the patient perspective

**Marketers and product designers who work together in earlier phases of product design and packaging to incorporate patients' natural daily routines may create more convenient products, improve compliance — and simultaneously improve brand marketability.**

**by Cara Latham** cara.latham@ubm.com

**The biggest barrier to** success in a patient's treatment is compliance and adherence to his or her medications, according to some industry leaders. Yet, in a scenario where a patient might have to take multiple drugs at various times each day, a focus on integrating the product into the patient's lifestyle has taken a back seat to the proven efficacy of the product.

However, packaging the drug – and the design of the product itself – as a convenient means for a patient to remain compliant not only helps patients remain healthy, industry leaders say, but can also help with marketing the brand and increase the likelihood that a patient will discuss that product as a treatment option with his or her healthcare provider at the point of prescribing.

"What we're finding is that having a good drug is no longer enough to equal a good treatment for the patient, a good experience for the patient," says Graham Reynolds, VP of marketing and innovation, pharmaceutical delivery systems, West Pharmaceutical Services, which works with pharmaceutical and biotech companies to help design, develop, and supply both the packaging systems for drug products and delivery systems. "Understanding how the patient will take the drug and how to make that easy for them, I think, is key to ensuring compliance to a treatment regimen and health of a patient."

Although marketers and ad agencies are rarely involved in this design process, marketers have to figure out how to differentiate the product from competition. Piquing a marketer's interest in learning how the design of the package or device itself can enable a product to stand out from competition – whether visually or functionally – can help generate interest in the process.

"We find a lot that marketing people, certainly within pharmaceutical companies, are getting involved in a much earlier phase of the development process to make sure that those types of things are considered," Mr. Reynolds says. "Certainly, we've seen a big growth in what's called 'device divisions' within pharmaceutical companies, whereas typically, pharmaceutical companies have had a bunch of scientists really focused on the way that that drug gets into a patient – whether it be through a device or some sort of package. Those device groups are getting more intimately involved with ways to understand a patient through research or marketing studies."

FDA requirements have also forced companies to consider human factors in engineering while designing devices and drug delivery systems, and Mr. Reynolds says his company's clients are beginning to pay more attention to devices' outer packaging and understanding how patients interact with it.

"If you have a drug that's packaged in some sort of unit that's inside a delivery device, you not only have to consider how that device would be used, but how the patient would gain access to that device," Mr. Reynolds says. "Is it a package that needs to be opened? Does it come with instructions? Are there instructions or hints built into the device itself? For instance, we have some systems where we have engineered in arrows or indications to show how the products should be used – actually onto the device itself."

If a patient has to take an injection on a regular basis, he or she will probably lean toward a product that is more discreet. With diabetes, for example, "people want a pen that they can slip into their pocket that doesn't necessarily look like a drug device," Mr. Reynolds says. In cases where the product is too bulky, patients may develop a tendency to leave their homes without bringing the product along because of its inconvenience, leading to the potential for risks and complications. Considering the design of the delivery system from the patient's point of view and whether that patient will be comfortable taking his or her medications as prescribed can help resolve the dilemma.

Many insulin pens for younger patients, for example, can be customized with various labels depicting cartoon characters. A sleeve that goes on the outside of the pen, or a customizable plastic piece that can be interchanged with different images are simple, but can be built into the device development process, Mr. Reynolds says.

Considering the brand experience for the patient and gaining an understanding of the patient early in the process enables designers to build the patient's preferences into the device and its package at the point of development.

Although many people might not think of the co-formulation of multiple medications into one pill – such as in certain HIV treatments – as a packaging solution, such innovation has helped product design professionals integrate medication more naturally into a patient's lifestyle, says Michael Parisi, managing partner, Ogilvy CommonHealth Worldwide.

Yet the need to be creative and innovative from a marketing perspective and the understanding of the challenges from a manufacturing and operational standpoint still create potential conflicts within the process. The real solution is to bring those two groups together at an early stage so that the two can move products forward jointly, industry leaders say.

Both marketers and product design professionals, though, have been focused on the infusion of technology into developing products that patients will find easy to use and remain compliant. Mr. Parisi says Ogilvy has focused on finding technological solutions to the idea of packaging and compliance – beyond the development of GlowCaps. Mr. Parisi points to the development of proprietary products that use a closed-loop system.


If Pfizer had developed a compliance package to separate the Lipitor brand from the generics that have since hit the market, the company may have had an easier time retaining the brand's place at the top of the market after going off patent at the end of 2011, industry leaders say.

"Whether it's a smart pill box, or adherence compliance bracelet, or some other technology, we've really been putting 75 percent of our energy into infusing technology into helping solve this idea of packaging and compliance," Mr. Parisi says.

Ogilvy, he says, has developed an adherence bracelet that uses communication technology to remind patients to take their medications, similar to the design of a Livestrong bracelet. The bracelet also uses technology to communicate back to a database when a patient does take his or her medication.

Mr. Parisi says his agency is also proactively researching a patient's natural environment to gain insights from the end user of the products so that the agency can inform its clients about considerations for aspects of the design before they start to manufacture a package. He points to contact lenses as an example. Because lenses are lasting longer, patients are sampling products less frequently, and a year's supply is usually shipped to the consumer, marketers and manufacturers need to focus on the interaction.

"How do you create regular behavior, so things like re-ordering products become simple, mindless, and almost automatic?" Mr. Parisi says. One solution may be determining a method for triggering an auto refill or a message to a patient reminding him or her to renew the prescription or to schedule an appointment with his or her doctor.

"Taking all the guesswork or all the roadblocks out of the journey is a really important piece of the puzzle as well," Mr. Parisi says. "You can reach ten reasons why not to go to the doctor, and the next thing you know, they're not refilling their scripts, and things fall apart. So, we're trying to really use technology and use research to inform the entire journey so we can create solutions that make sense."

In fact, the companies that are successful are those that have learned from the end user. Similar to the birth control dial packs that have become part of a woman's handbag, packaging a product in an easy-to-use solution can help a patient remain compliant. The use of film – like the Listerine mints that dissolve on a patient's tongue – in drug delivery is one example, says Mr. Parisi.

**Reckitt Benckiser** Pharmaceuticals Inc. (rb.com), the manufacturer of **Suboxone** sublingual film, a treatment for opioid addition, utilizes the film delivery solution. "The last thing someone wants to do is carry a bag of pills around when they're addicted to painkillers and prescription meds, so those little film tabs have made a tremendous impact on changing how that product is used," Mr. Parisi says.

Targeting similar packing solutions to chronic conditions like diabetes and hypertension may lead to greater compliance in the future. A good compliance package clearly separates a product from other commodity drugs, and more companies should be looking to the ways compliance packaging can help market a brand, even when a particular product has gone off patent.

"Good compliance packaging, particularly if a product is going off patent, would be a great motivator to get patients and physicians to continue to prescribe their product because the package is so unusual," says Sander Flaum, CEO, managing partner, Flaum Idea Group. "If you had a brand that was going off patent, and it was a compliance pack, you definitely would continue it because that brands you differently from the competition."

Mr. Flaum points to **Pfizer**'s (pfizer.com) **Z pack**, which has since gone off patent, but has still found success because of its unique packaging. If Pfizer had developed a compliance package to separate the **Lipitor** brand from the generics that have since hit the market – perhaps in a once-a-day pack of 30 – the company may have had an easier time retaining the brand's place at the top of the market after going off patent at the end of 2011.

When taking products for conditions such as hypoglycemia and hypertension, a patient must remain compliant on a daily basis to prevent illness.


Reckitt Benckiser Pharmaceuticals Inc., the manufacturer of Suboxone sublingual film, a treatment for opioid addic tion, uses a film delivery solution similar to the Listerine breath strips, which can help a patient remain compliant.

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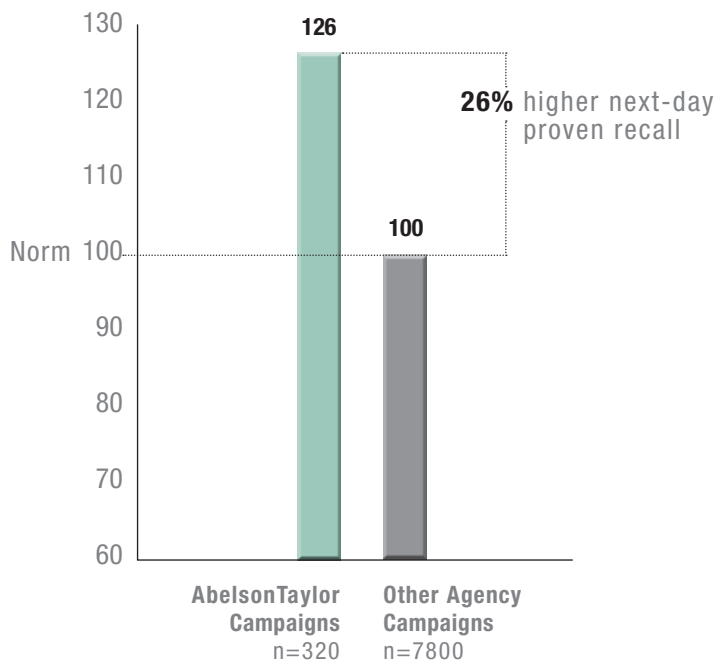


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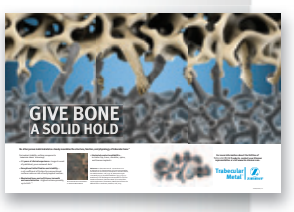



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"For the more acute products, you need it," Mr. Flaum says. "You're going to take your oncology medications every day, no matter how it is packaged. It's the hypertension, hypoglycemia, and those products that really need compliance."

From a consumer point of view, Mr. Reynolds says, a person who is presented with the choice between multiple brands of ketchup may choose a product based on the design of the bottle, or ease with which he or she can store the product (such as bottles that stand on their heads). In a competitive environment where multiple drugs treat the same condition, the determining factor may be the packaging.

"In a pharmaceutical market, the effectiveness of a drug needs to be the most critical factor," Mr. Reynolds says. "In a situation where there might be two different drugs that effectively do the same thing, then the decision criteria might be the way that it's handled by the patient, or the way that it's packaged, or the convenience."

In this regard, patients are carrying more influence in the decision process. "With the increasing use of the Internet and blogs, people learn from their peers about what works and what doesn't work, and they may have more power to go to their physician and say, 'I like this product because of these reasons,'" Mr. Reynolds notes. "Marketing groups within pharmaceutical companies are recognizing that and trying to address it through packaging and devices."

Although the use of electronic tools is not a trend in compliance packaging, healthcare companies are focusing on these tools to improve medication adherence and remind patients via texts, Tweets, and other methods to take their medications, says Walter Berghahn, executive director, the Healthcare Compliance Packaging Council (hcponline.org).

"What's really missing is to get some of those programs to be working with pharma manufacturers or providers to put a smart package in place such that you can combine the two," Mr. Berghahn says. "If you get a text reminder, but you're still dealing with your amber vial, and there's not much information on the vial, it's helpful – but it would be a lot more helpful if you had a smart, well-designed package, and now you're getting text reminders, and you're getting information back and forth, which is really teaching you about the drug, or teaching you about the disease, and that's kind of missing – the connection between these new smart devices and these tools that are being employed and improvements to antiquated packaging systems.

Making the connection between new technology and packaging will require greater interest from pharmaceutical manufacturers, Mr. Berghahn believes. "They're going to be told to do it, and they're going to be forced to change what they're doing," he says. "And it's the care provider and the insurance providers who I think have the muscle to make that happen."

## RXADHERENCE 2012

Changes within the healthcare industry, particularly the growth of accountable care organizations (ACOs) and pay for performance programs, are pressuring hospitals and caregiver organizations to demonstrate improved health outcomes. In turn, these groups are looking for ways to improve medication compliance and adherence.

"It's a very interesting opportunity for the packaging community if they will look in a slightly different direction than they have been for driving interest in compliance packaging," Mr. Berghahn says. "These things have been moving along for years now, and pharmaceuticals are getting into focus."

Programs such as the Five-Star Medicare Advantage also provide financial incentive to care providers who focus on improving medication adherence. The topic – "How Patient Adherence Improvements Affect The CMS 5 Star Rating System For Medical Practitioners," featuring John O'Brien, field director, Centers For Medicare & Medicaid Services, CMS Innovation Center – is on the agenda at the annual RxAdherence conference, which is now in its 20th year.

RxAdherence 2012, co-sponsored by HCPC and UBM Canon brands *Med Ad News, PharmaLive*, *Pharmalot*, and *Pharmaceutical & Medical Packaging News*, focuses specifically on patient adherence and compliance prompting pharmaceutical packaging. This year's event will be held on Tuesday, March 27 at the Hamilton Park Hotel and Conference Center in Florham Park, N.J. During the conference, expert speakers in the packaging niche will examine and address the latest trends and topics impacting the area of drug delivery.

Each year, the HCPC also solicits entries from the pharmaceutical industry for consideration in its Compliance Package of the Year competition to determine pharmaceutical packages that are best designed to optimize patient adherence. The 2011 Compliance Package of the Year winners will be recognized at the event.

The conference also provides an avenue of outreach to bring attention to better adherence and compliance practices. Mr. Berghahn believes the packaging community must find a way to present the message to marketers and brand managers to bring them on board.

Mr. Parisi believes marketers have always had an interest in understanding how to convince patients to follow adherence guidelines. "It will always be something we have to address, but we've been asking the wrong questions," he says. "We need to start asking the right questions to find out: What is the issue we're trying to solve?" ■ MEDADNEWS

# Just click here

Nearly every drug maker uses social media to organize and conduct clinical trials these days, and sooner than later, this will become ubiquitous. But the technology continues to pose challenges.

**By Ed Silverman** ed.silverman@ubm.com

**If you think using** social media for organizing and running clinical trials is a snap, consider the following scenario. A safety study had just gotten under way to test an experimental injectable drug for a chronic disease in which children typically die before they turn 20 years old. However, a few parents began comparing notes on a social media site about physical reactions – or the lack thereof – their children were encountering after receiving injections. And the discussions prompted some parents to suspect their children may have received a placebo. This posed an unexpected problem.

"All of a sudden, there were moms who were wondering whether they should keep their children on this therapy for a year and not take any other therapy," says Wendy White, president of Siren Interactive, a marketing agency that specializes in online media. "It typifies a huge issue that we're going to have to deal with. In the past, clinical trials had big walls between physicians and participants, and there was much less ability for a patient to know if they were on a placebo. But the landscape has changed and in the future, we have to look at ways to control that. But how do we that? Do we ask participants who sign up for a trial not to use social media? And is that actually possible?"

The conundrum underscores the opportunity – and the challenges – that social media offers drug makers, marketing agencies, contract research organizations, and clinical trial investigators as the Internet is increasingly embraced as a tool for organizing and conducting studies. On one hand, the potential for recruiting patients can be greatly increased. For instance, by making the world appear smaller, Siren's Eileen O'Brien, who is director of search and innovation, notes that using social media sites can make it easier to recruit patients for trials that are run simultaneously in different countries, especially when a study requires participants with specific genetic traits who are otherwise hard to find.

Meanwhile, dedicated Websites are increasingly being created to serve as forums and meeting grounds where people who are devoutly interested in health matters can not only learn more about an illness, but can also join what amounts to an easily found pool of potential recruits. Not surprisingly, these are generally a highly motivated group of people, including not only those who suffer from any number of diseases, but also their family members, caregivers, and patient-advocacy organizations.

"Typically, this is a self-selected population of patients and caregivers," says Brian Loew, president of Inspire, which runs such a site that also actively helps drug makers recruit patients for clinical trials. "So it's not scattershot. And if you ask them about participating in a trial, the hit rate will be higher. This means that a company is much further down the funnel than if they were looking at the broad population. Some people with a diagnosis don't do much about it, but a fraction will want to address that, and that's the kind of population you're dealing with" on such sites.

This contrasts with the general population. For instance, 94 percent of those surveyed recognize the importance of participating in clinical trial research in order to assist in advancing medical science, according to CenterWatch, a research company that tracks clinical trial trends. Yet 75 percent of the general public reports having little to no knowledge of clinical trials or the process for participating, according to still another survey conducted in 2008 by the Center for Information & Study on Clinical Research Participation, a non-profit organization dedicated to capturing and disseminating clinical trial data.

However, the increasing use of social media – by sponsors and their proxies, as well as patients – is likely to greatly alter such statistics over time, according to several experts. But for that to happen, social media has to be presented as an interactive opportunity and not just an updated substitute for traditional advertising, even if the effort is housed on a Website. The key is to view the process from the perspective of the patient and understand how and why they might respond to online information.

"The problem is that many agencies or groups take a DTC approach and look at it as advertising," says Kurt Mueller, chief digital and science officer at Roska Healthcare Advertising. "Any time you get into that promotional mindset, you can get yourself in trouble. Fundamentally, the process used by a person to enroll in a trial is not based on advertising. They're going through a continuum – Do they have a problem? What options are available? And there has to be acceptance – they have to be convinced that enrolling in a trial is a viable option."

In a widely discussed example of how this approach is being put to the test, **Pfizer** last year began what has been dubbed a clinical-trial-in-a-box. The company is running the first study to allow patients to participate from home by using computers and smartphones instead of visiting a clinic or doctor's office. By doing so, Pfizer hopes to create a model for saving money that will rely on personal technology to more easily recruit patients and monitor their progress.

The effort, which is known officially as the Remote trial, recruited patients through Internet ads; prospects can visit a Website that explains the trial, which is studying the Detrol overactive bladder medication, and permitted enrollment. All materials – the blinded study drug and a mobile app for ePRO, or electronic patient-reported outcomes – are sent to participants at home, although blood must be drawn at a local clinic or during home visits.

"The trial is well under way and the team is actively learning and adapting to various patient recruitment channels," says Craig Lipset, who heads clinical innovation in the worldwide research and development unit at Pfizer. "Some methods are certainly proving less productive than others, and the project team is reacting to data in real time."

Beyond using social media to engage the patient during the process, the trial is also designed to make use of telemedicine and remote patient monitoring. In this way, a principal investigator can monitor patient safety without requiring patients to visit an office. Although no one at Pfizer expected the experience would be a panacea, Mr. Lipset says the effort is yielding concrete intelligence about how to proceed in the future.

"The overwhelming response to the public announcement of the program demonstrates the critical need for innovation in clinical trials," he says. "While not intended as a global solution for all protocols, Remote demonstrates that we are able to bring creative new solutions to regulated clinical trials while maintaining our ethical, regulatory, and legal responsibilities."

Indeed, drug makers and their proxies must be mindful of these requirements, especially given privacy concerns on the Internet. Any online effort should have regulatory experts on hand to vet each step of the process, says David Coman, who is senior VP of communications and patient recruitment at Quintiles, the contract research organization, which has aggressively embraced the Internet to bolster its recruitment efforts. Quintiles' ClinicalResearch.com Website, for instance, is linked to the corporate Facebook page and has some 165,000 registered users who receive various newsletters.


Pfizer recently launched the Remote trial of the overactive bladder medication Detrol, the first study to allow patients to participate from home by using computers and smartphones instead of visiting a clinic or doctor's office.

Not surprisingly, the CRO says using social media, which is now a component of just about every clinical trial that is launched, is saving time and money – and will increasingly do so as the Internet becomes more widely used and accepted as a recruitment tool, according to Mr. Coman. For instance, social media recruiting often shaves the amount of time needed to recruit patients, which traditionally can take between nine months to a year for a so-called average trial.

"Social media is proving that we can recruit patients in decent numbers with a decent level of investment," he says. "The challenge now is to take it from the incubation phase to full-out execution, where you recruit all patients through social media … We've made a massive investment to make that happen – search engine marketing, search engine optimization – that takes out traditional advertising costs. Of course, even tapping into the Facebooks of the world, there's still an advertising cost."

Just the same, the increasingly global reach of clinical trials poses a challenge for using some social media. As drug makers run studies in more and more countries, patients may not receive exactly the same information during a clinical program's rollout.

For instance, there are some countries where Facebook offers an advantage, because certain types of direct communications with prospective patients are illegal, says Marie Emms, managing director of the advertising agency Fast4wd Ogilvy.

"Certain trial sites may benefit from social media, but others more so from a newspaper advertisement," she says. "A lot of our clients, when they have a clinical trial running, it could be in different countries, so social media is often a very small part of the recruitment program. Facebook is important and can get good results, but it's not the be-all and end-all. It has a place as much as TV or radio advertising. The real issue with social media is knowing what works best or better for each patient population, and the trial site as well. That's the key." ■ MEDADNEWS


Quintiles' ClinicalResearch.com Website is linked to the company's Facebook page and has 165,000 registered users who receive various newsletters.

YANC/ISTOCKPHOTO.COM

**By Joshua Slatko** joshua.slatko@ubm.com

# Novartis settles sales rep overtime suit

**The law firm** of Sanford Wittels & Heisler LLP and **Novartis** Pharmaceuticals have reached a $99 million settlement to resolve a nation-wide wage and hour class action originally brought by SWH in the Southern District of New York in March 2006 on behalf of current and former Novartis sales representatives. In this class and collective action lawsuit, thousands of Novartis sales representatives claimed that they were owed overtime pay under state and federal labor laws because they work more than 40 hours during a work week.

The settlement followed a series of judicial victories by the plaintiffs. In July 2010, the United States Court of Appeals for the Second Circuit agreed with the Novartis sales representatives, confirming that Novartis should pay overtime to its sales representatives. In February 2011, the United States Supreme Court refused Novartis' application to review the Second Circuit's decision, allowing that decision to stand. Following the Supreme Court's denial of review, counsel for Novartis and SWH engaged in negotiations to explore settlement of the plaintiffs' overtime class action. In January 2012, the parties' discussions were successful and they reached a $99 million settlement to resolve the suit.

"We are pleased to have secured a $99 million settlement wherein Novartis compensates its sales representatives for years of overtime pay," says David Sanford, lead counsel for the plaintiffs. "While we remain confident that the United States Supreme Court later this year will uphold the Department of Labor's interpretation of wage and hour law, the risks of further litigation are great. We are proud that over seven thousand current and former Novartis sales representatives will be able to participate in this settlement. It is a fair and equitable result and can serve as an exemplar for companies around the United States that face wage and hour litigation."

Sanford Wittels & Heisler was the first law firm in the United States to bring a class action suit alleging wage and hour violations on behalf of pharmaceutical representatives against a pharmaceutical company. Since this suit against Novartis was filed in March 2006, numerous other firms around the country have brought similar suits against other pharmaceutical companies. The majority of federal and state courts have ruled against plaintiffs in those actions. SWH is the only firm to win on both the administrative and outside sales exemptions at the federal appellate level.

The settlement was reached against the background of a looming United States Supreme Court decision on whether pharmaceutical sales representatives are entitled to overtime pay. Although the Supreme Court declined in February 2011 to review the Second Circuit's ruling in *Novartis* that the pharmaceutical representatives were entitled to overtime pay, the high court changed course in November 2011, agreeing to decide whether the outside sales exemption applies to pharmaceutical sales representatives in *Christopher, et al. v. SmithKlineBeecham Corp.* Resolution of the matter is expected in the summer of 2012. In reaching the $99 million settlement, SWH's attorneys say they were keenly aware that if the Supreme Court ruled that pharmaceutical representatives are exempt outside salespersons, the plaintiffs in the Novartis case would not be able to recover any overtime pay, notwithstanding the Second Circuit's favorable ruling.

SWH took several other risks into account when negotiating the settlement. For example, if the upcoming presidential elections produce a change in administration, the firm's attorneys feared that the United States Department of Labor would take the position that pharmaceutical sales representatives are exempt from overtime pay. The Supreme Court also might not certify a class including Novartis sales representatives from April 2007 to the present in light of Novartis' representation that it has changed the duties of sales representatives and has reduced the hours that sales representatives work each week; or might apply the fluctuating work week method of calculating overtime pay, thereby greatly reducing damages; and the the "highly compensated employee" exemption might be applied, thereby excluding thousands of employees from the class.

January 25, 2012, Judge Paul A. Crotty in the United States District Court for the Southern District of New York preliminarily approved the $99 million settlement as fair and adequate.

"We believe this settlement is in the best interest of our employees and the company," says André Wyss, president of Novartis Pharmaceuticals Corp. (novartis.com) "We have been litigating this case for nearly six years and the company has determined that it is time to resolve these wage and hour claims. We consistently compensate all employees fairly in accordance with the U.S. Fair Labor Standards Act and applicable state laws. We remain confident that sales representatives should continue to be classified as exempt from overtime because their autonomy and incentive compensation are typical of exempt employees as defined by U.S. law."

# Patient-pharmacist interaction program improves adherence

**A CVS Caremark study** has found that the company's integrated pharmacy-based program, Pharmacy Advisor, increased medication adherence rates and physician initiation of prescriptions for concomitant medications, improving care for diabetes patients and resulting in savings for health plans.

Pharmacy Advisor promotes interactions between diabetes patients and pharmacists, either in face-to-face counseling or on the phone. The study, "An Integrated Pharmacy-Based Program Improved Medication Prescription and Adherence Rates in Diabetes Patients," was published in the January issue of *Health Affairs* and highlights the central role pharmacists can play in improving the health of their patients.

"Ensuring adherence and appropriate treatment has long been the domain of primary care providers," says Troyen A. Brennan, M.D., executive VP and chief medical officer of CVS Caremark and lead author for the study. "However, as demands on the time of these providers increase, interventions carried out by pharmacists can complement primary care. Indeed, pharmacists are in the unique position to monitor patient adherence and effectively intervene when indicated."

According to Dr. Brennan, the study also added insight into the problem of time-limited healthcare interventions. "This study showed that patients stay on their medications while they are actively counseled, but once those pharmacist-patient conversations ended, adherence fell quickly," he says. "We need to continue these kinds of interventions to make sure patients benefit from the full beneficial impact of their medications."

Researchers from Harvard University and Brigham and Wom-

*Continued on page 21*

## Epocrates, M3 form HCP research partnership

Two of the largest market research sample providers in the pharmaceutical industry, Epocrates, Inc. and M3 Inc., have launched a partnership to create the world's largest verified physician and healthcare provider panel. By combining their high-quality, opted-in physician panels, the companies hope to offer a global market research sampling solution.

The partnership, company leaders say, will offer research companies, pharmaceutical marketers, and investors greater access to qualified physicians and other healthcare professionals. The new unified panel covers more than 70 countries with more than 1.7 million physicians globally. The top 10 medical specialties worldwide are highly represented, including oncology, cardiology, and family practice.

The Epocrates market research panel is composed of verified U.S. physicians and other healthcare professionals who use the company's mobile clinical reference application, which company executives say helps create stronger engagement and higher responsiveness.

"An audit within the industry revealed that M3 has the same quality assurance and values that we uphold for our research business," says Peter Brandt, interim president and CEO of Epocrates. "Together, we are elevating the integrity and delivery standards across the research industry."

M3 Inc. operates globally with physician communities across the world including m3.com, MDLinx.com, Doctors.net.uk, Medquarter.de, and Medigate.net. This enabled the development of a proprietary healthcare professional panel with international diversity and extensive reach. M3 is a founding member of the Trust Alliance, recently introduced to promote trust in online physician research.

"Both companies have established deep relationships with panel members, providing faster turnaround and more quality responders all over the world," says Aki Tomaru, M3's U.S. CEO. "The goal of this partnership is to create some of the best healthcare market research coverage globally, featuring more consistent and comprehensive solutions for the industry."

## FACTS & FIGURES

U.S. healthcare spending experienced historically low rates of growth in 2009 and 2010 according to the annual report of national health expenditures by analysts at the Centers for Medicare & Medicaid Services. According to the report, the increase in spending for 2009 represents **the lowest rate of increase in the entire 51-year history of the NHE**. The low rate of growth, the data show, reflects lower utilization in healthcare than in previous years. The report notes that U.S. healthcare spending grew only **3.9 percent** in 2010, reaching **$2.6 trillion** or **$8,402 per person**, just **0.1 percentage point faster** than in 2009.

In 2010, as health spending growth remained low, growth in the U.S. economy as reflected in gross domestic product (**4.2 percent**) rebounded. As such in 2010, the health spending share of the overall economy was unchanged at **17.9 percent**. In the past, this share has increased, rising over time from **5.2 percent** in 1960.

Household healthcare spending equaled **$725.5 billion** in 2010 and represented **28 percent** of total health spending, slightly lower than its **29 percent** share in 2007. Growth in total private health insurance premiums slowed in 2010 to **2.4 percent** from **2.6 percent** in 2009, continuing a slowdown that began in 2003. Despite this deceleration, for the first time in seven years, the growth in premiums exceeded the growth in insurer spending on healthcare benefits, with the net cost of insurance increasing by **8.4 percent** or **$11.3 billion** in 2010. Out-of-pocket spending by consumers increased **1.8 percent** in 2010, accelerating from **0.2-percent** growth in 2009.

Retail prescription drug spending (**10 percent** of total healthcare spending) grew only **1.2 percent** to **$259.1 billion** in 2010, a substantial slowdown from **5.1-percent** growth in 2009 and the slowest rate of growth for prescription drug spending recorded in the NHE.

The federal government financed **29 percent** of the nation's healthcare spending in 2010, an increase of **six percentage points** from its share in 2007 of **23 percent**, and reached **$742.7 billion**. Part of that increase came from enhanced Federal matching funds for state Medicaid programs under the American Recovery & Reinvestment Act, which expired in 2011. Medicare spending grew **5 percent** in 2010, a deceleration from growth of **7 percent** in 2009. Medicaid spending increased **7.2 percent** in 2010, slowing from **8.9-percent** growth in 2009.

The state and local government share of total health spending declined from **18 percent** in 2007 to **16 percent** in 2010 and totaled **$421.1 billion**, in part due to the temporary assistance in the Recovery Act.

Hospital spending, which accounted for roughly **30 percent** of total healthcare spending, grew **4.9 percent** to **$814 billion** in 2010, compared to growth of **6.4 percent** in 2009. Growth in private health insurance spending for hospital services, which in 2010 accounted for **35 percent** of all hospital care, slowed considerably in 2010.

Physician and clinical services spending, which accounted for **20 percent** of total healthcare spending, grew **2.5 percent** to reach **$515.5 billion** in 2010, slowing from **3.3-percent** growth in 2009.

Private businesses financed **$534.5 billion**, or **21 percent** of total health spending in 2010, down from a **23 percent** share in 2007.

## MOST-RECOGNIZED BRANDS

### DIABETIC BRANDS



**The most-recognized diabetic brand** in North America is **metformin**. The brand was most recognized by 11 percent of physicians in a survey conducted by **Brand Institute** Inc. during the third quarter of 2011. Metformin is the generic name for Glucophage, listed next; the drug was prescribed more than 48 million times in the United States in 2010, ninth-most among all prescription products.

**Glucophage** is the second most-recognized diabetic brand in North America. About 10.3 percent of physicians recognize this brand the most. Glucophage, comprising metformin, is marketed by **Bristol-Myers Squibb** Co. (bms.com). The drug was first approved by FDA in December 1994 as monotherapy as an adjunct to diet to lower blood glucose in patients with type 2 diabetes mellitus whose hyperglycemia cannot be satisfactorily managed on diet alone, and concomitantly with a sulfonylurea when diet and Glucophage or a sulfonylurea alone do not result in adequate glycemic control. An extended release formulation was approved in October 2000, and a pediatric indication was added in December 2000.

The third most-recognized diabetic brand in North America is **Actos**. About 7.3 percent of physicians recognize this brand the most. Actos, comprising pioglitazone, is marketed by **Takeda** Pharmaceuticals North America Inc. (tpna.com). The product was approved by FDA in July 1999 as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes as monotherapy or in combination with a sulfonylurea, metformin, or insulin when diet and exercise plus the single agent does not result in adequate glycemic control.

The most-recognized diabetic brand in Europe is metformin. About 8.8 percent of physicians recognize this brand the most.

Glucophage is the second most-recognized diabetic brand in Europe. About 7.1 percent of physicians recognize this brand the most.

The third most-recognized diabetic brand in Europe is **insulin**. About 5.2 percent of physicians recognize this brand the most. Insulin is a naturally-occurring hormone secreted by the pancreas; FDA first approved treatment with insulin in 1939, and a variety of companies supply the product in vial, syringe, or cartridge form.

Brand Institute (brandinstitute.com) surveyed more than 2,000 physicians and hospital and retail pharmacists in North America and Europe to determine the most-recognizable brands in the category of diabetes. Brandpoll is a marketing tool designed to help clients monitor the competitive marketplace and identify the potential strengths and weaknesses of their brands.

*Continued from page 20*

en's Hospital assisted the CVS Caremark researchers in the analysis of the pharmacy claims data of benefit members at a large Midwest manufacturing company and focused on interventions with diabetic patients between October 2009 and April 2010. The study included an intervention group of 5,123 people who were proactively counseled by retail and call center pharmacists and a control group of 24,124 patients with diabetes who did not receive specialized counseling. The researchers measured gains in patient adherence and medication initiation rates of concomitant therapies for diabetes, such as statins, angiotensin converting enzyme inhibitors and angiotensin receptor blockers.

The research showed that contacts by pharmacists with the patients and their doctors increased therapy initiation rates by as much as 39 percent for the full sample and an even higher 68 percent for the group counseled at retail stores, and increased medication adherence rates by 2.1 percent. The researchers noted that face-to-face interventions by retail store pharmacists resulted in increasing adherence rates by 3.9 percent.

CVS's integrated pharmacy-based program featured counseling by pharmacists at 12 retail stores near the manufacturing client's headquarters, and counseling through a dedicated pharmacist call center for those identified as having diabetes. CVS Caremark launched Pharmacy Advisor for diabetes in 2009 because the cost and prevalence of that disease continues to rise. The American Diabetes Association estimates the cost of the disease to the United States in 2007 at $174 billion.

The study estimated that the employer saved more than $600,000 through healthcare cost avoidance with the intervention group, while expenditures for the counseling totaled $200,000, a return on investment of $3 for every $1 spent on additional counseling.

"In a healthcare system eagerly seeking programs that can reduce costs and improve care, such simple, pharmacist-based counseling programs to improve adherence to existing medication regimens and initiate missing therapies should be of great value," the researchers conclude.

CVS Caremark has been working in a three-year collaboration with Harvard University and Brigham and Women's Hospital to research pharmacy claims data in order to better understand patient behavior, particularly around medication adherence. Annual excess healthcare costs due to medication non-adherence in the United States have been estimated to be as much as $290 billion annually.

The Pharmacy Advisor program is being expanded in 2012 to include counseling for patients with cardiovascular disease, in addition to the more than 12 million members who are part of the diabetes-focused counseling. Through Pharmacy Advisor, CVS Caremark has engaged PBM members who are diagnosed with diabetes, according to their expressed preferences at points when they are most receptive about their prescribed therapy: face-to-face when members choose to fill their prescriptions at a CVS/pharmacy or by phone if the members use home delivery. According to company leaders, the use of the integrated tactics drives behavior change in the short term and over time leads to better clinical outcomes. In addition to improving medication adherence, thus saving money and improving the quality of treatment, the program closes gaps in care and directs members with chronic conditions to existing disease management programs where they can obtain additional support.

## Follow the money: where pharma is investing

**By Ed Silverman**

Everyone talks about how the pharmaceutical industry is increasingly investing in facilities – R&D and manufacturing – in China and India. But just how much money is flowing into those countries? And how does that compare with the level of investment in other places, not just the United States, but still other locales that are thought to be up and coming or, conversely, on the decline?

Well, between 2007 and 2010, the United States received the largest investment – $73.3 billion, followed by China with $29.8 billion, Singapore with $17.7 billion, India with $16.8 billion, and $16 billion pumped into Ireland. The results are not surprising, yes? Other countries that also ranked high were Italy, Germany, Switzerland, Canada, and Brazil.

The ranking contrasts remarkably, though, with the period between 2003 and 2006, when investments in the United States hit $38.7 billion. Next up was Ireland with $37.1 billion, Singapore with $27.6 billion, China with $19.7 billion, and Germany with $14.8 billion. The top 10 was rounded out by Spain, France, Puerto Rico, India, and Sweden. As you can see, four countries dropped off the most recent list.

The findings, which were published in a new report by Jones Lang Lasalle, the commercial real estate company, underscore how drugmakers are seeking low-cost venues for their most labor-intensive activities. For instance, in Asia, investment has been growing rapidly in Taiwan, Malaysia, and the Phillipines. Similarly, Argentina, South Africa, and Egypt are designated up-and-coming venues.

Meanwhile, the report finds "a number of higher-cost locations in Europe are starting to see the balance of investment shift away from manufacturing to R&D." The United Kingdom is a prime example, while France, Belgium, and Sweden appear to be heading in this direction. The data also suggest many European locations will continue to see healthy levels of investment, since pharma has not yet turned to the Middle East or Africa as "a platform for operating margin improvement or revenue growth."

A couple of other observations – Puerto Rico is on the decline. Last year, the island government passed a law that imposes a 4 percent tax next year on companies that conduct manufacturing on the island, but are headquartered elsewhere. Ever since, some drugmakers have grumbled about the possibility of picking up and leaving.

And while the report predicts that Canada will become a more important R&D hub, Johnson & Johnson apparently does not agree. In January, the drugmaker disclosed plans to shutter an R&D center in March, which will put 126 people out of work, including 36 employees and another 90 who were hired by outside contractors, some of whom work at an manufacturing plant.

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**By Cara Latham** cara.latham@ubm.com **and Joshua Slatko** joshua.slatko@ubm.com

# FDA breaks silence on social media

**Although not as specific as some** industry professionals have expected, FDA has finally provided some guidance to pharmaceutical companies with respect to social media and other digital communication, including online forums and threads.

The agency has issued draft guidance for industry responses to unsolicited requests for off-label information about prescription drugs and medical devices. Within the document, FDA addresses drug or medical device companies' use of "emerging electronic media." The set of four proposed recommendations, released December 27, are currently in a 90-day period during which FDA will accept comments on the draft guidance.

"Although falling short of what some may have hoped for from the FDA in the way of sweeping dos and don'ts, the draft guidance is the first time the agency has addressed the specific topic of off-label information and the Internet when it comes to unsolicited, public requests," says Ed Silverman of Pharmalot.com. "And here's a crucial take-away: if a drugmaker adheres to the draft guidance, the FDA will not use the response as evidence that there was intent to promote off-label."

Within the document, FDA addresses a company's responses to public, unsolicited requests for off-label information about its products, including those encountered through emerging electronic media. A company should respond only when the request pertains specifically to its owned named product (and is not solely about a competitor's product), FDA regulators write.

To determine whether a company's response is appropriate to the unsolicited request, the level of specificity of the question posed in a public forum is important, FDA states. For example, a company would be appropriate in responding to a person who asks in a public forum whether a certain drug or device can be used to treat a specific condition – if the question was not prompted by the company.

"However, if an individual poses the non-specific question, 'What drug/device can be used for condition Y?' in a public communication thread, and the company manufactures or distributes drug/device X, which is not FDA-approved or cleared for condition Y, the company should not respond to the request because the question is not specific to drug/device X," regulators write in the document.

However, FDA also specifies that a company's public response to public unsolicited requests for off-label information about its named products should be limited to providing the company's contact information and should not include any off-label information.

The company's response should convey that the question pertains to an unapproved or uncleared use of the product and should direct all information requests to the medical/scientific representative or the medical affairs department of the company. Specific contact information, including e-mail address, telephone number, or facsimile, should be included so that the person can follow up in a non-public, one-on-one manner.

"Regardless of the fact that the original, unsolicited off-label question may have been available to a very broad audience, the company should not make its detailed response with off-label information publicly available within the same forum," FDA officials write.

Mr. Silverman says the agency does address the use of Twitter in discussing solicited requests. If a drugmaker tweets about a study and somehow suggests an off-label use is safe and effective, FDA would consider any comments and requests to the original Tweet about off-label use to be solicited.

"Similarly, if a drugmaker encourages people to post videos about using one of its products on, say, YouTube, and the content includes off-label use that prompts questions, this also would be considered a solicited request," Mr. Silverman writes. "And the FDA tries to be quite clear that solicited requests 'may be considered evidence of a (drugmaker's) intent that a drug … be used for a use other than that specifically approved or cleared' by the agency."

FDA has also addressed regulations regarding individuals who respond publicly to unsolicited requests for off-label information. Regulators say these individuals should clearly disclose their involvement with a particular company. The individual must disclose he or she is a particular company's representative and include the name of the company. He or she must list the department to contact should the person who requested information want to follow up directly with the company in a non-public forum. All of these responses should not be promotional in nature or tone, FDA has recommended. FDA also states that in addition to a company's contact and disclosure information, a public response should also include a mechanism for providing readily accessible current FDA-required labeling, if any, for the product.

"For example, a public online response should include a direct link to the current FDA-required labeling, if any, but should not include links to any other information (e.g. product Websites, product promotional materials, company Websites, third-party Websites)," FDA states in the draft guidance.

The URL or web address where viewers are directed to obtain the FDA-required labeling should not itself be promotional in tone or content. For example, bestcancercure.com would be inappropriate, FDA officials say.

"If a company responds to public unsolicited requests for off-label information, including those encountered through emerging electronic media, in the manner described above, FDA does not intend to use such responses as evidence of the company's intent that its product be used for an unapproved or uncleared use," FDA writes. "Such responses also would not be expected to comply with the disclosure requirements related to promotional labeling or advertising."

## Lundbeck "click" campaign keeps Huntington's clinic open

An extraordinary online fundraising effort by a pharma company has helped save a clinic for Huntington's disease patients.

In January, the U.S. division of H. **Lundbeck** AS (lundbeck.com) announced the results of its second Build Hope for HD campaign, benefitting the Casa Hogar Amor y Fe (House of Love and Hope). The Casa Hogar is a clinic that provides care for people affected by Huntington's disease. Lundbeck and the Hereditary Disease Foundation rallied support to maintain this clinic because of its significant contributions to HD research in the past and potential contributions in the future. As a result of the campaign, along with additional support from Lundbeck, more than $185,000 was donated to the clinic so that it may continue to provide treatment, food, care, and an integrated nursing home to thousands of family members with HD who live along the shores of Lake Maracaibo in Venezuela.

Build Hope for HD, which launched on Sept. 15, 2011, consisted of an online "click" donation campaign on BuildHopeforHD.com, as well as direct donations to the Hereditary Disease Foundation that were matched by Lundbeck. The campaign generated more than 1,550 clicks and 60 personal donations to HDF, resulting in the maximum match from Lundbeck. In all, Lundbeck contributed $160,000 to Casa Hogar, which included $110,000 in matching donations through the Build Hope for HD campaign and a $50,000 charitable donation earlier in the year to support the clinic's immediate financial needs.

"We are so incredibly thankful for Lundbeck's amazing generosity and to everyone who clicked and donated to help support the Casa Hogar," says Dr. Nancy Wexler, president of the Hereditary Disease Foundation and Higgins Professor of Neuropsychology, Columbia University. "The families living around the shores of Lake Maracaibo have revolutionized HD research, and the lives of people living with HD around the world. Thanks to them, we were able to locate the HD gene in 1983 and find the gene itself in 1993."

According to Dr. Wexler, the Casa Hogar is a model for best care practices for Huntington's disease, even though the patients, families, and caregivers are living in extreme circumstances of poverty and duress. Opened in 1999, the clinic was built in gratitude to the families whose help was critical to researchers who identified the HD gene in 1983 and isolated it in 1993. The clinic is now home to more than 65 people and provides care and food to many more from the surrounding community. By policy of the Casa Hogar, almost all of the people who work there are family members of people with HD.

"We are inspired by the support of the hundreds of individuals who participated in this year's Build Hope for HD campaign," says Staffan Schüberg, president of Lundbeck in the U.S. "As a company committed to the HD community, we are proud to support the important work of the Casa Hogar."

## Veeva hearts Group DCA

Veeva Systems' Veeva CRM and Group DCA's digital detailing platform will combine to deliver a new multichannel selling solution with a single, integrated view of the customer, according to leaders of both companies. The new integration aims to enable seamless synchronization of insights gained from all interactions with the customer – from traditional channels such as one-on-one details to the latest interactive channels including self-directed, online educational details – all accessible within Veeva CRM. The result, company leaders hope, will be better coordination across channel and, as research suggests, improved sales performance versus personal promotion alone.

Group DCA, a pharmaceutical marketing agency now part of PDI, a provider of outsourced pharmaceutical commercial services, created its comprehensive digital detailing solution for healthcare providers to access relevant product information any time, through any browser. The Group DCA eDetailing solution currently includes almost 200,000 physicians who have "opted in" to receive relevant eDetails. The solution, in

The new Veeva/Group DCA integration aims to enable seamless synchronization of insights gained from all interactions with the customer.

use by more than 75 brands in the United States, delivered 100,000 eDetails in 2011.

"At Group DCA's portal, physicians had been spending an average of seven minutes watching eDetails," says Jo Ann Saitta, chief information officer, PDI and general manager, Group DCA. "That's truly amazing, especially considering that most reps barely get more than two minutes of a physician's time during visits. Clearly, here was another channel that physicians were using and that pharmaceutical companies need to be embracing. In fact, research shows that combined eDetail and rep detailing increases sales effectiveness as much as 60 percent."

Veeva CRM's multitenant cloud-based architecture is designed to integrate with any outside system for unlimited extensibility of the platform. Specifically, the Group DCA integration falls in line with Veeva Systems' strategy to enable a seamless dialogue across all customer engagement channels while empowering pharmaceutical companies with the full gamut of multichannel selling capabilities.

"Veeva will continue to embrace multichannel innovation with both internal development and through collaboration with leading partners such as Group DCA," says Paul Shawah, VP, product marketing, Veeva Systems.

Recently, 600 PDI field sales users went live with Veeva CRM integrated with Group DCA HCP web portals. These sales reps now have visibility into HCP self-directed information inquiries and digital interactions from Group DCA's digital detailing channel as it is funneled through the company's Veeva CRM system. Additionally, sales reps are able to trigger marketing activities from the Veeva platform to drive and support physician engagement efforts.

ARTVEA/ISTOCKPHOTO.COM

# Business

**By Cara Latham** cara.latham@ubm.com

# Lilly on track despite earnings decline


Eli Lilly is anticipating revenue and earnings decline in 2012 due to patent expiration of its antipsychotic drug, Zyprexa.

**Eli Lilly** and Co. expects to meet or exceed its financial projections for 2011, but the company is anticipating revenue and earnings decline in 2012 due to patent expiration of its antipsychotic drug, **Zyprexa**.

Lilly executives are estimating 2012 revenue to be between $21.8 billion and $22.8 billion. The projection includes an expected decline of more than $3 billion in Zyprexa sales due to patent expirations in most markets outside of Japan. Company leaders expect the reduction in revenue, however, to be partially offset by growth in key franchises including **Cymbalta** (depression/axiety), **Cialis** (erectile dysfunction), **Humalog** (type 1 diabetes), **Humulin** (diabetes), and **Forteo** (osteoperosis), as well as continued growth of newer products such as **Effient** (used to prevent blood clots forming in acute coronary syndrome patients), **Axiron** (used to treat low levels of testosterone), and **Tradjenta** (type 2 diabetes mellitus). Lilly leaders also anticipate continued strong, double-digit revenue growth from its Elanco Animal Health business.

"2012 is an important year for Lilly, having entered the period when we face patent expirations on some of our largest products, most notably Zyprexa late last year and Cymbalta in the United States at the end of 2013," says John C. Lechleiter, Ph.D., chairman, president, and CEO, Lilly. "We've been preparing to meet these challenges for many years, and have the plans in place to enable us to bridge this period and return to sustainable growth after 2014. We remain focused on executing this plan."

The company also expects both Japan and emerging markets to post continued strong underlying volume growth. However, Lilly leaders expect pricing actions in Japan and the anticipated impact of patent expirations, including Zyprexa, in some emerging market countries, will adversely affect overall revenue growth in these markets in 2012. The company anticipates that gross margin as a percent of revenue will be about 77 percent.

As a result of ongoing productivity efforts, Lilly leaders expect this year's operating expenses will remain essentially flat compared to 2011. The company also anticipates marketing, selling, and administrative expenses to be flat-to-declining and in the range of $7.4 billion to $7.8 billion, while research and development expense will be flat-to-increasing and in the range of $5 billion to $5.3 billion. Company leaders also expect 2012 earnings per share to be in the range of $3.10 to $3.20 on both a reported and non-GAAP basis.

Lilly executives also expect operating cash flows to be more than sufficient to fund capital expenditures of about $800 million, as well as anticipated business development activity and the company's current dividend.

"2012 is an important year for Lilly, having entered the period when we face patent expirations on some of our largest products, most notably Zyprexa late last year and Cymbalta in the United States at the end of 2013," says John C. Lechleiter, Ph.D., chairman, president ,and CEO, Lilly (lilly.com). "We've been preparing to meet these challenges for many years, and have the plans in place to enable us to bridge this period and return to sustainable growth after 2014. We remain focused on executing this plan."

At the end of 2011, Lilly's R&D pipeline included 12 molecules in Phase III development, exceeding the company's goal of 10. For 2011, the company expects to meet or exceed its current earnings per share guidance. According to the company, 2011 EPS guidance is currently in the range of $3.84 to $3.89 on a reported basis, or $4.30 to $4.35 on a non-GAAP basis when excluding $.23 of in-process research and development charges associated with the Boehringer Ingelheim collaboration and $.18 of asset impairment and restructuring charges through the first nine months of 2011, as well as an estimated $.05 asset impairment charge in the fourth quarter of 2011 related to the **Xigris** withdrawal.

The company remains on track to meet or exceed the mid-term minimum financial performance outlined in June. Through 2014, on an annual basis, Lilly leaders still expect revenue to be at least $20 billion, net income to be at least $3 billion, and operating cash flow to be at least $4 billion. Company executives have also reaffirmed commitment to fund a dividend at least at the current level.

"Our 2012 financial guidance reflects the three key elements of our bridging strategy," Dr. Lechleiter says. "First and foremost, we are replenishing and advancing our pipeline. We've successfully rebuilt our mid to late-stage pipeline to position Lilly for growth post-2014, with 12 assets now in Phase III, exceeding our goal of 10 by the end of 2011. We continue to revamp our discovery efforts to ensure a more sustainable flow of innovation for the long-term. Second, we're investing to drive growth in the key brands that don't lose patent protection during this period and in our countercyclical growth engines that don't have the same cycle of patent expirations as our U.S. and European pharmaceutical businesses. These include Japan, select emerging markets, and our animal health business. Third, we continue to drive productivity gains across our business to fund the R&D necessary to fuel our future growth, recapitalize our physical assets, and maintain our dividend at least at its current level."

## BMS to acquire Inhibitex

**Bristol-Myers Squibb** Co. has announced its agreement to acquire Inhibitex for an aggregate purchase price of about $2.5 billion. The boards of directors of both companies have approved the transaction.

Inhibitex is a clinical-stage biopharmaceutical company that develops products to treat or prevent serious infections, with a primary focus on the development of nucleotide/nucleoside analogs for the treatment of hepatitis C virus. The company's lead HCV asset is **INX-189**, an oral nucleotide polymerase (NS5B) inhibitor in Phase II development that has exhibited potent antiviral activity, a high barrier to resistance, and pan-genotypic coverage. Nucleotides/nucleosides are emerging as an important class of antivirals that may play a critical role as the backbone of future direct-acting, antiviral-only combination approaches to HCV treatment.

"The acquisition of Inhibitex builds on Bristol-Myers Squibb's long history of discovering, developing, and delivering innovative new medicines in virology and enriches our portfolio of investigational medicines for hepatitis C," says Lamberto Andreotti, CEO, Bristol-Myers Squibb.

"The acquisition of Inhibitex builds on Bristol-Myers Squibb's long history of discovering, developing, and delivering innovative new medicines in virology and enriches our portfolio of investigational medicines for hepatitis C," says Lamberto Andreotti, CEO, Bristol-Myers Squibb (bms.com). "There is significant unmet medical need in hepatitis C. This acquisition represents an important investment in the long-term growth of the company."

Bristol-Myers Squibb officials say the addition of Inhibitex's nucleotide polymerase inhibitor to the company's own promising portfolio, which includes other direct-acting antivirals, brings additional options to develop all-oral regimens with better cure rates, shorter duration of therapy, and lower toxicity than the current standard of care.

Company officials expect the transaction to be dilutive to earnings for Bristol-Myers Squibb through 2016, with an expected impact on earnings per share of approximately 4 cents in 2012 and about 5 cents in 2013.

## BUSINESS BRIEFS

### Takeda to acquire Intellikine

**Takeda** leaders have announced that one of the company's subsidiaries, Takeda America Holdings Inc., will acquire Intellikine Inc. for $190 million upfront and up to $120 million in additional potential clinical development milestone payments.

Intellikine is a privately held company focused on the discovery and development of innovative small molecule drugs. The company has assembled a portfolio of proprietary small molecule kinase inhibitors that selectively target isoforms of the phosphoinositide-3 kinase/mammalian target of rapamycin (PI3K1/mTOR2) pathway.

The company's most advanced drug candidate, **INK128**, a novel mTORC1/2 inhibitor, has generated encouraging data in multiple Phase I studies and is expected to enter Phase II studies this year. **INK1117**, a novel and selective inhibitor of the PI3K alpha isoform, entered human clinical testing in September 2011.

"Intellikine has advanced three programs against the PI3K/mTOR pathway into human clinical testing in just four years," says Troy Wilson, Ph.D., president and CEO, Intellikine. "We are pleased that Takeda recognizes the potential of our clinical-stage programs as well as our strong pipeline and discovery engine. Together, with Millennium and Takeda, we can bring the resources and expertise necessary to enable our drug candidates to reach their full potential in the treatment of patients with cancer."

Takeda's (takeda.com) business unit responsible for global oncology strategy and development—Millennium: The Takeda Oncology Company—will have global development responsibility for INK128 and INK1117.

"INK128 and INK1117 are potential best-in-class inhibitors of critical pathways driving cancer cell growth," says Deborah Dunsire, M.D., president and CEO, Millennium. "As single agents or in different combinations with novel molecules within our robust pipeline, we anticipate that these assets will be able to deliver transforming therapies to cancer patients."

### Allergan plans $350 million expansion in Ireland

**Allergan** Pharmaceuticals has announced an investment of $350 million in the company's expansion efforts in Ireland. The investment will expand the company's development and manufacturing capabilities at Allergan Pharamceuticals Ireland's Westport operation.

Company leaders believe the expansion will result in the creation of about 200 new jobs at the site over the next four years and an estimated 250 indirect jobs locally during the construction period.

The investment will enable Allergan to expand the manufacturing capacity for **Botox** (botulinum toxin type A), used to improve the appearance of facial frown lines, treat chronic migraine headaches, certain kinds of muscle stiffness and contraction, severe underarm sweating, abnormal twitch of the eyelid, a condition in which the eyes are not properly aligned, and urinary incontinence in people with neurologic conditions such as spinal cord injury and multiple sclerosis who have overactivity of the bladder. Allergan (allergan.com) also plans to develop a manufacturing base for the next generation of biologic products currently in the Allergan pipeline.

## THE LEADER'S EDGE

### Commoditization (Ugh!) Is The Enemy—Isn't It?

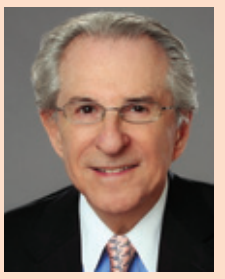
**By Sander A. Flaum, managing partner, Flaum Idea Group, and chairman Fordham Leadership Forum, Fordham Graduate School of Business**

I want to tell you about a book that led to a change in our company's name.

Chances are, if you encountered this book in a bookstore (remember them?), you wouldn't give it a second glance. Titled *Kick-Ass Business and Marketing Secrets—How to Blitz Your Competition*, it has no obvious relevance to pharma. And even if you glanced at the first few pages, your opinion might not change. The author, Bob Pritchard, a well-known business writer and speaker, argues that most advertising today doesn't work because the product categories have become commoditized—differentiated primarily on price.

At this point, it's easy to be smug. "We're pharma! Doctors don't 'buy' our products—they prescribe them. New products in oncology and orphan diseases command premium prices. Our products aren't commoditized!" Really? When the hottest new pharma marketing tactics are savings cards and e-vouchers designed to sugar-coat the cost of our products?

Too often, we fail to differentiate our products primarily on our customers' needs. We're in love with our products' features (and I'm using the word "products" because it's not always clear how many drugs deserve to be called "brands"). To maximize success today, you have to avoid the commoditization pitfall. And that requires being able to solve two really tough problems.


Sander Flaum

First, what do your customers think? Why do they like your product (or its profile)? Why do they use your competitor's products? Why don't people use your or your competitors' products? Answering these questions will help you find an emotional resonance with your customer, which leads to the second problem: What value do you or your brand bring to the customer?

Pritchard calls this the consumer purchasing benefit (CPB). It's not the familiar "USP," which usually turns out to be just another feature. The CPB avoids the commoditization trap by calling attention to your brand's unique emotional appeal.

Here's a story from the days when I ran the Becker agency (now Euro RSCG Life). We had the good fortune to launch a series of billion-dollar blockbusters: Plavix, Mobic, Flomax, Effexor XR, Lovenox, Spiriva, and Prandin, to name a few. One day, I opened the pages of a leading pharma trade journal (probably the one you're reading now), and I saw an ad for a rival agency (today you know them as Torre Lazur McCann) proclaiming themselves "The Launch Agency."

Now, I really like Joe Torre; but I wasn't too fond of him just then. Joe had nailed the CPB of product managers everywhere by positioning his agency as the partner that would make them stars. All I could do was grumble—and tip my hat.

In pharma, our products are technically unique (at least while they're on patent), but far too often practically undifferentiated. The features we fall in love with mean little to our customers. Yet we still cough up hairball claims like "The first and only [therapeutic category] with a 9.7-hour half life!"

The key to "kick-ass" marketing is finding the real benefit or solution that makes our product unique and driving it with the same level of energy as our consumer counterparts. "The ultimate driving machine," "Breakfast of Champions," "Melts in your mouth, not in your hands," "When you absolutely, positively have to have it overnight." I don't need to fill in the brands' names.

Last fall, after reading Pritchard's book, I began thinking about our company name: Flaum Partners. Did this really describe us? Or was it a bit commoditized? What did it say about us that mattered? So, one of our partners did some one-on-one research with our clients—and our non-clients. And we came to realize that what our clients really look to us for are big, game-changing ideas that will solve the problems that keep them up at night.

So today, we're the Flaum Idea Group. That's how we're fighting commoditization. How about you?

*Editor's note: The Leader's Edge is a series of guest articles written by Sander A. Flaum, managing partner of Flaum Idea Group and chairman of Fordham Graduate School of Business Leadership Forum. He can be reached at sflaum@flaumideagroup.com.*

# PeopleontheMove

**By Joshua Slatko** joshua.slatko@ubm.com

# Teva leaders to retire

**Shlomo Yanai,** president and CEO of Teva Pharmaceutical Industries Ltd., plans to retire from the company effective May 2012, and the board of directors has named Dr. **Jeremy Levin**, a former senior executive at Bristol-Myers Squibb, to succeed him at that time.

The plan is the result of a decision by Mr. Yanai to move on to a new phase in his career after five years as president and CEO of Teva, during which he led a growth strategy that has taken the company from an $8.4 billion mainly generics business in 2006 to a more diversified pharmaceutical company with expected 2012 revenue of about $22 billion, and an expanded footprint in the European, Asian, and Latin America markets.

The board conducted an extensive search process and concluded that Dr. Levin, with his recognized strategic vision and deep knowledge of the pharmaceutical industry, is the right person to lead Teva going forward. Dr. Levin has more than 25 years of experience in the global pharmaceuticals industry, leading companies and people in the creation, development, and delivery of medicines. He joined Bristol-Myers Squibb in 2007, and has had direct responsibility for strategy, alliances and transactions, and managed its portfolio of alliances.



Before joining Bristol-Myers Squibb, Dr. Levin served from 2003 to 2007 as global head of business development and strategic alliances at Novartis. Earlier, he was CEO of Cadus Pharmaceuticals, a company he took public.

"Dr. Levin is an exceptionally talented business leader with a deep understanding of the opportunities and challenges of the pharmaceutical industry," says Phillip Frost, M.D., chairman of Teva's board of directors. "He brings to Teva a wealth of experience and the hands-on skills required to foster the growth of a global pharmaceutical business. As a business leader and as a physician, he is passionately committed to bringing effective treatments to patients worldwide. His combination of vision, creative energy and an effective team-building management style make him an ideal choice to lead Teva into its next growth phase."

Dr. Levin, 58, was born in South Africa and has lived in the United States since 1986. In addition, he has lived in Zimbabwe, Great Britain, Switzerland, and Israel. He received an undergraduate degree from Oxford University in Zoology, masters and doctoral degrees from Oxford University in Molecular Biology, and a medical degree from Cambridge University. Among numerous honors, he was the 2005 recipient of the Albert Einstein Award for Leadership in Life Sciences, awarded by Shimon Peres. Dr. Levin has served as a practicing physician at university hospitals in South Africa, the United Kingdom, and continental Europe. He and his wife, Margery Feldberg, have been married for 25 years and have two college-age daughters.


"I have known and admired Teva for many years, not just as a global leader in generic drugs, but as an outstanding innovator in pharmaceutical development and new strategic approaches to serve patients worldwide," Dr. Levin says. "Demographic trends and economic pressures in developed and emerging markets are intensifying the challenge to provide good medicines at affordable prices. Teva, with its multiple platforms in generics, branded, and OTC drugs, is in an especially good position to meet this challenge. It will be a privilege to work with the talented and dedicated people of Teva to fulfill this mission."

Shlomo Yanai, 59, has been president and CEO of Teva since March 1, 2007. Before joining Teva, he was the president and CEO of Makhteshim Agan Industries from 2003 through 2006. Until his retirement from the Israel Defense Forces as a major general, he held positions as head of the Planning Branch of the Israel Defense Forces (1998-2001), commanding officer of the Southern Command (1996-1998), and head of the army R&D division (1994-1996). In 1973 he received the Distinguished Service Medal from the Israeli Defense Forces. He is a graduate of the Harvard Business School's AMP program, and also holds an M.A. from George Washington University in national resource administration. He received a B.A. cum laude in political science and economics from Tel Aviv University, and is also a graduate of the U.S. National War College. He and his wife Ahuva have three children and three granddaughters.

"Over the past five years, Teva has been transformed from a successful generics business into a major global pharmaceutical company," Mr. Yanai says. "We have achieved double-digit increases in sales and earnings, and have built, acquired, or partnered to create new opportunities to support future sustainable growth. I believe 2012 will be yet another year of profitable growth. I look forward to completing my tenure at Teva and moving on to my next challenging venture. I am confident that Jeremy Levin will lead Teva to its next stage of success."

Teva has also announced that Dr. **Rob Koremans** has been appointed president and CEO, Teva Europe, and will join the company in March 2012. Dr. Koremans joins Teva after serving as CEO for Zentiva and most recently as senior VP generic strategy and development at Sanofi-Aventis. He will replace Dr. **Gerard van Odijk**, who has decided to step down after six years in the role. In the next few months, Dr. Koremans and Dr. van Odijk will work closely together to ensure a smooth transition. Dr. van Odijk will remain with Teva to support the EU region for the remainder of 2012.

Dr. Koremans holds a medical degree from Erasmus University of Rotterdam, Netherlands. He began his career in 1988 at Sanofi SA. In 1993 he joined the Serono Group and was appointed VP Europe in 1998; from 2007 to 2009, he was CEO of Cryo-Save, Europe's leading stem cell storage company. Dr. Koremans returned to Sanofi in 2009 as senior VP Generics Europe, Sanofi-Aventis, and CEO of Zentiva. He was appointed president of Zentiva in July 2010 and later became Sanofi's senior VP, generic strategy and development.

## BIOTECH/BIOPHARMA


■ **John Varian** has been appointed CEO, Xoma Corp. Mr. Varian has been serving as interim CEO since Aug. 31, 2011, and has been a member of the board since December 2008. Xoma (xoma.com) discovers and develops novel antibody therapeutics.

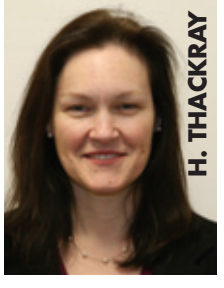
■ **C. Glenn Begley** is appointed senior clinical advisor and non-executive director, Oxford BioTherapeutics. Mr. Begley was VP and global head of hematology and oncology research at Amgen. Oxford BioTherapeutics (oxbt.co.uk) is a biotechnology company focused on the development and commercialization of innovative antibody-based cancer medicines, with integrated diagnostics, against novel targets that it has discovered in its unique OGAP proteomic database.



■ **David E. Holliday** has joined Octapharma USA as VP of commercial development, assuming immediate responsibility for all U.S. product marketing, sales, and commercial activities and coordination with global portfolio development initiatives. Mr. Holliday most recently served as VP of global marketing operations and hemophilia with Baxter Bioscience. Octapharma AG (octapharma.com) is one of the largest human protein products manufacturers in the world and has been committed to patient care and medical innovation for nearly 30 years.

■ Dr. **Gordon Ng** is named to the position of VP, preclinical research and development, Zymeworks Inc. Dr. Ng joins Zymeworks with more than 15 years of biotechnology and pharmaceutical drug-discovery experience from the Myelin Repair Foundation, Amgen, and the Merck Frosst Center for Therapeutic Research. During his nine years at Amgen he served as a scientific director and was instrumental in advancing multiple preclinical candidates towards the clinic, as well as managing multiple internal and partnered research initiatives. Zymeworks (zymeworks.com) is a biotechnology company that is developing best-in-class antibody therapeutics for the treatment of oncology, autoimmunity, and inflammatory diseases.


■ GlycoMimetics Inc. has promoted **Helen Thackray**, M.D., to chief medical officer and VP of clinical development, and **Brian Hahn** to chief financial officer. Dr. Thackray joined GlycoMimetics in 2006. Previously, she was VP of clinical product development at Biosynexus Inc. for five years. Mr. Hahn joined GlycoMimetics in 2010. Previously, he served as executive director of finance at MiddleBrook Pharmaceuticals. GlycoMimetics (glycomimetics.com) is a biotechnology company that capitalizes on advances in the field of glycobiology.





■ **Richard Bagger** is appointed senior VP, corporate affairs and strategic market access, Celgene Corp. Mr. Bagger joins the company after most recently serving as chief of staff for New Jersey Governor Chris Christie. Previously, he served as senior VP of worldwide public affairs and policy for Pfizer. Celgene (celgene.com) is an integrated global pharmaceutical company engaged primarily in the discovery, development, and commercialization of innovative therapies for the treatment of cancer and inflammatory diseases through gene and protein regulation.

■ **James B. Weissman** is named chief business officer, Dicerna Pharmaceuticals. Mr. Weissman joins Dicerna from MannKind Corp., where he was VP of business development. Dicerna Pharmaceuticals (dicerna.com) is an RNAi-focused biopharmaceutical company developing novel therapeutic agents and related drug-delivery systems in oncology and other disease areas based on its proprietary Dicer Substrate Technology platform and Dicer Substrate siRNA molecules.

■ **Howard Levy**, M.D., Ph.D., has joined

Inspiration Biopharmaceuticals as chief medical officer, while **Daniel Regan** has joined the company as chief commercial officer, and **Karen Tubridy** as VP and Factor IX launch team leader. Dr. Levy has more than 22 years' experience in the pharmaceutical and medical industries, most recently serving as chief medical officer at Sangart Inc. Mr. Regan joins Inspiration from Genzyme Corp., where he held positions of increasing responsibility since 1999, most recently serving as general manager, senior VP of the U.S. Personalized Genetic Health business unit. Ms. Tubridy most recently served as executive director, clinical operations and regulatory affairs, translational medicine at Alexion Pharmaceuticals. Inspiration Biopharmaceuticals (inspirationbio.com) is dedicated exclusively to developing treatments for hemophilia, with a primary mission to broaden access to care to safe and effective recombinant therapies and advance innovation for people living with these conditions.

## SPECIALTY PHARMA

■ **Thomas F. Krucker** is named president of operations, Compass Biotechnologies Inc. Mr. Krucker previously served with Toyota USA for 11 years and held national positions as IR director and import director for the USA operations. Compass Biotechnologies Inc. (compassbio.net) is a specialty pharmaceutical company focused on building value in several key market areas, including women's health, hepatitis anti-viral drugs and prophylactic vaccines, recombinant protein therapeutics called "biobetters," and cytokine reagents and growth factor supplements for the cell culture and biotech manufacturing industries.


■ **Niranjan Y. Sardesai**, Ph.D., is promoted from senior VP research and development to chief operating officer, Inovio Pharmaceuticals Inc. In his expanded role, Dr. Sardesai will be responsible for corporate and business development for the company in addition to continuing to oversee research and development. Inovio also announced the retirement of **Kevin W. Rassas**, former senior VP business development. Inovio (inovio.com) is developing revolutionary vaccines to extend the profound medical benefits of the 20th century's immune-system-stimulating vaccines by preventing and treating today's cancers and challenging infectious diseases.

■ **August J. (Augie) Moretti** is named senior VP and chief financial officer, Depomed Inc. Mr. Moretti joins Depomed from Alexza Pharmaceuticals Inc., where he served as chief financial officer, senior VP, general counsel, and secretary. Depomed Inc. (depomed.com) is a specialty pharmaceutical company with two approved and marketed products.

## SERVICE SUPPLIERS

■ **Debbie Warner** is named VP in the Commercial Planning group, Kantar Health. In this role, Ms. Warner will lead Kantar Health's Oncology Commercial Strategies team. She has more than 20 years of experience in the pharmaceutical industry with Merck, Astra Merck, and AstraZeneca, including positions in field sales, national accounts, brand management, medical affairs, and managed markets strategy. Kantar Health (kantarhealth.com) is a global, evidence-based decision support partner to the world's leading pharmaceutical, biotech, device, and diagnostic companies.


■ **Bhushan Pradhan** is named corporate accountant in Photosound's Finance Group. Mr. Pradhan joins Photosound from The Health Foundation, bringing strong financial experience and expertise to support Photosound's global programs and financial operations. Photosound (photosound.com) is a global brand communications agency serving the healthcare industry.

■ **Ian McGuinness** is appointed to the position of VP, business development, Qforma. Mr. McGuinness joins Qforma from IMS Health, formerly SDI, where he spent nine years, initially in a consulting role and then as a senior sales executive. Qforma (qforma.com) is a provider of advanced analytics and predictive modeling for the health sciences industry.

■ **David Riding** has been named VP client services for the StemScientific division of KnowledgePoint360 Group. Most recently, Mr. Riding was a senior client services director at Parexel.


**Michael Friedin** has been named VP of eMedFusion, the digital healthcare agency at KnowledgePoint360 Group. Most recently, Mr. Friedin was president of Matthew & Grace, a consulting company offering guidance in brand management, sales and marketing, infrastructure and operations, and social media. KnowledgePoint360 (kp360group.com) provides a broad range of healthcare information, communications, and advisory services including digital solutions, training, benchmark-based advisory services, medical education, publication support, live educational meetings ranging from international congresses to dinner meetings, scientific content development, exhibit design, workflow and compliance solutions to support speaker programs, and strategic consulting.

## RESIGNATIONS

■ **Daniel Park** has resigned as chief business officer, Isotechnika Pharma Inc. He remains a director of the company. Mr. Park currently serves as executive VP of ILJIN Life Science Co., Isotechnika's second largest shareholder. In that capacity, he has informed Isotechnika's board of directors that ILJIN is planning to "increase their level of control within the company." In order to avoid any conflict of interest that may arise as a result of this discussion, in addition to resigning from his executive position with Isotechnika, Mr. Park has committed not to participate in any board discussions related to ILJIN, including the contemplated verbal proposal and/or other strategic alternatives that the board may consider. In connection with this verbal proposal and Mr. Park's resulting resignation, Dr. **Robert Foster** has relinquished the title of chairman of the board to Dr. **Peter Wijngaard**. Dr. Foster remains CEO and a director of the company. This change is designed to allow Dr. Foster to continue to focus on Phase III development activities of the company's leading product candidate, voclosporin, for the prevention of kidney transplant rejection, and to continue licensing opportunity discussions. Isotechnika Pharma (isotechnika.com) is a biopharmaceutical company focused on the discovery and development of immunomodulating therapeutics designed to offer key safety advantages over currently available treatments.



■ **James L. Moulds** has resigned as executive VP and chief financial officer of Nuvo Research Inc. to pursue other opportunities. **Stephen L. Lemieux**, currently VP, finance and corporate controller, will become VP and chief financial officer. Nuvo Research (nuvoresearch.com) is a Canadian specialty pharmaceutical company building a portfolio of products for the treatment of pain through internal research and development and by in-licensing and acquisition.

■ **Hongyu Pan** has resigned as chief financial officer, China Sky One Medical Inc. for personal reasons. The company has initiated a search for a new chief financial officer and will make an announcement as soon as a candidate has been chosen. China Sky One Medical (cski.com.cn) engages in the manufacturing, marketing, and distribution of pharmaceutical, medicinal, and diagnostic products.

■ **Fuad El-Hibri** will retire as CEO, Emergent BioSolutions Inc., effective April 1, 2012. Mr. El-Hibri will continue to serve as executive chairman of the board of directors and will focus on corporate strategy as well as merger and acquisition opportunities for the company. **Daniel J. Abdun-Nabi**, currently president and chief operating officer since 2008, will become president and CEO on April 1, 2012. Mr. El-Hibri has been chairman and CEO of Emergent since the company's founding in 1998. Emergent BioSolutions (emergentbiosolutions.com) protects and enhances life by developing and manufacturing vaccines and therapeutics that are supplied to healthcare providers and purchasers for use in preventing and treating disease.

# AdAgencyUpdate

**By Cara Latham** cara.latham@ubm.com

# Agencies to build momentum from 2011 growth

"It's been such a positive year, and it's gratifying to know that we were able to identify a new path for Medisys and then find the courage to take it," says Anna Walz, CEO and founder, Medisys.

**Two agencies** – **StrikeForce** Communications and **Medisys** Health Communications – have entered 2012 with a year of growth behind them. While StrikeForce has announced the agency tripled its revenue in 2011, Medisys leaders have announced their own company has experienced 100 percent growth.

StrikeForce Communications has opened 2012 with the launch of a new DTC campaign and the appointment of a new partner. Agency leaders expect to continue growing this year, following a "banner year" in 2011, during which StrikeForce also opened a new headquarters in the Meat Packing District in New York City.

Mike Rutstein, founder and CEO, StrikeForce (strikeforcenyc.com), credits the agency's latest wins to its ability to capitalize on pharma's growing frustration over shrinking budgets, a sluggish economy, and increased competition.

"The bottom line – for nearly all clients nowadays – is how to accomplish more with less," Mr. Rutstein says. "We're able to provide a lot more value by matching top talent to specialized drugs and devices. The result is better people, better creative, and better prices. Marketers, who are being forced to stretch their budgets more than ever, recognize the value of this way of working."

StrikeForce has also appointed Patricia Prugno as partner and managing director of the agency. Ms. Prugno, who is in charge of client services and day-to-day operations, has more than 25 years of experience working with blue chip agencies and major pharmaceutical companies. She has been a consultant to StrikeForce since early 2011.

Before joining StrikeForce, Ms. Prugno was senior VP and group management director at **Draftfcb**, where she and Mr. Rutstein met and built the agency's healthcare practice from the ground up. Ms. Prugno has spearheaded launches for a number of blockbuster products, including **Plan B** Emergency Contraception, **Pataday** allergy eye drops, **Neulasta**, **Strattera**, **Meridia**, and **Fosamax**.

"She is the consummate relationship-builder with clients," Mr. Rutstein says of Ms. Prugno. "She has exceptional operational skills to help build this new company from the ground up, as we did the division at Draftfcb, and she brings to the table over two decades of combined consumer experience and healthcare experience, helping build some of the biggest and most powerful healthcare brands in the category."

StrikeForce is also making a significant investment in business development. An advisory board, consisting of business leaders from other industries, meets once each quarter to review key issues and explore new ways of "breaking out of the mold," agency leaders say.

"There comes a time when the status quo won't cut it," Mr. Rutstein says. "Healthcare is changing. And that's why we, as an agency, are changing the business model. Precision pairing means that we can pair the process, the people, and the pricing to meet the needs of a specific brand. We're not stuck in a box, and our clients aren't either."

Launched in the fall of 2009, StrikeForce has a number of agency of record accounts on both the professional and consumer side. Clients have included Teva, Alcon, Pfizer, Abbott Laboratories, Azur, Sucampo, Pozen, Orexigen and KCI. The agency specializes in advertising for prescription drugs, OTC products, and medical devices.

Meanwhile, Medisys Health has ended the year on a strong note, with a 100 percent growth in 2011 – after undergoing a change in business model and a radical downsizing in 2010.

The redesigned agency now focuses squarely on scientific platform development and strategic message evolution through the ISIS (Integrated Scientific Information Sharing) innovative methodology. This proprietary platform serves as a data gathering method, a system for creating consistent language to describe a drug, distilling the data to its most important elements, and helping clients achieve conformity of thought within their organization. Medisys' ISIS platform is easy to use, logical, forward thinking, and available to all global constituents in real-time, agency leaders say.

The agency's shift occurred after the flagging economy and competition from much larger companies had an impact on Medisys in 2010. Anna Walz, CEO and founder, made the decision to downsize and eliminate more than three-quarters of the agency's revenue-generating services and product offerings to grow the business.

In 2011, though, the agency added five major clients to its roster. "It's been such a positive year, and it's gratifying to know that we were able to identify a new path for Medisys and then find the courage to take it," Ms. Walz says. "2011 turned out better than we ever could have anticipated. We earned 80 percent of our increased revenue exclusively from ISIS products, demonstrating what we suspected – that there is a obvious need for a clear and concise methodology for scientific platform development in the pharma/biotech space."

To start the new year, Ms. Walz has been named one of 2012's Enterprising Women of the Year by *Enterprising Women* magazine. According to the magazine's Website, the award recognizes the finest women entrepreneurs in North America and beyond and is widely considered one of the most prestigious awards for women business owners.

Nominees are judged based on the revenue growth of their companies, the leadership they have exhibited in their local communities and/or at the state, national, or international levels, and the ways in which they have given back to the women's business community by mentoring or supporting other women in business. The editors at the magazine narrowed the field to a group of semifinalists, after which the members of the magazine's advisory board assisted in the final screening process. The 10th annual Enterprising Women of the Year Awards celebration will be held March 12 and 13 in Fort Lauderdale, Fla.

Medisys Health Communications (medisyshealth.com) is a private, woman-owned, minority-owned company. The agency works with pharma, biopharma, and device companies to formulate strategies from the ground up, starting with solid scientific and medical data and ending with a consistent narrative articulating a product's key attributes and clinical benefits.

## Green Room and GCI expand

Two healthcare public relations agencies have recently expanded their businesses. **Green Room** Public Relations has opened its second office in Cambridge, Mass., while **GCI Health** has opened a new office in Chicago.

Green Room's new office at 195 Binney Street in Cambridge's Kendall Square section will serve the agency's growing roster of local clients and as a base for expansion into the life science industry hub.

Agency partners Karen Carolonza and Deborah Sittig, who are communications and healthcare industry veterans with deep roots in journalism, will oversee the new office from the agency's Boonton, N.J. headquarters.



Green Room Cambridge will be staffed in the agency's hybrid model, which combines full-time employees and independent industry veterans to create customized, skill-based client teams.

"The additional resources Green Room is investing in the Boston area will enable us to better serve our clients and expand our footprint in the region," Ms. Carolonza says. "We also want to leverage the wealth of talent and opportunity endemic to such an innovation-focused environment to continually build our healthcare knowledge base and bring value to our clients' communications goals."

Massachusetts is home to a cluster of more than 400 biopharmaceutical and healthcare companies that are fueled by a broad ecosystem of academic and investment organizations, agency leaders say. Green Room (greenroompr.com) provides global healthcare companies with communications expertise for all stages of drug, device, and diagnostics development and commercialization including regulatory filings to patient advocacy, media relations, corporate communications, and crisis management.

"The extraordinary growth and opportunity we've enjoyed this year are the key drivers behind our long term strategy of dual locations," Ms. Sittig says. "In this fast paced, high-tech world, nothing can replace one-on-one engagement. With this local presence, we can respond more nimbly to the opportunities that continue to present themselves."

Meanwhile, GCI Health has opened its newest office, GCI Health Chicago. As the only WPP agency specializing in healthcare public relations in Chicago, the new office will bring to the Midwest its award-winning support of pharmaceutical companies, medical societies, patient advocacy groups, and hospitals, as well as medical device and technology companies, agency officials say.

Wendy Lund, CEO, GCI Health, will oversee management of GCI Health Chicago from the agency's New York headquarters. The office launches with a team of seasoned GCI Health (gcihealth.com) staff members.

"GCI Health offers clients an unwavering commitment to anticipating the rapidly evolving communications landscape from every angle," Ms. Lund says. "Opening a new office in the Midwest is an opportunity to further deepen our support for current clients and build capabilities and relationships across the region."

## Ogilvy PR acquires Mind Resource

Janet Yeung, founder of Mind Resource

**Ogilvy** Public Relations Worldwide Hong Kong has announced an agreement to acquire a majority stake in Mind Resource Healthcare Consulting Limited, a Hong Kong-based healthcare communications company.

With the acquisition, Ogilvy is targeting the $12.1 billion Hong Kong healthcare industry and further extending the company's market position there. Company leaders believe the acquisition will help Ogilvy move further into Hong Kong's growing healthcare industry that includes pharmaceuticals, healthcare services, and medical devices, where demand has been spurred by the growing affluence and aging of the population.

Founded in 2007, Mind Resource represents some of the top multinational pharmaceutical companies, medical associations, medical service providers, and professionals. Mind Resource will become the Hong Kong arm of Ogilvy's global integrated healthcare communications service group OgilvyHealth.

Steve Dahllof, president and CEO, Asia Pacific, Ogilvy Public Relations Worldwide

"Many global pharmaceutical brands are turning to Asia for growth opportunities," says Steve Dahllof, president and CEO, Asia Pacific, Ogilvy Public Relations Worldwide (ogilvypr.com). "Now more than ever, they need partners who can manage communications outside the United States and Europe and have a deep understanding of the local regulatory environment and market nuances."

Janet Yeung, founder of Mind Resource, will retain a minority interest in the company following completion of the transaction and continue to serve as the general manager of Mind Resource. Ms. Yeung will work with the current senior management team and OgilvyHealth's newly appointed Regional Director Rohit Sahgal to provide the same level of service that Mind Resource has become known for in this market, with the added advantage of the backing of the Ogilvy group, company executives say.

"With Hong Kong as a growing healthcare center in the region, we have managed the patient education and market communications for a wide spectrum of clients including medical associations and multi-disciplinary medical specialists, as well as over 50 leading pharmaceutical brands in Hong Kong since 2007, and carved out a strong position in the market," Ms. Yeung says. "We now recognize that joining a powerful group like Ogilvy can help us expand and broaden our services in this fast-changing environment."

## AGENCY PEOPLE ON THE MOVE

### AbelsonTaylor

AbelsonTaylor (abelsontaylor.com) has appointed **Erich Voigt** to the position of art director, digital and **Emily Chee** to mock-up artist. Mr. Voigt comes to AbelsonTaylor from ARS Interactive, a digital agency, where he worked on strategy, design, and art direction for an e-commerce platform launch. Ms. Chee spent the last two years as a freelancer for several Chicago-based marketing, advertising, and branding companies, including AbelsonTaylor, Ragan Communications, Core Marketing, and Compass Media Group, a political campaign design company.

### CDM Group

The CDM Group has promoted **Kyle Barich** to president of CDM New York. In addition, **Lori Klein** will assume the responsibilities of director of client services of CDM New York, and **Chris Palmer** and **Ben Ingersoll** have been promoted to executive creative directors of CDM New York. Mr. Barich, Ms. Klein, Mr. Ingersoll, and Mr. Palmer form the executive leadership team of the CDM New York organization. They will be supported in leading the agency by **Christine Finamore**, chief digital officer; **Mark Friedman**, creative director; **Debra Polkes**, creative director; and **Chris Fiocco**, director of account planning. The moves are reflective of the transition of **Ed Wise**, chairman and CEO; **Carol DiSanto**, president; and **Josh Prince**, chief creative officer, to full-time roles bearing the same titles within The CDM Group (thecdmgroup.com), the leadership organization that oversees CDM New York as well as eight other business units, including AgencyRx, CDMiConnect, CDM World Agency, Entrée Health, Link 9, SSCG Media Group, CDM Princeton, and Platform Advisors.


### Dudnyk

**Drew Desjardins** has joined Dudnyk (dudnyk.com) as senior VP, strategic planning and account management. Mr. Desjardins joins the agency after nearly two decades in pharmaceutical marketing at Wyeth and Pfizer.

### Natrel Communications

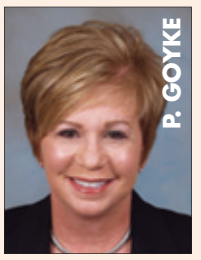
**Meg Griswold** is promoted to account group supervisor from account supervisor, Natrel Communications (natrelusa.com). Ms. Griswold spent the last five years in agency account management, gaining experience in product launches and strategic and tactical planning. **Olivia Ganguzza** is promoted to account supervisor from senior account executive. Ms. Ganguzza's seven-year healthcare marketing career includes several years as a sales representative, which has given her insight into relationship building with physicians.

**Alane Amato** is promoted to account executive from senior traffic coordinator. A five-year employee of Natrel, Ms. Amato supports upper management on the agency's accounts, including launch preparation, client-relationship management, and budget and timeline development. **Marie Fitzsimmons** is promoted to traffic coordinator from administrative assistant. Ms. Fitzsimmons, a two-year employee of Natrel, works on the agency's largest accounts.

### Pacific Communications

**Maáza Martin** is named program manager, Pacific Communications (pacific-com.com). Ms. Martin will manage strategic communications for the Restasis brand. She was previously a market planning manager for Genentech, a member of the Roche Group, in South San Francisco.

### Publicis Healthcare Communications Group




**Pamela Goyke** has joined Publicis Touchpoint Solutions Inc. as senior VP, client operations. Publicis Touchpoint Solutions (touchpointsolutions.com) is a division of Publicis Healthcare Communications Group. Ms. Goyke joins Touchpoint after serving as chief information officer and senior VP at ICT Group.

### Roska Healthcare Advertising

Roska Healthcare Advertising (roskahealthcare.com) has increased its staff by 10 percent to accommodate recent new business wins and organic growth of existing accounts.


**Anupam Singh** joins Roska Healthcare in a newly created position as VP of integrated strategy. Mr. Singh will lead the agency's integrated approach to marketing in both online and offline channels, with a heavy emphasis on digital. He comes to Roska Healthcare with pharmaceutical marketing experience from Digitas Inc., where he oversaw enterprise-wide digital strategy for a variety of domestic and global pharmaceutical clients.

**Lauren Taylor** has been hired as an account supervisor for one of Roska Healthcare's oncology teams, where she is taking the lead in developing multi-channel patient marketing programs in support of a new oncology launch. Previously, Ms. Taylor held project management positions at Euro RSCG Life Catapult and Bristol-Myers Squibb


**Krista Cohen** has been hired as an account executive on one of the agency's new virology accounts. She and the team will be developing multilingual communications targeting healthcare professionals and consumers in the Asian American community. Ms. Cohen brings experience to her new role at Roska Healthcare from positions previously held at BGB New York and Rosetta Marketing Group.


Roska Healthcare has also added two new associate team members, **Matt Riley** and **Kristen Roberts**, to manage the increased account and administrative needs that have come with the agency's continued growth.

## It's what you don't know that gets you fired

**by Adam Turinas, senior partner, Relationship Audits & Management**

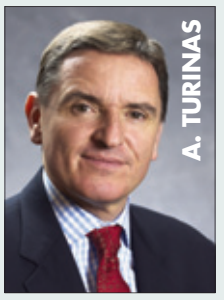
In this article, I want to introduce you to a new concept called Relationship Risk Management. The notion of risk management is a well-established business idea. While managing stakeholder relationships is not traditionally associated with risk management, the risk could be the biggest one you are not managing, in our view.

According to Wikipedia, "Risk management is the identification, assessment, and prioritization of risks followed by coordinated and economical application of resources to minimize, monitor, and control the probability and/or impact of unfortunate events or to maximize the realization of opportunities."

Typically, risk management is applied to financial services, complex project management, and rational, statistically-measurable events. Risk management doesn't consider account intangible issues, including relationships between key stakeholders, which can be disastrous.

A case in point was the launch of Terminal 5 at London's Heathrow Airport. In March 2008, the opening of this state-of-the-art airport terminal was one of the most eagerly awaited events of the year. Instead, the event was a total disaster. In the first 10 days after T5's launch, 42,000 bags failed to travel with their owners, and more than 500 flights were cancelled. The catastrophe severely hurt the reputation of British Airways and BAA, the two key parties behind the terminal.

According to a government inquiry, the failure was due to three problems: inadequate staff training, insufficient system-testing, and poor communication between the two key stakeholders, British Airways and BAA.




"However well the airport operator and the airline operator, BA, are working it is vital that the two are absolutely integrated and together … Around about or just prior to the opening of T5 it seems that that togetherness deteriorated," Colin Matthews, CEO of BAA, reportedly said after the event. "It is that togetherness that allows you to cope with the issues that arise on the day." He also said that if he had his time again, he "would focus resolutely and determinedly on keeping British Airways and BAA in the same room tightly together."

Billions of dollars of investments and hundreds of thousands of hours went into the design and construction of T5 – no doubt underpinned by a sophisticated project management plan to manage every risk. Well, that is except for one risk, it seems: the relationship between the two key stakeholders.

As a marketer or agency executive, you may be asking, what's that got to do with me? The point is that people are the wild card in business. Yet, they are a manageable risk. For agency executives, the notion of Relationship Risk Management could not be more important. The consequences of getting it wrong are disastrous. What's the risk of losing one of your key clients? Loss of income, staff insecurity, low morale, staff defection, further client defection, lower new business win rate?

Every year, major agencies go into a tailspin, precipitated by the loss of a major client, followed by additional losses. In the majority of cases, clients defected for unidentified service-related issues, especially poor communications. When a major piece of business goes into review, in the vast majority of cases it should not have been a surprise. Agencies could have prevented the defection by identifying and managing the most important risk: unknowns in the relationships.

For marketing executives, relationship risk is an equally big issue. Poor relationships with an agency result in lower effectiveness in output and poorer results. They are dependent on you for their livelihood, but you are dependent on them to achieve your goals.

The world's best marketers manage their agencies with disciplined processes around providing the agency with feedback and providing clear actionable direction and crystal clarity on expectations.

Managing the client-agency relationship is a shared and critical risk to mutual success. We call this principle the three Ms of Relationship Risk Management:

- Measure your relationship
- Minimize your risk
- Maximize your opportunity

The health of a business relationship can and should be measured. This can be achieved by a periodic client agency assessment. As specialists in this field, we recommend a 360 process that involves both quantitative and qualitative questions, where the client and agency provide feedback on each other in a constructive forum. The goal should be to gain actionable intelligence about the relationship.

Key relationship attributes such as attitude, quality of output, and level of expertise are scored by both parties. In addition, actionable feedback is solicited through open-ended questions like, "What is the single most important thing the agency can do to improve?"

The outcome of this is an accurate picture of the state of the relationship with clear actions. In addition, the quantitative data provides both clients and agencies the ability to benchmark versus other parties and track performance over time. We illustrate relative risk via our proprietary Relationship Risk Index.

Whether you do it through a formalized process or not, the key thing is to recognize that your business relationships are measurable and manageable risk. Treating this like any other business risk could be the smartest thing you do for your business this year.

*Adam Turinas is a senior partner with Relationship Audits & Management, a specialist in agency assessment.*

**By Cara Latham** cara.latham@ubm.com

# FDA submits PDUFA recommendations

**FDA has completed** its recommendations for three user fee programs that officials say will help speed safe and effective drugs and lower-cost generic drug and biosimilar biological products to patients. Kathleen Sebelius, secretary, Health and Human Services, has transmitted the recommendations to Congress.

The programs include the fifth authorization of the Prescription Drug User Fee Act (PDUFA), and new user fee programs for human generic drugs and biosimilar biological products. Officials concluded work on the proposals before the agency's mid-January deadline.

Under a user fee program, industry agrees to pay fees to help fund a portion of FDA's drug review activities, while FDA agrees to overall performance goals such as reviewing a certain percentage of applications within a particular timeframe.

Under the recommendations, fees paid by industry would support continued timely review of critical prescription drugs, as well as advance the development of drugs for rare diseases, provide for enhanced communication with small or emerging companies, increase the use of standardized electronic data to improve quality and efficiency, and foster the use of new clinical endpoints that improve drug development times and help address unmet medical needs.

The proposed new Generic Drug User Free program would provide FDA with needed funding at a time when generic drug applications are on the rise, officials say. Generic drug user fees would help ensure consumers timely access to safe, high-quality, and effective generic drugs, which account for two-thirds of all prescriptions dispensed in the United States.

"These final recommendations offer a great example of what can be achieved when the FDA, industry, and other stakeholders work together on the same goal," says Margaret A. Hamburg, M.D., FDA commissioner. "At a time of greater budgetary constraint, user fees provide a critical way for leveraging appropriated dollars, ensuring that FDA has the resources needed to conduct reviews in a timely fashion."

FDA receives 800 to 900 new generic-drug-related applications annually. These applications are increasingly complex and frequently involve products manufactured outside of the United States. In exchange for fees on facilities and product applications, the proposal includes performance metrics such as review timeframes and a commitment to achieve parity between surveillance inspections of foreign and domestic establishments by the 2017 fiscal year. As a result, FDA expects that the proposal would effectively eliminate the review backlog and significantly reduce review times.

The Generic Pharmaceutical Association (GPhA) has commended FDA for completing and submitting the recommendations for GDUFA to Congress.

"This is an important landmark that could not have been achieved without the extraordinary efforts of the FDA, my colleagues in the generic industry, and all other stakeholders," says Ralph G. Neas, president and CEO of GPhA. "We now look forward to working with members of Congress in the weeks and months ahead to ensure that the final program is one that expedites access to low-cost, high-quality generic drugs for Americans and further safeguards the quality and accessibility of our nation's drug supply."

PDUFA was created by Congress in 1992 and must be reauthorized every five years. The current program, known as PDUFA IV, will expire on September 30, 2012, unless reauthorized by Congress. FDA developed the recommendations for PDUFA V in consultation with drug industry representatives and with patient and consumer advocates.

The proposed Biosimilar and Interchangeable Products User Fee program is intended for products approved under a new abbreviated approval pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed biological product. The Affordable Care Act of 2010 contains a subtitle called the Biologics Price Competition and Innovation Act (BPCI) of 2009, which established this pathway.

Prior to this act becoming law, competition in the biologic drug market was stifled. Officials believe the enactment of BPCI will spark the development of a new segment of the industry, where companies will be able to develop alternative products. This will help spur innovation, improve consumer choice, and drive down costs, officials say.

The recommended user fee program for biosimilars includes fees for products in development to generate revenue in the near-term and to provide FDA with the resources needed to support development-phase meetings with sponsors of biosimilar biological product candidates.

## ON THE FAST TRACK

■ **Product:** AC607
**Developer:** AlloCure Inc. (allocure.com)
**Status:** Phase I trial completed for the treatment of acute kidney injury.

■ **Product:** ACH-1625
**Developer:** Achillion Pharmaceuticals Inc. (achillion.com)
**Status:** Phase II clinical trial for the treatment of chronic hepatitis C virus.

■ **Product:** CPP-115
**Developer:** Catalyst Pharmaceutical Partners Inc. (catalystpharma.com)
**Status:** Phase II(b) trial for the treatment of cocaine dependency.

## MARKETERS WARNED

■ **Marketer:** Mutual Pharmaceutical Company Inc. (urlmutual.com)
**Product:** Colcrys (colchicine, USP) tablets for oral use
**Indication:** For prophylaxis and the treatment of acute gout flares
**Action:** A pharmacy sell sheet and professional video titled, "Myth vs. Reality" are false or misleading because they omit and minimize risk information associated with the use of Colcrys. Furthermore, the video is false or misleading because it makes unsubstantiated safety and superiority claims and overstates the efficacy of Colcrys.

Although the sell sheet and video include some information regarding the risk of rhabdomyolysis associated with Colcrys, they omit important material facts regarding the risk. Specifically, the warnings and precautions section of the PI states: "Colchicine-induced neuromuscular toxicity and rhabdomyolysis have been reported with chronic treatment in therapeutic doses. Patients with renal dysfunction and elderly patients, even those with normal renal and hapatic function, are at increased risk." The omission of this important risk information misleadingly suggests that Colcrys is safer than has been demonstrated by substantial evidence or substantial clinical experience.

The sell sheet includes the headline claim, "Tough, but Gentle" in conjunction with a graphic of a man wearing motorcycle gear delicately holding a china teacup. This presentation minimizes the risks associated with Colcrys by implying that Colcrys is not risky or harmful, when this is not supported by substantial evidence or substantial clinical experience. Such claims and presentations are particularly concerning in light of the serious risks that are mentioned in the PI for Colcrys, including fatal overdoses, blood dyscrasias, life-threatening and fatal drug interactions, and neuromuscular toxicity.

The sell sheet also includes the claim, "Colcrys tolerability is comparable to placebo." Similarly, the video includes the claim that Colcrys has a "tolerability similar to placebo." Such claims minimize risk by implying that the safety profiles for Colcrys and placebo are not different or that the difference is minimal, when this is not the case. According to the Adverse Reactions section of the PI, 23 percent of patients experienced diarrhea in the recommended low-dose group versus 14 percent in the placebo group.

*Continued on page 30*

### FDA approves shared REMS for TIRF

FDA has approved a single, shared Risk Evaluation and Mitigation Strategy (REMS) for the transmucosal immediate-release fentanyl (TIRF) products. Regulators say the new system will ease the burden on the healthcare system by replacing the individual REMS and allowing prescribers and pharmacies to enroll into just one system.

TIRF medicines, which include the brand-name drugs **Abstral**, **Actiq**, **Fentora**, **Lazanda**, and **Onsolis**, are narcotic pain medicines called opioids used to manage pain in adults with cancer who routinely take other opioid pain medicines around-the-clock.

Called the TIRF REMS Access Program, the new system will begin in March and will be used by all sponsors of TIRF products.

"This TIRF REMS will ensure safe use and access to these drugs for patients who need them," says Janet Woodcock, M.D., director of FDA's Center for Drug Evaluation and Research. "We have worked with the sponsors of both the innovator and generic drugs to develop this single, shared system that will streamline the process and decrease the burden of the REMS on the healthcare system."

Prescribers and pharmacies already enrolled in an individual REMS program for at least one TIRF medicine will automatically be transitioned to the shared TIRF REMS Access program. Healthcare professionals who prescribe TIRF medicines that will only be used in an in-patient setting (hospitals, hospices, or long-term care facilities) will not be required to enroll in the TIRF REMS Access program. Similarly, patients who receive TIRF medicines in an in-patient setting are not required to enroll in the program. Long-term care and hospice patients who obtain their medications from outpatient pharmacies, however, must still enroll.

### FDA warns about mix-ups between Durezol and Durasal

FDA officials have alerted pharmacists and other healthcare professionals to potential injury caused by confusion between the FDA-approved eye medicine **Durezol** (difluprednate ophthalmic emulsion) 0.05 percent and the unapproved prescription topical wart remover **Durasal** (salicylic acid) 26 percent.

Federal regulators say they have received one report of serious injury that occurred when a pharmacist mistakenly gave an eye surgery patient Durasal, the salicylic acid–containing wart remover, instead of the prescribed Durezol eye drops. Durezol is approved for treatment of inflammation and pain association with ocular surgery.

The agency has received several other reports of cases arising from confusion between Durezol and Durasal. Federal regulators have also received complaints from healthcare practitioners concerning the similarity between the names. As a result, FDA officials say pharmacists should be vigilant when filling prescriptions for the ophthalmic solution Durezol.

FDA, as part of the drug approval process, screens proprietary names for similarities to the names of other products currently on the market. However, Durasal is an unapproved product that did not undergo the agency's drug approval process. The agency, therefore, was not able to evaluate Durasal for potential name confusion prior to its entry into the market. Additionally, Durasal entered the market shortly after FDA approved Durezol.

**Elorac Inc.**, the distributor of Durasal, has not responded to FDA's inquiry into removing the product from the marketplace, FDA officials say. To date, Elorac has also not recalled the product in response to FDA's inquiry regarding the risk to patients.

FDA officials have encouraged healthcare professionals and patients to scrutinize packaging and labeling information carefully and to report any potential for confusion arising from similar drug names to FDA's MedWatch Safety Information and Adverse Event Reporting program.

## MARKETERS WARNED

*Continued from page 29*

The main part of the video omits discussion of serious and significant risks, including contraindications, warnings, and precautions, such as fatal overdoses, blood dyscrasias, monitoring for toxicity, and neuromuscular toxicity, and the most commonly reported adverse events. The overall effect of this presentation undermines the communication of important risk information, minimizing the risks associated with Colcrys and misleadingly suggesting that the drug is safer than has been demonstrated by substantial evidence or substantial clinical experience.

The video includes claims, including, "NSAIDS, which have a black box, are not indicated nor have they ever been approved for the prophylaxis of gout flares. As with all medication, please remember that your gout patients suffer from many comorbid conditions, and caution is needed in the concomitant medications you prescribe for your patients," and "REALITY NSAIDS have never beeen FDA approved for gout flare prophylaxis. Many patients with gout have comorbid conditions that preclude the use of NSAIDS long term. Colcrys is approved for prophylaxis of gout flares as part of the management of gout."

The totality of this presentation is misleading because it minimizes the risks associated with the use of Colcrys by suggesting that there are not significant safety concerns for Colcrys in patients who have comorbid conditions and are taking concomitant medications, when this has not been demonstrated by substantial evidence or substantial clinical experience. Furthermore, this presentation misleadlingly implies that Colcrys is clinically superior in patients with comorbid conditions and has fewer drug interactions when taken with concmitant medications compared to NSAIDS. FDA is not aware of adequate and well-controlled head-to-head studies to support this implication.


The sell sheet includes the headline claim, "Tough, but Gentle" in conjunction with a graphic of a man wearing motorcycle gear delicately holding a china teacup. This presentation minimizes the risks associated with Colcrys by implying that Colcrys is not risky or harmful, when this is not supported by substantial evidence or substantial clinical experience.

■ **Marketer:** Ortho-McNeil-Janssen Pharmaceuticals Inc. (jnj.com)
**Product:** Nucynta (tapentadol) immediate-release oral tablets C-II
**Indication:** For the relief of moderate-to-severe acute pain in patients 18 years of age or older.
**Action:** An Ortho-McNeil-Janssen representative made oral statements Dec. 8, 2010, at the 2010 American Society of Health-System Pharmacists (ASHP) MidYear Clinical Meeting and Exhibition in Anaheim, Calif., that promote an unapproved use for Nucynta, make unsubstantiated superiority and other claims about the drug, and minimize the serious risks associated with Nucynta.

First, the sales representative indicated that Nucynta is useful in the treatment of diabetic neuropathic pain. Although FDA has acknowledged that Nucynta's indication for the relief of moderate-to-severe acute pain is general, Nucynta is not approved by FDA for the treatment of diabetic neuropathic pain, a chronic pain condition that would require a specific indication. The PI does not include any information about the safety or efficacy of Nucynta in the treatment of diabetic neuropathic pain. Therefore, the oral statements misbrand the drug by creating a new "intended use" for Nucynta for which the PI does not provide adequate directions for use.

The representative further indicated that DPNP patients stay on Nucynta for longer, and Nucynta provides 10 milligrams of opioid/oxycodone pain control, similar to tramadol, but with less GI, constipation, nausea, and vomiting. This claim misleadingly implies that Nucynta is clinically superior to oxycodone and tramadol for DPNP patients. Specifically, it implies that Nucynta has been shown to have less gastrointestinal adverse reactions in comparison to oxycodone and/or tramadol, when this is not the case. Although safety data was collected from patients taking Nucynta and oxycodone during the clinical studies for Nucynta, FDA determined that the studies were not adequately powered for the analysis of multiple safety endpoints, and that the dose of oxycodone used as a comparator was not desmonstrated to be equianalgesic to the doses of Nucynta studied. Therefore, safety comparative data were not considered clinically meaningful and were not included in the approved PI for Nucynta. In addition, FDA is not aware of any adequate and well-controlled, head-to-head clinical trials comparing the incidence of constipation, nausea, or vomiting for Nucynta versus tramadol.

The claim that Nucynta results in less constipation, nausea, and vomiting minimizes the risks associated with the use of Nucynta and suggests the drug is safer than has been demonstrated by substantial evidence or substantial clinical experience. The most common adverse reactions associated with the use of Nucynta during clinical studies include nausea and vomiting, and these were also among the most common reasons for discontinuation of treatment with Nucynta. Additionally, 8 percent of Nucynta-treated patients experienced constipation as an adverse event in clinical studies versus 3 percent in the placebo arm.

The sales representative also indicated that when physicians prescribe Nucynta, they "won't have to put patients on docusate or senna, patients get out of the hospital a day earlier, which saves thousands of dollars because they are going to be able to have a bowel movement." This claim misleadingly implies that treatment with Nucynta has been shown to reduce length of hospital stay in comparison to oxycodone and tramadol.

The sales representative's statement that Nucynta provides 10 milligrams of opioid/oxycodone pain control similar to tramadol is misleading because it implies Nucynta has been shown to be non-inferior to oxycodone, tramadol, or other opioids. The claim implies that Nucynta has been shown to provide equivalent "pain control" when compared to other opioids, including oxycodone and tramadol. Although oxycodone was included as an active comparator arm in the clinical studies for Nucynta, FDA determined that the analyses to obtain a non-inferiority claim regarding the efficacy of Nucynta compared to oxycodone were inadequate and could not be included in the PI. FDA is not aware of any well-controlled head-to-head clinical trials comparing the efficacy of Nucynta to tramadol or any other opioids.

# DrugApprovals

**By Cara Latham** cara.latham@ubm.com

# FDA approves extended use of Prevnar 13

**Following similar approval** in Europe recently, FDA has granted approval of **Pfizer**'s pneumococcal conjugate vaccine, **Prevnar 13**, for active immunization for the prevention of pneumonia and invasive disease caused by *Streptococcus pneumoniae* in adults 50 years and older.

FDA has approved the new use for Prevnar 13 under the agency's accelerated approval pathway, which allows for earlier approval of treatments for serious and life-threatening illnesses. The pathway allows for the demonstration of effectiveness of a vaccine using an immune marker that is reasonably likely to predict clinical benefit.

"Pneumococcal disease, including pneumonia, in adults 50 years and older, represents a significant personal and societal health burden in the United States," says Ian Read, chairman and CEO, Pfizer (pfizer.com). "The FDA approval of Prevnar 13 for these adults offers the potential to contribute to the health of millions of aging Americans. This approval is representative of Pfizer's dedication to discovering and bringing to market life-changing medicines and vaccines."

In randomized, multi-center studies in the United States and Europe, people 50 and older received either Prevnar 13 or **Pneumovax 23**, a licensed pneumococcal vaccine also approved for use in this age group. The studies showed that for the 12 common serotypes, Prevnar 13 induced antibody levels that were either comparable to or higher than the levels induced by Pneumovax 23.

Officials evaluated the safety of Prevnar 13 in about 6,000 people ages 50 and older who received Prevnar 13 and who had and had not previously received Pneumovax 23. Common adverse reactions reported with Prevnar 13 were pain, redness, and swelling at the injection site, limitation of movement of the injected arm, fatigue, headache, chills, decreased appetite, generalized muscle pain, and joint pain. Officials observed similar reactions in those who received Pneumovax 23.

FDA grants accelerated approval on the condition that a clinical trial is conducted during the post-approval marketing of the vaccine to verify the anticipated clinical benefit. An additional trial in 85,000 people ages 65 years old and older, with no previous history of receiving Pneumovax 23, is underway to confirm the clinical benefit of Prevnar 13 in the prevention of pneumococcal pneumonia.

"As adults grow older they become more susceptible to infectious diseases, such as pneumococcal pneumonia, due to their aging immune systems," says Thomas M. File, Jr., M.D., president-elect, National Foundation for Infectious Diseases. "As a conjugate vaccine, Prevnar 13 offers an important new option for adults 50 years and older to include as part of their preventive strategy for healthy aging."

FDA first approved Prevnar 13 in February 2010 for the prevention of invasive pneumococcal disease in infants and young children from 6 weeks through 5 years of age. In addition to the United States, Prevnar 13 has been approved for various indications in adults 50 years of age and older in the European Union, Australia, Mexico, and more than 10 other countries.

## AROUND THE WORLD

■ **Product:** Edarbyclor (azilsartan medoxomil and chlorthalidone)
**Month approved:** December 2011
**Region:** Europe
**Marketer/developer:** Takeda Pharmaceutical Co. (takeda.com)
**Indication:** For the treatment of hypertension to lower blood pressure in adults

■ **Product:** Subsys fentanyl sublingual spray
**Month approved:** January 2011
**Region:** United States
**Marketer/developer:** Insys Therapeutics (insysrx.com)
**Indication:** For the treatment of episodes of breakthrough cancer pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain

## NEW FORMULATIONS

■ **Product:** Remodulin (treprostinil)
**Month approved:** December 2011
**Marketer/developer:** United Therapeutics Corporation (unither.com)
**New formulation:** Intravenous use
**Indication:** For the treatment of pulmonary arterial hypertension.

Remodulin is now approved for intravenous use in the treatment of pulmonary arterial hypertension.

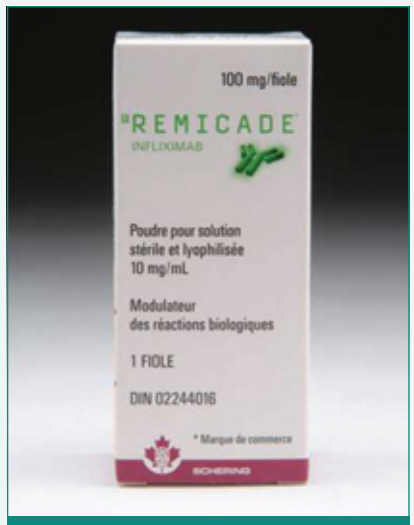
## NEW INDICATIONS

■ **Product:** Isentress (raltegravir)
**Month approved:** December 2011
**Region:** United States
**Marketer/developer:** Merck (merck.com)
**New indication:** For use with other antiretroviral drugs for the treatment of HIV-1 infection for children and adolescents ages 2 to 18; a chewable form of the tablet has been approved for use in children ages 2 to 11.
**Already approved for:** The treatment of HIV-1 infection in adult patients.


Isentress is now approved in the United States for use with other antiretroviral drugs for the treatment of HIV-1 infection for children and adolescents ages 2 to 18.

■ **Product:** Onon Dry Syrup 10 percent
**Month approved:** December 2011
**Region:** Japan
**Marketer/developer:** Ono Pharmaceutical Co. (ono.co.jp/eng)
**New indication:** Allergic rhinitis
**Already approved for:** Bronchial asthma

■ **Product:** Remicade (infliximab)
**Month approved:** December 2011
**Region:** Canada
**Marketer/developer:** Janssen Inc. (janssen-ortho.com)
**New indication:** For the induction and maintenance of clinical remission and mucosal healing and the reduction of corticosteroid use in adult patients with moderately to severely active Crohn's disease who have had an inadequate response to a corticosteroid and/or aminosalicylate.
**Already approved for:** The treatment of Crohn's disease.




Remicade has been approved in Canada for the induction and maintenance of clinical remission and mucosal healing and the reduction of corticosteroid use in adult patients with moderately to severely active Crohn's disease.

### Generic Truvada approved

FDA has granted tentative approval of emtricitabine/tenofovir disoproxyl fumarate tablets, 200 milligrams/300 milligrams – the generic version of Gilead's **Truvada** Tablets, a combination of **Emtriva** and **Viread** that is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients 12 years of age and older.

Tentative approval means that FDA has concluded that a drug product has met all required quality, safety, and efficacy standards, but is not eligible for marketing in the United States because Truvada continues to be subject to patent protections.

The tentative approval does, however, make the product eligible for purchase outside the United States under the President's Emergency Plan for AIDS Relief (PEPFAR) program. This product was reviewed under expedited review provisions for PEPFAR.

Hetero Labs Limited of Hyderabad, India, manufacturers the tablets.

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## Recruitment

### Senior Manager, Positioning Strategy

Our brand positioning company, located in Bergen County, NJ, just minutes from the George Washington Bridge, is growing. If you are energetic and highly motivated and are looking for the potential for high reward for your hard work, we may be the company for you.

**The Job**
A Senior Manager of Positioning Strategy is responsible for the day-to-day management of highly visible strategic marketing projects across multiple clients, primarily within the pharmaceutical industry. The right individual will continue to develop our existing clients and assist in expanding our new client base. Previous client management experience, the ability to handle complex projects, managing/developing various internal and external team members, and being comfortable working with high level client teams such as Market Research Directors, Product Management, and Marketing Directors are important skills for this position. The Senior Manager of Positioning Strategy must exercise strong initiative, possess organization and problem solving skills, excellent written and verbal communications skills, the ability to direct his/her team to ensure that project goals are accomplished within the prescribed time frame and agreed-upon project scope. The candidate must be highly detail oriented, have a strong sense of urgency, the ability to prioritize, and the desire to stay abreast of emerging industry trends.

**What We Are Looking For**
- 5+ years of pharmaceutical/biotechnology marketing/communication experience
- 3+ years of client management experience
- Proven track record of successful project management and team leadership
- Excellent verbal and written communications skills
- Ability to develop, foster, and maintain business relationships

**Traits Of The Ideal Candidate**
- Strong organizational skills
- Ability to solve problems creatively and analytically
- Excellent presentation development and delivery skills
- Familiarity with market research methodologies and interpretation
- Highly detail oriented

**Icing On The Cake**
- Advertising agency or product management experience
- Experience in brand positioning and strategy development

**Expectations**
- Develop strong working knowledge of product and therapeutic categories for client projects
- Work directly with client and internal team members to ensure all deliverables meet and exceed client expectations
- Attend client meetings, market research, and new business pitches as necessary
- Work independently and with shared resources to ensure all work is completed in a thorough and timely manner
- Prospect for new projects and other opportunities within existing clients
- Manage multiple project assignments simultaneously

**Other Things You Need To Know**
- Domestic and international travel may be required based on project assignments and may exceed 25% at times during the course of a project
- We are an Equal Opportunity Employer
- Salary is competitive and commensurate with experience
- Yearly bonus and profit sharing based on individual and corporate performance

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