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SPECIAL REPORT

FIRST YEAR AFTER LAUNCH

The new medicines introduced to the U.S. market during 2011 include a variety of blockbuster products that will help restore growth for the pharmaceutical industry.

By Andrew Humphreys andrew.humphreys@ubm.com

For the global pharma arena, 2012 is noted as the year of the patent cliff, with roughly $38 billion in prescription drug sales lost due to the exclusivity expiration of some of the all-time best sellers, including **Lipitor** and **Plavix**. As a result, total worldwide Rx brand sales uncharacteristically decreased year over year. But overall global sales growth for branded prescription drugs is expected to slightly increase in 2013, and is anticipated to gain better traction and increase by several percentage points during each of the next few years thereafter. Helping spur this sales growth is a variety of innovative medicines that were introduced to the U.S. marketplace during 2011 and performed strongly in 2012, their first full year of availability.

Battle for hepatitis C category share

Though this story concentrates on the 2012 and 2013 market performance of successful products launched in the United States during 2011, the latter is the year of most significance for **Incivek**. The drug became the fastest prescription medicine to top $1 billion in sales, doing so for developer **Vertex** Pharmaceuticals between May 2011 and January 2012.

Containing the active chemical telaprevir, Incivek is an orally administered hepatitis C virus (HCV) protease inhibitor. The product is available for adults with genotype 1 HCV infection in combination with pegylated-interferon (peg-IFN) and ribavirin (RBV). Patients are initially treated with Incivek, a weekly injection of peg-IFN, and RBV for 12 weeks. After three months, patients stop receiving Incivek and continue with peg-IFN and RBV for another 12 weeks or 36 weeks of treatment. Incivek is indicated for three-times-daily dosing, with regulatory filings awaiting approval for twice-daily use.

Telaprevir was discovered through a former collaboration between Vertex and **Lilly**. Approved by U.S. regulators on May 23, 2011, the drug was launched by Vertex in America shortly thereafter. Canadian approval was granted during August 2011, and Incivek was introduced to that market by Vertex two months later. Telaprevir gained regulatory clearance in the third quarter of 2011 in the European Union (branded as **Incivo**) and Japan (marketed as **Telavic**). **Johnson & Johnson** subsidiary **Janssen** Pharmaceutica is responsible for marketing in Europe and other countries, and **Mitsubishi Tanabe** Pharma commercializes the medicine in Japan.

Before the arrival of Incivek and **Merck**'s **Victrelis** during 2011, patients with genotype 1 HCV infection were treated with a combination of peg-IFN and RBV for 48 weeks. Those new treatment regimens incorporating HCV protease inhibitors offer substantially increased sustained viral response rates – and in many instances shorter treatment durations – for patients with genotype 1 HCV infection, versus peg-IFN and RBV alone.

Incivek attained rapid acceptance in the United States for treating patients with genotype 1 HCV infection. Vertex reported total sales (for the United States and Canada) of $950.9 million in 2011, increasing to $1.16 billion during 2012. But according to Vertex, because of competitive treatment regimens undergoing late-stage clinical development for which there have been reported improved viral cure rates and/or tolerability over available regimens, the marketplace has anticipated the approval of these newer regimens. Between the promising safety and efficacy data reported by Vertex competitors for potential treatment regimen rivals along with other factors, Incivek revenue has been declining since reaching a peak during fourth-quarter 2011. Vertex expected that the drug's revenue would continue decreasing in 2013 versus its 2012 performance. That projection came to fruition during first-half 2013 as Vertex's net revenue from Incivek totaled $361.4 million, versus $684.6 million for January-June 2012. The company attributed the reduced revenue to fewer HCV patients initiating treatment in the first half of 2013 compared to the first six months of 2012.

The antiviral drug Incivek can effectively cure most patients of the infectious disease hepatitis C.

Incivek is patent protected in the United States until 2025. Incivo's EU patent protection ranges until 2026.

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- **Mobile tops desktop for social sharing:** There was nearly twice as much social sharing activity on mobile as on the desktop, according to June 2013 research by ShareThis, a social sharing application platform.

- **Physicians expect more out of tablet-toting pharmaceutical sales reps:** With the tablet maturing as a device and adoption by pharmaceutical sales forces at near-universal levels, physicians give most tablet details middling ratings, according to Manhattan Research.


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tothepoint

By Christiane Truelove chris.truelove@ubm.com

Unhealthy habits

The pharma companies are making money with their old habits, but are undermining their health as surely as I was with my refusal to make any changes to my lifestyle or my diet.

I've recently gone back to the gym. Since the end of June to the time I am writing this, between working out at least five days a week and being more mindful of what I eat, I have lost 11 pounds and will probably close out the week with another pound in loss.

I'm not writing this for the congratulations (although those are always appreciated) but to talk about how setting up a good routine with good habits yields good results. A few years ago, I did WeightWatchers and joined a gym, and I got great results. Unfortunately, I let other factors undermine that momentum. I let my gym membership lapse. I ate less healthily. The weight started to creep back. I tried using the free fitness room at work, but the lack of equipment and the difficulty of carving out time from the office in the middle of the work day truly made it impossible. I knew what truly worked for me – I needed to get to a well-equipped gym by 7:30 AM at the latest, five days a week, do a mixed routine of cardio and weights, and watch what I ate – and I wasn't doing it. Instead, I was letting the power of bad habits reassert themselves. I knew what I was doing was bad. I just couldn't seem to shift gears, though. Until I woke up one morning and thought, "I am miserable. I need to change." And I went back to my original gym and renewed my membership.

Changing gears now, the GlaxoSmithKline Chinese bribery scandal continues to play out. At the time of this writing, according to the *New York Times*, other pharma companies used the same travel agency as GlaxoSmithKline did, but are not implicated in using that agency as a conduit for distributing bribes. The amount in bribes allegedly distributed in China by the agency on behalf of GlaxoSmithKline is $489 million.

A headline on *Forbes*' Website caught my eye: "Is Big Pharma Addicted to Fraud?" Contributor Erica Kelton points out that GlaxoSmithKline has had to pay out a lot in fines and settlements over the past few years – $3 billion last year, and $750 million in 2009 – and just about every major pharma company has a corporate integrity agreement with the U.S. Justice Department. They pay the settlements, and continue business as usual, it seems. And she also says, "But the combination of pharma's noncompliant corporate culture and the prevalence of corrupt business practices in China and other emerging economies could have a lethal impact on many more consumers as pharma shifts more research and development functions, manufacturing operations, and marketing efforts to those growing markets."

She goes on to say, "Though Big Pharma's practices in China are grabbing headlines, not much about them is truly new. Those tactics – the use of payments disguised as speaking and consulting fees, luxury travel, sex, and numerous other inducements to expand sales of prescription drugs – are marketing techniques homegrown in the U.S. They simply have been exported to emerging markets."

If you look at "set-in-their-ways corporate culture" as "set-in-their-bad-diet-and-exercise habits," you can begin to see the enormity of the problem here. Think about it: if one person (me) can't stick to a relatively simple diet and exercise program, how can you expect a company of tens of thousands of indivduals with all-too-human natures to change its ways? You could argue, "Well, they're sticking to those ways because they want to make money. You are sitting on the couch and eating Ben and Jerry's New York Super Fudge Chunk because you are lazy and a glutton."

Well, yes and no. Companies are sticking to bad corporate habits because they know they can make money this way – but also because of fear of the unknown and maybe some defeatism too. ("What if we try and it doesn't work anyway?") I was also sticking to my ways for fear. ("What if I try this and it doesn't work anyway?") In the case of GlaxoSmithKline or any other pharma company, making money is their goal. For me, the goal was sweet, sweet ice cream melting in my mouth. Or another bowl of pasta. You get the picture. You do the things you know "work" to fulfill your needs.

However, just because they work and are effective doesn't mean those habits are good ones. The pharma companies are making money with their old habits, but are undermining their health as surely as I was with my refusal to make any changes to my lifestyle or my diet. So unto the pharma industry I say: Get your butt to the gym. It will be initially painful, but the results will be worth it.

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Mobile tops desktop for social sharing
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Physicians expect more out of tablet-toting sales reps
With the tablet maturing as a device and adoption by pharmaceutical sales forces at near-universal levels, physicians give most tablet details middling ratings, according to Manhattan Research.

Doctors grow more comfortable with their patients' online searches
As Internet symptom-checkers improve, many healthcare providers say they feel fine with patients doing their own homework ahead of an appointment.

Apple is suddenly really interested in health tech
According to a new report, Apple has been bringing on board experts in sensors that monitor the human body.

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MOBILE TOPS DESKTOP FOR SOCIAL SHARING

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PHYSICIANS EXPECT MORE OUT OF TABLET-TOTING PHARMACEUTICAL SALES REPS

With the tablet maturing as a device and adoption by pharmaceutical sales forces at near-universal levels, physicians give most tablet details middling ratings, according to Manhattan Research.

DOCTORS GROW MORE COMFORTABLE WITH THEIR PATIENTS' ONLINE SEARCHES

As Internet symptom-checkers improve, many healthcare providers say they feel fine with patients doing their own homework ahead of an appointment.

APPLE IS SUDDENLY REALLY INTERESTED IN HEALTH TECH

According to a new report, Apple has been bringing on board experts in sensors that monitor the human body.

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WHAT'S IN PRINT

GLAXO OFFERS PATIENT-LEVEL TRIAL DATA ONLINE

Breaking ranks from many of its competitors, GlaxoSmithKline has created an online system for researchers to request access to patient-level trial data and released the names of a group of experts who will review requests from researchers seeking to examine trial data. Go to page 18

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With the Sunshine Act coming into effect on August 1, weaknesses in the pharmaceutical industry's preparations remain that could lead to reporting mistakes, angry physicians, employer embarrassment, and media frenzy. Go to page 20

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The healthcare industry is looking to cloud computing as a means to improve the quality of services while reducing costs, according to new research by Frost & Sullivan. Go to page 22

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Cadient Group has unveiled the next generation of its insights and analytics solution Reveal, a proprietary SaaS business intelligence solution that is engineered to simplify the data analysis and interpretation process for key decision makers in a company. Go to page 24

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Victrelis (boceprevir) is an innovative oral medicine marketed by Merck for treating certain adults with chronic hepatitis C. The medication is used for patients who still have some liver function, and who either have not been previously treated with drug therapy for their hepatitis C or who have failed such treatment. Victrelis is available for use in combination with peginterferon alfa and ribavirin. Victrelis is taken as a pill three times per day with food. The therapy belongs to a class of medicines referred to as protease inhibitors, which work by binding to the virus and preventing it from multiplying.

The drug was cleared for approval by U.S. regulators during May 2011 and by the European Commission in July 2011. Victrelis is approved in 70 countries and has been introduced in at least 45 of those markets. After generating global sales of $140 million in 2011, the figure reached $502 million for 2012. Merck reported that Victrelis' 2012 performance was spurred by post-launch growth in the United States and internationally, particularly in Europe.

Victrelis sales for the first three months of 2013 amounted to $110 million, compared to $111 million during January-March 2012. According to Merck, the sales decline included a 2 percent negative impact from foreign exchange. Lower U.S. sales for the oral hepatitis C virus protease inhibitor were partially offset by continued growth in international markets.

Victrelis is patent protected in the United States until 2024 (with pending Patent Term Restoration). Some industry trackers had previously projected full-year 2013 worldwide sales of more than $700 million, with that figure declining in the ensuing years due to the arrival of newer and better competition.

U.S. PRESCRIPTION PRODUCT LAUNCHES OF 2011: TOP SELLERS

Medicine	2013 global sales estimate ($ in millions)	2012 global sales ($ in millions)	2011 global sales ($ in millions)	Companies	Primary disease/ medical use	First approval date and/or launch date
Xarelto	1,656	414+	111+	Bayer and Johnson & Johnson	Deep-vein thrombosis	EU approval: Oct. 1, 2008 U.S. approval: July 1, 2011
Eylea/Eylia	1,639	856	25	Regeneron Pharmaceuticals and Bayer	Wet age-related macular degeneration	Eylea U.S. launch: November 2011 Eylia EU launch: Fourth-quarter 2012
Zytiga	1,478	961	301	Johnson & Johnson	Prostate cancer	U.S. approval: April 28, 2011 EU approval: Sept. 7, 2011
Yervoy	924	706	360	Bristol-Myers Squibb	Metastatic melanoma	U.S. approval: March 2011 EU approval: July 2011
Incivek/ Incivo/Telavic	723+	1,162+	951+	Vertex Pharmaceuticals and Mitsubishi Tanabe Pharma	Hepatitis C	Incivek U.S. launch: May 2011 Incivo EU approval: Sept. 20, 2011 Telavic Japan approval: September 2011 Incivek Canada launch: Oct. 11, 2011
Victrelis	452	502	140	Merck	Hepatitis C	U.S. approval: May 13, 2011 EU approval: July 18, 2011
Zelboraf	365	250	33	Roche	Metastatic melanoma	U.S. launch: August 2011

Note: + = Product sales are assumed to be higher than the represented total as some figures were not provided by each company or found by *Med Ad News* editors.

Many companies, including Vertex, are pursuing the development of treatment regimens for HCV infection that could potentially offer improved safety, efficacy and/or tolerability – such as shorter duration therapies, therapies that do not necessitate administration of

By taking Victrelis with other meds, some patients can clear hepatitis C infection from their bodies with shorter treatment durations than previously available regimens.

peg-IFN, and those that do not result in side effects evident with currently approved HCV protease inhibitors. Various companies are investigating combination regimens that bring together one or more of an HCV protease inhibitor, an HCV nucleotide analog, an HCV non-nucleotide polymerase inhibitor or an NS5A inhibitor; each of which inhibit HCV viral replication via different mechanisms of action. Clinical studies of these investigational combination regimens are being carried out in a different types of patient populations, including treatment-naïve and treatment-failure patients, and across all HCV genotypes, which respond differently to various combinations of molecules employing different mechanisms.

Vertex is sponsoring Phase IIIb clinical trials to evaluate telaprevir-based combination treatment regimens for patients with genotype 1 HCV infection who also have HIV infection and for patients who experience recurrent genotype 1 HCV infection following a liver transplant.

The next wave of genotype 1 HCV infection drugs to reach the marketplace are expected to be part of a treatment regimen that includes peg-IFN and RBV, with regulatory approval possible coming in late 2013 or early 2014. All-oral treatment regimens that do not contain the injectable peg-IFN additionally are in late-stage clinical trials, and the first of those treatment regimens could gain U.S. clearance by late 2014.

The biopharma company **Gilead** Sciences has completed Phase III studies evaluating treatment regimens for patients with HCV infection. During April 2013, Gilead filed for approval with U.S. and EU health regulators for the use of **sofosbuvir** (product code GS-7977) and ribavirin as an all-oral therapy for patients with genotype 2 and 3 HCV infection, and for sofosbuvir in combination with RBV and pegylated interferon for treatment-naïve patients with genotype 1, 4, 5 and 6 HCV infection. On May 17, the Marketing Authorisation Application (MAA) for the once-daily oral nucleotide analog inhibitor sofosbuvir was announced as fully validated and under assessment by the European Medicines Agency. Gilead announced in June that FDA had granted priority review for sofosbuvir. The U.S. regulatory agency has set a target review date under the Prescription Drug User Fee Act of Dec. 8, 2013.

Janssen also has a combination treatment for genotype 1 chronic hepatitis C undergoing priority review by FDA, as of May 2013. **Simeprevir** (product code TMC435) is an investigational NS3/4A protease inhibitor administered as a 150-mg capsule once daily with pegylated interferon and ribavirin for treating genotype 1 chronic hepatitis C in adult patients with compensated liver disease. Jointly developed by Janssen and **Medivir**, the intended indication for simeprevir includes every stage of liver fibrosis. The drug works by blocking the protease enzyme that allows the hepatitis C virus to replicate in host cells. Janssen has also filed simeprevir for marketing authorization to health regulators in Japan and Europe.

Top-line results reported by Gilead and Janssen from Phase III studies for sofosbuvir and simeprevir suggest that their safety and efficacy profiles will position them to potentially take a significant portion of the market for HCV therapies. Industry analysts have projected that various sofosbuvir-based products could generate more than $9 billion in combined sales during 2018.

As for the development of all-oral treatment regimens for HCV infection, Vertex is studying different options including its HCV nucleotide analog **VX-135/ALS-2200** in Phase II trials. VX-135 studies include the drug compound as part of all-oral treatment regimen with ribavirin as well as other direct-acting antivirals. Vertex intends to start pivotal development of VX-135 as part of all-oral treatment regimens in 2014, pending data from the Phase II trials.

The uridine nucleotide analog pro-drug VX-135 is designed to inhibit the replication of HCV by acting on the NS5B polymerase. ALS-2200 has demonstrated pangenotypic activity in vitro. Vertex acquired global rights to ALS-2200 via an exclusive licensing deal inked with **Alios** BioPharma during June 2011. The pact includes a research program that concentrates on the discovery of additional nucleotide analogs that act on the hepatitis C polymerase. Vertex has the option to choose more compounds for development emerging from the research program.

Gilead is conducting Phase III development an all-oral treatment regimen for HCV infection. The ION-1 study is evaluating a once-daily fixed-dose combo of sofosbuvir and the NS5A inhibitor **ledipasvir** with and without ribavirin for 12 or 24 weeks among treatment-naïve genotype 1 patients with HCV infection. Sofosbuvir/ledipasvir is additionally being studied in the Phase III ION-2 trial launched during January 2013. Fully enrolled, ION-2 is evaluating sofosbuvir/ledipasvir with RBV for 12 weeks, and with and without RBV for 24 weeks, among 400 treatment-experienced genotype 1 HCV patients. Participants in this clinical trial failed to respond to past therapy containing peg-IFN plus a protease inhibitor.

AbbVie is performing Phase III development for an investigational direct-acting antiviral (DAA) combination with and without ribavirin for treating genotype 1 (GT1) hepatitis C virus infection. The Phase III program for the all-oral, triple-DAA combination consists of more than 2,000 patients with HCV genotype 1, with trial sites in 29 countries. The DAAs in the program include **ABT-450/r** (protease inhibitor and ritonavir), **ABT-267** (NS5A inhibitor) and **ABT-333** (non-nucleoside polymerase inhibitor). Treatment durations being studied are 12 weeks in non-cirrhotic patients, and 12 or 24 weeks in cirrhotic patients. Every patient will be followed for 48 weeks post-treatment. Co-formulated tablets of ABT-450/r and ABT-267 are being used in the Phase III studies.

The interferon-free, direct-acting antiviral combo gained Breakthrough Therapy designation from FDA, as announced by AbbVie during May 2013. This designation is intended to expedite the development and review of drugs for serious or life-threatening conditions. Criteria includes preliminary clinical evidence showing a drug may have substantial improvement on at least one clinically significant endpoint versus available therapy. According to U.S. regulators, Breakthrough Therapy designation conveys all of the fast track program features in addition to more intensive FDA guidance on an efficient drug development program.

The designation is based, in part, on positive data from the company's clinical development program, including the Phase IIb study M11-652 known as "Aviator." The Aviator trial was carried out in 571 patients infected with HCV GT1. Results from the treatment arms evaluating ABT-450/r plus ABT-267 plus ABT-333 with and without ribavirin showed that the regimen provided high sustained viral response rates (SVR) with 12 weeks of therapy in patients who had not been previously treated (treatment naive) and in those who had failed previous therapy with pegylated interferon and ribavirin (null responders).

Despite the assumed rivalry between the aforementioned companies and their HCV therapies, a number of them are teaming up to investigate combination regimens of their drug candidates, with or without the addition of RBV. For instance, Vertex entered into separate non-exclusive collaborations to study VX-135 in combination with Janssen's simeprevir and **GlaxoSmithKline**'s HCV NS5A inhibitor **GSK2336805**. Janssen is evaluating simeprevir in combination with Gilead's sofosbuvir. Janssen additionally is assessing simeprevir in combination with **Idenix** Pharmaceuticals' HCV NS5A inhibitor **IDX719**.

Vertex announced separately in early November 2012 two non-exclusive deals to conduct Phase II proof-of-concept studies of all-oral regimens for treating hepatitis C; one

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The novel drug Yervoy is the first demonstrated to prolong the lives of people with the skin cancer melanoma.

consists of VX-135 with simeprevir, and the other involves VX-135 with GSK2336805. The studies are evaluating safety, tolerability and viral cure rates using a 12-week combination of VX-135/simeprevir and VX-135/GSK2336805. Vertex is jointly sharing costs associated with the different studies between Janssen and GlaxoSmithKline. GSK2336805 is an investigational NS5A replication complex intended for the treatment of hepatitis C.

Idenix revealed in late May 2013 the start of the Phase II HELIX-1 study evaluating an all-oral, direct-acting antiviral HCV combo regimen. The combination regimen consists of Idenix's once-daily pan-genotypic NS5A inhibitor **samatasvir** (product code IDX719) and simeprevir. The collaboration, announced in January 2013, is investigating different combinations including samatasvir, simeprevir, and **TMC647055**. A potent non-nucleoside hepatitis C polymerase inhibitor, TMC647055 has broad genotypic coverage. In addition to the HELIX-1 Phase II study, the companies intend to initiate HELIX-2 to evaluate a three-DAA combination of samatasvir, simeprevir and TMC647055/r, with and without ribavirin. The clinical trials will be carried out by Idenix. The biopharma entity Idenix and Janssen retain all rights to their respective compounds.

Zelboraf is the first FDA-approved treatment for BRAF V600E mutation positive metastatic melanoma.

Three oncology drugs on their way to blockbuster status

The anti-cancer agent **Zytiga** nearly generated $1 billion in sales during its first full calendar year on the market. Containing the active chemical abiraterone, Zytiga is available as a treatment for metastatic castration-resistant prostate cancer. The drug is intended for use in combination with the steroid prednisone for patients who have received prior docetaxel (chemotherapy). Zytiga was FDA-approved as the first oral, once-daily medication for this indication on April 28, 2011. Zytiga's new drug application was reviewed via FDA's priority-review program, which provides for an expedited six-month review for drugs that may offer major advances in treatment, or provide a treatment when no adequate therapy exists. During fourth-quarter 2012, Zytiga was approved by U.S. and EU regulators for an expanded indication, allowing for use before chemotherapy. Initial marketing clearance for the product was granted by EU health officials in September 2011.

Available as a pill, abiraterone targets a protein called cytochrome P450 17A1 (CYP17A1). This protein plays a significant role in producing the hormone testosterone. Abiraterone functions by decreasing the production of this hormone that would stimulate cancer cells to continue growing. The oral androgen biosynthesis inhibitor works by inhibiting the CYP17 enzyme complex, which is required for the production of androgens at three sources: testes, adrenal glands, and tumor tissue.

Zytiga is marketed in the United States by the **Johnson & Johnson** affiliate Janssen Biotech. The drug's worldwide 2012 sales came to $961 million after producing $301 million during its launch year. Of the 2012 total, $463 million derived from the United States and $498 million was generated in international markets. The strong momentum carried over into 2013 as first-quarter global sales rose to $395 million, up 70.3 percent over January-March 2012.

Another cancer medicine that has been a market success since its 2011 launch is **Yervoy**. The product was approved by U.S. regulators on March 25, 2011, and by EU health authorities on July 14, 2011, to treat patients with late-stage (metastatic) melanoma. The most dangerous type of skin cancer, melanoma is the No. 1 cause of death from skin disease.

Yervoy is the first therapy for unresectable or metastatic melanoma to show a significant improvement in overall survival based on results from a pivotal randomized, double-blind Phase III trial. The recombinant, human monoclonal antibody is the first FDA-cleared cancer immunotherapy that blocks cytotoxic T-lymphocyte antigen-4. CTLA-4 may have a role in slowing down or turning off the body's immune system, affecting its ability to fend off cancerous cells. The drug may work by enabling the body's immune system to recognize, target, and attack cells in melanoma tumors. Containing the active ingredient ipilimumab, Yervoy is administered intravenously.

CTLA-4 acts as a negative regulator of T-cell activation. Ipilimumab binds to cytotoxic T-lymphocyte antigen-4 and blocks the interaction of CTLA-4 with its ligands, CD80/CD86. CTLA-4 blockade has been demonstrated to augment T-cell activation and proliferation. The mechanism of action of ipilimumab's effect in patients with melanoma is indirect, potentially via T-cell mediated antitumor immune responses.

Yervoy was discovered by **Medarex** and jointly developed by that company and **Bristol-Myers Squibb**. Medarex now operates as a subsidiary of BMS. Yervoy was granted orphan drug status during 2004, a designation provided to medicines that treat rare diseases. In 2006, the biological product gained fast-track designation. During August 2010, Yervoy was given priority-review designation.

Global sales for Yervoy totaled $360 million for 2011 and $706 million during 2012. Of the 2012 amount, $503 million was generated in the United States and $203 million was produced outside America. Sales growth continued throughout first-quarter 2013, with the global figure up 49 percent year over year to $229 million.

Yervoy is being studied for new indications such as lung cancer, adjuvant melanoma, and hormone-refractory prostate cancer. Industry forecasters have estimated Yervoy global sales of more than $1.6 billion for 2020. The product's basic exclusivity loss is set to occur during 2020 in Canada, 2021 in the European Union, and 2023 in the United States.

The novel, oral small molecule **Zelboraf** (vemurafenib) gained FDA approval and was launched in the United States during August 2011. The drug is available for treating patients with BRAF V600E mutation-positive inoperable or metastatic melanoma as detected by an FDA-approved test. The cobas 4800 BRAF V600 Mutation Test is a DNA-based companion diagnostic used to identify patients whose tumors carry the BRAF mutation. The test was simultaneously FDA-approved with Zelboraf, and is CE marked and commercially available in Europe.

Vemurafenib was discovered via **Plexxikon**'s structure-guided chemistry platform, and the company started the drug's clinical development in 2006. Zelboraf was jointly developed through a 2006 license and collaboration deal between Plexxikon and **Roche**. Plexxikon became a member of the **Daiichi Sankyo** Group in April 2011. Zelboraf is jointly promoted in the United States by Daiichi Sankyo and the Roche company **Genentech**. Roche Molecular Diagnostics developed the cobas 4800 BRAF V600 Mutation Test following a 2005 pact with Plexxikon.

As of November 2012, Zelboraf had been used to treat 11,000 patients globally and was approved in 43 countries. The European Commission during February 2012 approved it as the first personalized skin cancer medicine that allows individuals with BRAF V600 mutation-positive metastatic melanoma to live significantly longer. Zelboraf has been proven to help patients with BRAF V600 mutation-positive metastatic melanoma in two significant ways: it stalls the growth or spread of cancer and helps patients survive longer, extending life expectancy beyond one year for many patients.

A mutated form of the BRAF protein takes place in about half of all melanoma patients. After the companion test identifies patients with this specific mutation, Zelboraf sets forth a targeted attack against the tumor. This is the first treatment for this aggressive skin cancer to considerably improve quality of life and prolong survival, according to Roche.

Roche says the product performed well in 2012 and emerged as a key growth driver for the Swiss company. Roche reported Zelboraf sales of SFr234 million ($250 million) for 2012, rising from SFr31 million ($33 million) during 2011.

Roche is building on its extensive clinical experience with the first-in-class BRAF inhibitor Zelboraf to explore various combination approaches. One potential combination is Zelboraf with Roche's investigational MEK inhibitor **GDC-0973**. Roche scientists believe that one reason why patients treated with BRAF inhibitors stop responding to therapy is because they have acquired resistance to drugs that inhibit the RAS-RAF pathway. The company has started a Phase III trial investigating the potential of GDC-0973 with Zelboraf.

GDC-0973 (also known by the product code XL518) is a potent, highly selective inhibitor of MEK, which is a serine/threonine kinase that is a component of the RAS/RAF/MEK/ERK pathway. GDC-0973 is being developed by Genentech via a collaboration deal with the biopharmaceutical company **Exelixis**.

Eye-health market receives a boost

Eylea – also known as VEGF Trap-Eye – is making strong inroads in the eye-care arena. VEGF (Vascular Endothelial Growth Factor) is a naturally occurring protein within the body. VEGF's normal role in a healthy organism is to trigger formation of new blood vessels (angiogenesis) supporting the growth of tissues and organs. But in certain diseases such as wet age-related macular degeneration, it is additionally associated with the growth of abnormal new blood vessels in the eye, which exhibit abnormal increased permeability that results in edema. Scarring and loss of fine-resolution central vision often takes place. In central retinal vein occlusion and branch retinal vein occlusion, a blockage results in the main blood vessel that transports deoxygenated blood away from the retina. VEGF levels rise in response, contributing to macular edema. For clinically significant diabetic macular edema (DME), VEGF-mediated leakage of fluid from blood vessels in the eye leads to vision interference.

A recombinant fusion protein, Eylea (aflibercept) contains portions of human VEGF receptors 1 and 2 extracellular domains fused to the Fc portion of human IgG1 and formulated as an iso-osmotic solution for intravitreal administration. The drug acts as a soluble decoy receptor that binds VEGF-A and placental growth factor (PlGF) and thereby can inhibit the binding and activation of these cognate VEGF receptors. Eylea is specially purified and consists of iso-osmotic buffer concentrations, enabling injection into the eye.

Eylea is marketed in the United States for treating wet AMD and macular edema following CRVO. The product is additionally available in the United Kingdom, Germany, Switzerland, Australia, Japan, and various other countries for treating wet AMD. **Regeneron** Pharmaceuticals launched the drug in the United States for the wet AMD indication during November 2011 and the macular edema indication as of September 2012. **Bayer** HealthCare introduced the drug in Europe, Japan, and Australia for treating wet AMD in November 2012. Regulatory filings submitted by Bayer in other countries for the treatment of wet AMD are awaiting clearance. Additionally, Bayer filed applications for marketing authorization for Eylea in Europe during December 2012 and in Japan during January 2013 for macular edema following CRVO.

Since October 2006, Regeneron and Bayer HealthCare have had a worldwide development and commercialization deal for Eylea outside the United States. Bayer is responsible for marketing the medicine outside the United States, where, for countries other than Japan, the companies equally share the profits and losses from Eylea sales. For Japan, Regeneron is entitled to a royalty on the product's sales. Regeneron holds U.S. exclusive rights to Eylea and is entitled to all profits from those sales.

On track to gain blockbuster status in 2013, Eylea can ease vision problems for patients with wet age-related macular degeneration.

Regeneron reported Eylea U.S. net product sales of $837.9 million for 2012 and $24.8 million during 2011. The drug's net sales outside of the United States as recorded by Bayer totaled €14 million ($18 million) in 2012.

Eylea is undergoing Phase III trials for treating DME and macular edema following BRVO. In Asia, the drug is being studied in

Phase III for choroidal neovascularization of the retina as a result of pathologic myopia (mCNV).

Some industry trackers expect big things from Eylea, including potential annual peak sales exceeding $4.5 billion.

According to Bayer, the patent expirations for Eylea/**Eylia** are set for 2020 in Germany, France, the U.K., Italy, Spain, Japan, China, and Canada. The U.S. patent for Eylea is not expected to expire before that year.

The most broadly indicated novel oral anticoagulant

Bayer is also jointly marketing another recent U.S. launch success, the innovative anticoagulant **Xarelto** (rivaroxaban). The anticipated blockbuster medicine was discovered at Bayer's Wuppertal Research Center in Germany during 1999. In 2005, after a comprehensive selection process with various top pharma companies, Bayer entered into a collaboration with Janssen to increase the drug's worldwide potential by expanding its range of indicated uses. The development program for Xarelto is expected to enroll almost 100,000 patients by its completion. Rivaroxaban is the most studied oral, direct Factor Xa inhibitor globally.

Xarelto has been cleared for more indications than any other oral anticoagulant. The product was initially approved for marketing by Canadian health authorities in 2008 for the prevention of venous thromboembolism in adult patients following elective hip or knee replacement surgery. FDA granted approval for the prevention of venous thromboembolism

Used to prevent stroke among patients suffering from atrial fibrillation, Xarelto is on its way to generating annual multi-billion sales.

in adult patients following elective hip or knee joint replacement surgery and to reduce the risk of stroke in patients with non-valvular atrial fibrillation during 2011. U.S. regulators via priority review approved Xarelto in the treatment of deep vein thrombosis or pulmonary embolism and in secondary prevention of recurrent VTE during November 2012. Janssen Pharmaceuticals holds the U.S. commercialization rights for Xarelto. Bayer HealthCare supports the Janssen Pharmaceuticals sales team in selected U.S. hospitals and specialty markets.

The drug is registered in 120-plus countries and is marketed for VTE prophylaxis by Bayer HealthCare outside the United States. During 2011 the product was cleared in the European Union for stroke prevention in patients with atrial fibrillation, the treatment of deep-vein thrombosis (DVT), and the prevention of recurring DVT and pulmonary embolism following acute DVT in adult patients. EU marketing authorization was granted in November 2012 for treating pulmonary embolism and the secondary prevention of recurrent deep vein thrombosis and pulmonary embolism. In Japan, Xarelto was approved during January 2012 for the prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation, and launched during April 2012.

Xarelto's annual sales potential has been projected by health-care analysts to reach several billion dollars. Bayer reported Xarelto sales of €86 million ($111 million) in 2011 and €322 million ($414 million) for 2012. According to the company, sales advanced strongly in all regions – particularly in Germany, the United States and Japan – following additional product launches and indication expansions in 2012.

Xarelto's patent-expiration years include 2020 in Germany, Japan, China and Canada; 2021 in the United States; and 2023 in France, the U.K., Italy and Spain. ■ MEDADNEWS

Wide and deep

Oncology drugs continue to be a major focus for pharmaceutical and biotechnology companies, and the ASCO meeting highlighted what oncologists are most anticipating.

By Christiane Truelove (chris.truelove@ubm.com)

The late-stage pipeline of oncology drugs remains large, consisting of a wide array of new molecular entities as well as already-marketed medicines being explored for new indications and formulations (please see the chart starting on page 14). The entire oncology market is estimated to grow about eight percent annually during the next five years. New growth drivers will include anticipated blockbuster anticancer agents such as **nivolumab** from **Bristol-Myers Squibb** and **Ono** Pharmaceutical; **ibrutinib** from **Janssen** Biotech and **Pharmacyclics**; and **Reolysin** from **Oncolytics** Biotech.

At June's meeting of the American Society of Clinical Oncologists (ASCO), more than 25,000 attendees heard presentations from researchers about new drugs in development and new procotols for treating diverse cancers. Experts at Encuity Research, a division of Campbell Alliance, did an after-conference study of attendee perceptions of the presentations and their potential impact on future treatment. According to Encuity, oncologists attending ASCO 2013 reported that the most important pieces of clinical information presented at the conference were about new treatments for melanoma, with an emphasis on PD-1 treatments; and advances in the treatment of cervical cancer, particularly **Avastin**.

Of the 100 attendees surveyed, 66 percent rated the info presented on **Genentech/Roche**'s Avastin as very or extremely valuable. Information on **Bayer/Onyx** Pharmaceuticals' **Nexavar** in thyroid cancer received the second-highest rating, with 58 percent of the attendees saying it was valuable to them.

Also receiving high ratings were nivolumab in lung, melanoma and kidney cancer, with 57 percent of those surveyed finding the information valuable; **Merck** & Co.'s **lambrolizumab** (product code MK-3475) for advanced melanoma, with 54 percent finding the information of value; Janssen Biotech's **Zytiga** (abiraterone acetate) in castrate-resistant prostate cancer, with 53 percent finding the information valuable; Bristol-Myers Squibb's **Yervoy** (ipilimumab) in melanoma, with 53 percent finding the info of value; Genentech/Roche's **MPDL3208A** in advanced lung, skin, kidney, and other cancers; **GlaxoSmithKline**'s **trametinib** in melanoma and **dabrafenib** in metastatic melanoma with 49 percent saying the information on each was valuable; and Genentech/**Daiichi Sankyo**'s **Zelboraf** (vemurafenib) in melanoma, also with 49 percent finding the info valuable. (For more information about Janssen's oncology pipeline and Zytiga, see the Q&A below with John Wilson, VP of Sales & Marketing, Oncology, for Janssen Biotech.)

Surprisingly, oncologists told Encuity researchers that ASCO 2013 had significantly less of an impact on their future behavior than the 2012 conference. Just 16 percent of attendees from this year's ASCO reported that they are likely to change

Q&A with Janssen Biotech

Med Ad News spoke with John Wilson, VP of Sales & Marketing for Janssen Biotech, about the company's oncology pipeline, its R&D endeavors, its development of cancer diagnostics, and coordination of the development and commercialization teams.

Med Ad News: What was your goal for your presentations at ASCO? Do you believe that you met that goal?

John Wilson: Zytiga data presented by key opinion leaders at ASCO includes additional analyses from both our COU-AA-301 trial in chemo-refractory patients and COU-AA-302 trial in chemo-naïve patients. These data further support use of Zytiga for the treatment of patients with mCRPC (metastatic castration-resistant prostate cancer). Zytiga plus prednisone resulted in a 57 percent reduction in the risk of radiographic progression or death in this clinical trial of mCRPC. It also delayed the median time to opiate use for prostate cancer pain, and increased the median time to chemotherapy. Much of the safety information was consistent with what was observed earlier in the post-docetaxel trial.

Med Ad News: What were you hearing from physicians at ASCO about your oncology pipeline? What unmet needs are you trying to meet, and based on feedback gathered from ASCO, do you believe you are meeting those needs?

John Wilson: In terms of our portfolio, physicians saw that what we have said about our strategy and our focus is paying off. Our focus on disease area strongholds, particularly in prostate cancer and hematologic malignancies, has enabled us to maximize the expertise we have cultivated across our organization, putting us in a unique position to potentially provide solutions for patients across the full continuum of cancer care.

Med Ad News: What oncology areas have you made breakthroughs in?

John Wilson: Our priority areas of development in the U.S. include prostate cancer and hematologic malignancies. Within these areas, we are keenly interested in identifying new targets for drug development. Understanding the tumor microenvironment will help us deliver innovative solutions – Zytiga is an example of where we successfully brought to market an innovative treatment option in mCPRC, while ibrutinib is an example of a promising investigational compound for certain B-cell (hematologic) malignancies, being developed with Pharmacyclics.

Med Ad News: What is coming up in your pipeline that you are particularly excited about right now and why?

John Wilson: We are very excited about ibrutinib, which we are jointly developing with Pharmacyclics. Ibrutinib received three breakthrough therapy designations from the FDA earlier this year, and we have recently taken a major step forward in our development program for ibrutinib with the filing of a new drug application with the U.S. Food and Drug Administration for previously treated patients with chronic lymphocytic leukemia/small lymphocytic lymphoma and previously treated patients with mantle cell lymphoma. If approved, it would provide a much-needed option for these patients.

We are also excited about daratumumab, through our licensing agreement with Genmab. It also was recently granted breakthrough therapy designation for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy, including a proteasome inhibitor and an immunomodulatory agent or who are double refractory to a PI and an IMiD.

Med Ad News: What are your development goals with Zytiga?

John Wilson: In December 2012, the U.S. FDA approved an expanded use of Zytiga to treat men with metastatic castration-resistant prostate cancer prior to receiving chemotherapy. In prostate cancer, androgens – which are primarily produced in the testes and adrenal glands – play a significant role. In castration-resistant prostate cancer, the tumor itself can be a source of androgen production. Zytiga is an important option for patients in this later stage of disease where there are limited options approved for use following progression on androgen deprivation therapy.

There are ongoing Zytiga studies outside the U.S. for breast cancer.

As noted earlier, prostate cancer is an important area of focus for Janssen. We are also cultivating collaborations to explore additional innovative approaches to treat prostate cancer patients.

Med Ad News: Tell me more about the incorporation of biomarker-based diagnostics as part of drug development. Can you point to any products in the pipeline that are being developed concurrently with diagnostics?

John Wilson: Biomarkers are an increasingly important part of our R&D group's development activities. We see enormous potential in transforming predictive biomarkers into companion diagnostic tests to help guide targeted, individualized use of our therapies. For instance, Janssen Diagnostics is leading the use of CTC technologies and focuses on supporting our efforts to bring complementary and companion diagnostics to market beyond CTCs.

We, along with Pharmacyclics, are collaborating with Abbott as they develop a FISH-based companion diagnostic test to identify high-risk CLL patients who have a deletion within a specific chromosome (del17p) and may respond to our investigational compound, ibrutinib.

Med Ad News: When it comes to marketing oncology drugs, what role if any do the marketing teams play in the development process?

John Wilson: One of the things that differentiates our approach at Janssen is that all functional areas supporting the therapeutic area are involved in the development process. Our disease area strategy engages all teams to work collaboratively, with joint accountability on key decisions in the development process.

We therefore work closely with our global commercial and R&D partners early on in the process to ensure we are beginning the important foundational work at the appropriate times, from disease education to gaining market insights. The work of market preparation, developing patient access programs, and other clinical elements are essential to ensuring readiness at launch.

Med Ad News: What kinds of partnerships are you seeking in oncology drug development? What are some of your particularly noteworthy partnerships?

John Wilson: Janssen fosters strategic alliances with external industry partners who share a passion for innovation and transforming treatment paradigms for populations where unmet medical needs continue to exist, in the areas of immunology and oncology.

These partnerships are a building block of our business strategy – mainly for the ongoing need to develop and offer new treatment solutions to our patients in need. There are many factors when embarking on a new collaboration, including looking for partners that have a culture that is compatible with ours. The focus must be on the patient with differentiated products that prove real value. This tends to build trust in the alliance and real synergy in what we can accomplish.

Some of our notable recent collaborations include our work with Cougar to develop Zytiga and our more recent collaboration with Pharmacyclics to develop ibrutinib.

patient treatments, compared with 40 percent in 2012.

Among the products that had the strongest impact on physicians were Avastin, with 22 percent of physicians saying they will consider using more of it following the conference; **Erbitux**, with 10 percent of physicians saying they would use it more; and 9 percent of physicians said they planned to extend the use of **AstraZeneca**'s **Nolvadex** (tamoxifen) to 10 years versus the current standard of five years.

When asked which companies provided the most valuable information at the conference, Genentech was mentioned the most frequently, garnering mentions from 84 percent of those surveyed, followed by Bristo-Myers Squibb with 43 percent of mentions. **Novartis** ranked third with 29 percent of mentions; Merck ranked fourth with 20 percent, followed by **Celgene** with 16 percent of mentions. Also among the top 10 were **Amgen** and **Pfizer**, each with 15 percent of the mentions; Bayer with 10 percent of the mentions; GlaxoSmithKline with 8 percent of the mentions; and Janssen/**Johnson & Johnson** and **Eli Lilly**, each with 6 percent of the mentions.

Millennium was cited most often as an up-and-coming company in treating cancer with 13 percent of attendee mentions. **Seattle Genetics** followed, garnering 11 percent of the mentions. **Sanofi**, Pharmacyclics, Onyx, and **Astellas** each got 9 percent of the mentions.

According to Encuity, more than two thirds of physicians indicated that they visited the exhibit hall at the 2013 conference. Of the attendees surveyed, 29 percent indicated that Genentech/Roche had the most effective exhibit booth, followed by Bristol-Myers Squibb at 10 percent and Amgen at 8 percent. About 5 percent of attendees each rated Pfizer's, Novartis', and Celgene's booth as most effective.

When asked to rate the product info they heard, with 1 being "not valuable" and 7 being "extremely valuable," 44 percent of those surveyed gave Novartis' **Afinitor** and Pfizer's **Sutent** in metastatic renal cell carcinoma a 6 or 7. Oncologists ranked info for **Merrimack** Pharmaceuticals' **MM-398** in pancreatic cancer, colorectal cancer, and glioma, and Amgen's **T-VEC** (talimogene laherparepvec) for melanoma among the least valuable, with 26 percent in each case rating it a 6 or 7. ■ MEDADNEWS

TOP-SELLING ONCOLOGY PRESCRIPTION MEDICINES BY 2012 GLOBAL SALES

Medicine	2012 sales ($ in millions)	2011 sales ($ in millions)	2010 sales ($ in millions)	2012 reporting company	Primary disease/medical use	First approval date and/or launch date
Rituxan/MabThera	7,153+	6,404+	6,778+	Roche, Chugai Pharmaceutical, Zenyaku Kogyo *Note: Biogen Idec reports U.S. joint-promotion profit.*	Non-Hodgkin's lymphoma	Rituxan U.S. approval: Nov. 26, 1997 MabThera EU approval: June 2, 1998 Rituxan Japan launch: September 2001
Herceptin	6,280	5,602	5,790	Roche and Chugai Pharmaceutical	Breast cancer	U.S. approval: Sept. 25, 1998 Japan launch: June 2001
Avastin	6,147	5,644	6,890	Roche and Chugai Pharmaceutical	Colorectal cancer	U.S. approval: Feb. 26, 2004 Japan launch: June 2007
Gleevec/Glivec	4,675	4,659	4,265	Novartis	Leukemia	Gleevec U.S. approval: May 10, 2001
Revlimid	3,767	3,208	2,469	Celgene	Multiple myeloma and myelodysplastic syndrome	U.S. approval: Dec. 27, 2005
Alimta	2,594	2,461	2,209	Eli Lilly	Non-small cell lung cancer	U.S. approval: Feb. 4, 2004
Velcade	2,269	1,887	1,616	Johnson & Johnson and Takeda Pharmaceutical	Multiple myeloma	U.S. approval: May 13, 2003
Lupron/Leuplin (leuprolide)	2,029	2,084	1,976	Takeda Pharmaceutical and Abbott Laboratories	Prostate cancer	Lupron U.S. approval: April 9, 1985 Leuplin Japan launch: September 1992
Erbitux	1,843	1,790	1,716	Bristol-Myers Squibb and Merck KGaA *Note: Eli Lilly receives Erbitux net royalties.*	Colorectal cancer	EU Approval: Dec. 1, 2003 (Switzerland) U.S. approval: Feb. 12, 2004
Tarceva	1,786	1,690	1,672	Roche, Chugai Pharmaceutical, Astellas Pharma	Non-small cell lung cancer	U.S. launch: Nov. 22, 2004 Japan launch: Dec. 18, 2007
Gardasil	1,631	1,209	988	Merck & Co.	Cervical cancer	U.S. approval: June 8, 2006
Xeloda	1,624	1,444	1,521	Roche and Chugai Pharmaceutical	Cancer	U.S. approval: April 30, 1998
Sutent	1,236	1,187	1,066	Pfizer	Cancer	U.S. approval: Jan. 26, 2006
Eloxatin/Eloxatine	1,229	1,377	549	Sanofi	Colorectal cancer	France launch: September 1996 U.S. approval: Aug. 9, 2002
Sprycel	1,146	883	660	Bristol-Myers Squibb and Otsuka Pharmaceutical	Leukemia	U.S. launch: July 2006 Japan launch: March 2009
Zoladex	1,100	1,186	1,123	AstraZeneca and Kissei Pharmaceutical	Prostate cancer, breast cancer, endometriosis	U.S. approval: Dec. 29, 1989
Nexavar	1,018	932	907	Bayer *Note: Bayer and Onyx Pharmaceuticals co-promote Nexavar in the United States. Bayer recognizes all revenue from the sale of Nexavar.*	Advanced kidney cancer and liver cancer	U.S. launch: Dec. 21, 2005
Tasigna	998	716	399	Novartis	Chronic myeloid leukemia	U.S. and EU launches: Fourth-quarter 2007
Zytiga	961	301	0	Johnson & Johnson	Prostate cancer	U.S. approval: April 28, 2011 U.S. launch: 2011
Temodar	917	935	1,065	Merck & Co.	Brain tumors	U.S. approval: Aug. 11, 1999
Vidaza	823	705	534	Celgene	Myelodysplastic syndrome	U.S. launch: July 1, 2004
Afinitor/Votubia	797	443	243	Novartis	Afinitor: Renal cell carcinoma Votubia: Subependymal giant cell astrocytomas associated with tuberous sclerosis complex	Afinitor U.S. approval/launch: March 30, 2009 Votubia Switzerland approval: May 11, 2011
Xgeva	748	351	8	Amgen	Cancer-related bone loss	U.S. approval: Nov. 18, 2010
Taxotere	724	1,186	2,729	Sanofi	Breast, lung, prostate, head/neck, ovarian, gastritic, esophageal, endometrial cancer	EU approval: Oct. 27, 1995 U.S. approval: May 14, 1996
Yervoy	706	360	0	Bristol-Myers Squibb	Metastatic melanoma	U.S. approval: March 2011 U.S. launch: 2Q 2011 EU approval: July 2011
Faslodex	654	546	345	AstraZeneca	Breast cancer	U.S. approval: April 25, 2002
Iressa	611	554	393	AstraZeneca	Nonsmall cell lung cancer	U.S. approval: May 5, 2003

TOP-SELLING ONCOLOGY PRESCRIPTION MEDICINES BY 2012 GLOBAL SALES

Medicine	2012 sales ($ in millions)	2011 sales ($ in millions)	2010 sales ($ in millions)	2012 reporting company	Primary disease/medical use	First approval date and/or launch date
Treanda	608	505 (estimate)	393	Teva Pharmaceutical Industries	Chronic lymphocytic leukemia	U.S. launch: April 2008
Vectibix	557	503	387	Amgen and Takeda Pharmaceutical	Colorectal cancer	U.S. approval: Sept. 27, 2006
Arimidex	543	756	1,512	AstraZeneca	Breast cancer	U.S. approval: Dec. 27, 1995 U.S. launch: January 1996

NOTES/LEGEND:

- This chart presents the top-selling oncology medicines in order by their full-year 2012 sales. Certain products are represented by more than one company due to joint-marketing or joint-promotion accords. Joint-promotion profit or royalty revenue is not included in product sales totals.

*** All foreign product sales are reported in U.S. dollars using Federal Reserve exchange rates. The 2012 average exchange rates were used to translate all figures.**

* First approval date or launch date = anywhere worldwide; in some instances, additional approval and launch dates are provided.

*** Estimate = sales were not provided by company or found by *Med Ad News* editors, who made an estimate based on previous-year figures and/or other information provided.**

* + = Sales are assumed to be higher than the represented total.

*** Product entries may have their (chemical) listed depending on where and under which name the drug is marketed, or how the company reports the drug's sales.**

* All Japanese company 2012 product sales are for the fiscal year ended March 31, 2013 (2011 = year ended March 31, 2012; 2010 = year ended March 31, 2011), except for Chugai Pharmaceutical, which reports annual sales on a Dec. 31 calendar-year basis.

ONCOLOGY PRODUCTS IN LATE-STAGE DEVELOPMENT

Product	Chemical	Disease/Medical Use	Country	Company
Awaiting Approval				
Abraxane	Paclitaxel protein-bound particles (albumin-bound)	Pancreatic cancer	United States	Celgene
Adcetris	Brentuximab vedotin	Hodgkin's lymphoma	United States, Japan	Seattle Genetics and Millennium: The Takeda Oncology Company
Afatinib	Afatinib	Non-small cell lung cancer	European Union	Boehringer Ingelheim
Alpharadin	Radium-223 dichloride	Hormone-refractory prostate cancer	European Union	Bayer HealthCare Pharmaceuticals and Algeta
Amrubicin Hydrochloride	Amrubicin hydrochloride	Small cell lung cancer	China	Dainippon Sumitomo Pharma
Avastin	Bevacizumab	Glioblastoma multiforme, ovarian cancer	United States	Hoffmann-La Roche
Avastin	Bevacizumab	Ovarian cancer	Japan	Chugai Pharmaceutical
Caprelsa	Vandetanib	Medullary thyroid cancer	Japan	AstraZeneca
DC Bead	—	Liver cancer	China	SciClone Pharmaceuticals
Erbitux	Cetuximab	Head and neck cancer	China	Merck Serono
FOLFIRINOX regimen	Oxaliplatin, irinotecan hydrochloride, fluorouracil, and levofolinate calcium	Pancreatic cancer	Japan	Yakult Honsha
Halaven	Eribulin mesylate	Breast cancer	European Union	Eisai
Herceptin	Trastuzumab	Breast cancer	European Union	Hoffmann-La Roche and Halozyme Therapeutics
Ibrutinib	Ibrutinib	Mantle cell lymphoma, chronic lymphocytic leukemia, small lymphocytic leukemia	United States	Janssen Biotech and Pharmacyclics
Kadcyla	Trastuzumab-DM1	Breast cancer	European Union	Roche
MabThera	Rituximab	Non-Hodgkin's lymphoma	European Union	Biogen Idec and Roche
Masitinib	Masitinib	Pancreatic cancer and gastrointestinal stromal tumors	European Union	AB Science
Mechlorethamine	Mechlorethamine hydrochloride	Cutaneous T-cell lymphoma	United States	Ceptaris Therapeutics
Nexavar	Sorafenib tosylate	Thyroid cancer	United States, European Union	Onyx Pharmaceuticals and Bayer HealthCare Pharmaceuticals
Obinutuzumab	Obinutuzumab	Chronic lymphocytic leukemia	United States, European Union	Roche and Biogen Idec
Perjeta	Pertuzumab	Breast cancer	United States	Hoffmann-La Roche
Provenge	Sipuleucel-T	Prostate cancer	European Union	Dendreon
Ramucirumab	Ramucirumab	Gastric cancer	United States	Eli Lilly
Tafinlar	Dabrafenib	Melanoma	United States, European Union	GlaxoSmithKline
Tarceva	Erlotinib hydrochloride	Non-small cell lung cancer	European Union	Hoffmann-La Roche and Astellas Pharma
TAS-102	Trifluorothymidine and ipiracil hydrochloride	Colorectal cancer	United States, Japan	Taiho Pharma USA and Taiho Pharmaceutical
Tivopath	Tivozanib	Renal cell carcinoma	United States	AVEO Pharmaceuticals and Astellas Pharma US
Trametinib	Trametinib	Melanoma	European Union	GlaxoSmithKline
Trametinib/Dabrafenib Combination	Trametinib and dabrafenib	Melanoma	United States, European Union	GlaxoSmithKline
Trastuzumab Emtansine	Trastuzumab emtansine	Breast cancer	Japan	Chugai Pharmaceutical
Tyverb	Lapatinib	Breast cancer	European Union	GlaxoSmithKline
Velcade	Bortezomib	Multiple myeloma	European Union	Johnson & Johnson Pharmaceutical Research & Development and Millennium: The Takeda Oncology Company
Vintafolide	Vintafolide	Ovarian cancer	European Union	Merck
Votrient	Pazopanib hydrochloride	Renal cell carcinoma	Japan	GlaxoSmithKline
Phase III Development				
Abraxane	Paclitaxel protein-bound particles (albumin-bound)	Metastatic melanoma	United States	Celgene

ONCOLOGY PRODUCTS IN LATE-STAGE DEVELOPMENT

Product	Chemical	Disease/Medical Use	Country	Company
Adcetris	Brentuximab vedotin	Hodgkin's lymphoma, mature T-cell malignancies	United States, European Union	Seattle Genetics and Millennium: The Takeda Oncology Company
Adcetris	Brentuximab vedotin	CD30-positive cutaneous T-cell lymphoma	United States	Seattle Genetics and Millennium: The Takeda Oncology Company
Adcetris	Brentuximab vedotin	Post-ASCT Hodgkin's lymphoma, cutaneous T-cell lymphoma	European Union	Seattle Genetics and Millennium: The Takeda Oncology Company
ADI-PEG 20	—	Hepatocellular carcinoma	United States	Polaris Pharmaceuticals
AEZS-108	Zoptarelin doxorubicin	Endometrial cancer	United States, European Union	AEterna Zentaris
Afinitor	Everolimus	Lymphoma, breast cancer, hepatocellular cancer, non-functional neuroendocrine tumors	United States	Novartis Pharmaceuticals
AGS-003	—	Renal cell carcinoma	United States	Argos Therapeutics and Kyowa Hakko Kirin Pharma
Algenpatucel-L	Algenpatucel-L	Pancreatic cancer	United States	NewLink Genetics
Allovectin-7	DNA/lipid complex containing the human gene encoding HLA-B7	Metastatic melanoma	United States	Vical and AnGes
AMG 386	Trebananib	Ovarian cancer	United States	Amgen
AMG 386	Trebananib	Ovarian cancer	Japan	Takeda Pharmaceutical
AMG 479	Ganitumab	Pancreatic cancer	Japan	Takeda Pharmaceutical
Apaziquone	Apaziquone	Bladder cancer	United States	Spectrum Pharmaceuticals
Aplidin	Aplidine	Multiple myeloma	United States	PharmaMar USA
ARRY-380	—	Cancer	United States	Array BioPharma and Oncothyreon
Arzerra	Ofatumumab	Follicular lymphoma, diffuse large B-cell lymphoma, chronic lymphocytic leukemia	United States, European Union	Genmab and GlaxoSmithKline
Avastin	Bevacizumab	Ovarian cancer, non-small cell lung cancer, breast cancer, high-risk carcinoid	United States	Hoffmann-La Roche
Avastin	Bevacizumab	Breast cancer, non-small cell lung cancer, ovarian cancer	European Union	Roche
Avastin	Bevacizumab	Breast cancer, glioblastoma	Japan	Chugai Pharmaceutical
Bavituximab Anti-Cancer	Bavituximab	Non-small cell lung cancer	United States	Peregrine Pharmaceuticals
BBI608	—	Colorectal cancer	United States, Canada	Dainippon Sumitomo Pharma
BiovaxID	—	Follicular non-Hodgkin lymphoma	United States, European Union, Canada	Biovest International
BKM120	Buparlisib	Breast cancer	United States	Novartis Oncology
Caprelsa	Vandetanib	Medullary thyroid cancer	Japan	AstraZeneca
Ceplene	Histamine dihydrochloride	Acute myeloid leukemia	United States	EpiCept
ch14.18 MAb	—	Neuroblastoma	European Union	Apeiron Biologics
ch14.18 MAb	—	Neuroblastoma	United States	United Therapeutics
CPX-351	Cytarabine and danorubicin	Acute myeloid leukemia	United States	Celator Pharmaceuticals
CVac	—	Ovarian cancer	United States	Prima BioMed
Dacomitinib	Dacomitinib	Non-small cell lung cancer	United States	Pfizer
DCVax-L	—	Glioblastoma multiforme	United States, European Union	Northwest Biotherapeutics
DCVax-Prostate	—	Prostate cancer	United States	Northwest Biotherapeutics
DE-766	Nimotuzumab	Gastric cancer, non-small cell lung cancer	Japan	Daiichi Sankyo
Debio 8206 SC	Triptorelin	Prostate cancer	South Africa	Debiopharm
Decapeptyl	Triptorelin pamoate	Breast cancer	European Union	Debiopharm and Ipsen
Degarelix Three Month Formulation	Degarelix acetate	Prostate cancer	Japan	Astellas Pharma
Denosumab	Denosumab	Breast cancer	Japan	Daiichi Sankyo
E7080	Lenvatinib	Thyroid cancer, hepatocellular carcinoma	United States, European Union, Japan, Canada	Eisai and SFJ Pharmaceuticals
Elotuzumab	Elotuzumab	Multiple myeloma	United States	AbbVie and Bristol-Myers Squibb
Elplat	Oxaliplatin	Gastric cancer	Japan	Yakult Honsha
Erbitux	Cetuximab	Esophageal cancer	United States	Eli Lilly
Faslodex	Fulvestrant	Breast cancer	United States, European Union, Japan, China	AstraZeneca
Forodesine	Forodesine hydrochloride	Cutaneous T-cell lymphoma	United States	Mundipharma International
GA101/RG7159	Obinutuzumab	Indolent non-Hodgkin's lymphoma, aggressive non-Hodgkin's lymphoma	Japan	Chugai Pharmaceutical and Biogen Idec
Gilotrip	Afatinib	Head and neck cancer	United States	Boehringer Ingelheim Pharmaceuticals
Glufosfamide	Glufosfamide	Pancreatic cancer	United States	Eleison Pharmaceuticals
GV1001	Telomerase	Pancreatic cancer	United Kingdom	KAEL-GemVax
HA-Irinotecan	Irinotecan	Colorectal cancer	Australia	Alchemia
Halaven	Eribulin mesylate	Non-small cell lung cancer, sarcoma, breast cancer	United States	Eisai
Halaven	Eribulin mesylate	Non-small cell lung cancer, sarcoma	European Union	Eisai
Halaven	Eribulin mesylate	Non-small cell lung cancer	Japan	Eisai
Ibrutinib	Ibrutinib	Chronic lymphocytic leukemia	United States, European Union	Janssen Biotech and Pharmacyclics
Ibrutinib	Ibrutinib	Mantle cell lymphoma	European Union	Janssen Biotech and Pharmacyclics
Iclusig	Ponatinib	Chronic myeloid leukemia	United States	Ariad Pharmaceuticals
Idelalisib	Idelalisib	Chronic lymphocytic leukemia, indolent non-Hodgkin's lymphoma	United States	Gilead Sciences
IMA901	—	Renal cell cancer	United States, European Union	immatics biotechnologies
Imprime PGG	—	Colorectal cancer	United States	Biothera

ONCOLOGY PRODUCTS IN LATE-STAGE DEVELOPMENT

Product	Chemical	Disease/Medical Use	Country	Company
Inlyta	Axitinib	Renal cell carcinoma	Japan	Pfizer
Inotuzumab Ozogamicin	Inotuzumab ozogamicin	Acute lymphoblastic leukemia	United States	Pfizer
Iressa	Gefitinib	Non-small cell lung cancer	United States, European Union, Japan, China	AstraZeneca
Jevtana	Cabazitaxel	Prostate cancer	United States	Sanofi US
Kadcyla	Trastuzumab-DM1	Breast cancer	United States, European Union	Roche
KW-0761	Mogamulizumab	Cutaneous T-cell lymphoma	United States	Kyowa Hakko Kirin Pharma
Kyprolis	Carfilzomib	Multiple myeloma	United States, European Union	Onyx Pharmaceuticals
Leuplin 6 Month Depot	Leuprorelin acetate	Prostate cancer, breast cancer	Japan	Takeda Pharmaceutical
Livatag	Doxorubicin	Hepatocellular carcinoma	France	BioAlliance Pharma
LX1032	Telotristat etiprate	Carcinoid syndrome	United States, European Union	Lexicon Pharmaceuticals
MAGE-A3 Immunotherapeutic	—	Non-small cell lung cancer, melanoma	United States, European Union	GlaxoSmithKline
Masitinib	Masitinib	Metastatic melanoma, mastocytosis	France	AB Science
Masitinib	Masitinib	Multiple myeloma, mastocytosis	United States	AB Science
Mepact	Mifamurtide	Osteosarcoma	United States	Millennium: The Takeda Oncology Company
MetMAb/RG3638	Onartuzumab	Non-small cell lung cancer	Japan	Chugai Pharmaceutical
MLN8237	Alisertib	Peripheral T-cell lymphoma	United States, European Union	Millennium: The Takeda Oncology Company
MLN9708 Oral	Ixazomib citrate	Multiple myeloma, amyloidosis	United States, European Union	Millennium: The Takeda Oncology Company
MORAb-003	Farletuzumab	Platinum-sensitive ovarian cancer	United States, European Union, Japan	Morphotek
Motesanib	Motesanib diphosphate	Non-squamous non-small cell lung cancer	Japan	Amgen and Takeda Pharmaceutical
Multikine	Interleukin-2	Head and neck cancer	United States, Canada, Russia, Taiwan, India, Israel, Poland	Cel-Sci
Necitumumab	Necitumumab	Squamous non-small cell lung cancer	United States	Eli Lilly
Neratinib	Neratinib	Breast cancer	United States	Puma Biotechnology
Nexavar	Sorafenib tosylate	Liver cancer, kidney cancer, breast cancer	United States	Onyx Pharmaceuticals and Bayer HealthCare Pharmaceuticals
Nexavar	Sorafenib tosylate	Breast cancer	European Union	Onyx Pharmaceuticals and Bayer HealthCare Pharmaceuticals
NGR015	—	Mesothelioma	European Union	MolMed
NIK-333	Peretinoin	Liver cancer	Japan	Kowa
Nintedanib	Nintedanib	Non-small cell lung cancer, ovarian cancer, colorectal cancer, liver cancer, kidney cancer	European Union	Boehringer Ingelheim
Nintedanib	Nintedanib	Non-small cell lung cancer	United States	Boehringer Ingelheim Pharmaceuticals
NKTR-102	Etirinotecan pegol	Breast cancer	United States	Nektar Therapeutics
Obinutuzumab	Obinutuzumab	Indolent non-Hodgkin's lymphoma, non-Hodgkin's lymphoma, diffuse large B-cell lymphoma	United States	Hoffmann-La Roche and Biogen Idec
OGX-011/TV-1011	Custirsen sodium	Non-small cell lung cancer, castrate-resistant prostate cancer	United States	OncoGenex Pharmaceuticals and Teva Pharmaceuticals USA
OGX-011/TV-1011	Custirsen sodium	Castrate-resistant prostate cancer	European Union	OncoGenex Pharmaceuticals and Teva Pharmaceutical Industries
OncoVAX	—	Colorectal cancer	United States	Vaccinogen
ONO-4538/BMS-936558	Nivolumab	Melanoma	United States	Bristol-Myers Squibb and Ono Pharma USA
ONO-4538/BMS-936558	Nivolumab	Renal cell cancer, non-small cell lung cancer	United States	Bristol-Myers Squibb and Ono Pharma USA
ONO-4538/BMS-936558	Nivolumab	Renal cell carcinoma	Japan	Ono Pharmaceutical
Opaxio	Paclitaxel poliglumex	Ovarian cancer	United States	Cell Therapeutics
Orazol	Zoledronic acid	Bone metastases	European Union	Merrion Pharmaceuticals
Orazol	Zoledronic acid	Breast cancer	United States	Merrion Pharmaceuticals
Orteronel	Orteronel	Prostate cancer	United States, Japan, European Union	Millennium: The Takeda Oncology Company
Pacritinib	Pacritinib	Myelofibrosis	United States	Cell Therapeutics
Panobinostat	Panobinostat	Multiple myeloma	United States	Novartis Oncology
PD-0332991	Palbociclib	Breast cancer	United States	Pfizer
Perjeta	Pertuzumab	Breast cancer	United States, European Union	Roche
Perjeta	Pertuzumab	Breast cancer	Japan	Chugai Pharmaceutical
PKC412	Midostaurin	Acute myeloid leukemia	United States	Novartis Oncology
POL 103A	—	Melanoma	United States	Polynoma
ProstAtak	—	Prostate cancer	United States	Advantagene
Prostvac	—	Prostate cancer	United States	Bavarian Nordic
Provecta	—	Metastatic melanoma	United States	Provectus Pharmaceuticals
Ramucirumab	Ramucirumab	Breast cancer, colorectal cancer	United States	Eli Lilly
Redectane	—	Renal cell cancer	United States	Wilex
Rencarex	Girentuximab	Non-metastatic renal cell cancer	United States	Prometheus Laboratories
Rencarex	Girentuximab	Non-metastatic renal cell cancer	European Union	Wilex
Reolysin	Pelareorep	Head and neck cancer	United States, United Kingdom, Canada	Oncolytics Biotech
Revlimid	Lenalidomide	Myelodysplastic syndrome, chronic lymphocytic leukemia	United States	Celgene
RG3638	Onartuzumab	Non-small cell lung cancer	United States	Hoffmann-La Roche

ONCOLOGY PRODUCTS IN LATE-STAGE DEVELOPMENT

Product	Chemical	Disease/Medical Use	Country	Company
Rigosertib	Rigosertib	Myelodysplastic syndrome, pancreatic cancer	United States	Onconova Therapeutics
Rigosertib	Rigosertib	Myelodysplastic syndrome	European Union	Onconova Therapeutics and Baxter International
Rilotumumab	Rilotumumab	Cancer	United States	Amgen Astellas BioPharma
Rindopepimut	Rindopepimut	Glioblastoma multiforme	United States	Celldex Therapeutics
Rituximab	Rituximab	Follicular lymphoma	United States	Sandoz
S-1	Tegafur, gimeracil and oteracil	Gastric cancer	United States	Taiho Pharma USA
S-1	Tegafur, gimeracil and oteracil	Uterocervical cancer, hepatocellular cancer	Japan	Taiho Pharmaceutical
Sapacitabine	Sapacitabine	Acute myeloid leukemia	United States	Cyclacel Pharmaceuticals
SAR302503	—	Myelofibrosis	United States	Sanofi US
Somatuline	Lanreotide acetate	Functioning neuroendocrine tumors	United States	Ipsen
Somatuline Autogel	Lanreotide acetate	Nonfunctioning neuroendocrine tumors	United States	Ipsen
SP1049C	—	Gastrointestinal tract adenocarcinoma	United States	Supratek Pharma
Stimuvax	—	Non-small cell lung cancer	United States, European Union	Merck Serono
Stivarga	Regorafenib	Colorectal cancer	European Union, Australia, Israel	Bayer HealthCare Pharmaceuticals
Stivarga	Regorafenib	Gastrointestinal stromal tumors	United States	Bayer HealthCare Pharmaceuticals
Sutent	Sunitinib malate	Renal cell carcinoma	United States	Pfizer
Tabalumab	Tabalumab	Multiple myeloma	United States	Eli Lilly
Talimogene	Talimogene laherparepvec	Melanoma	United States	Amgen
Tarceva	Erlotinib hydrochloride	Non-small cell lung cancer, colorectal cancer, pediatric ependymona	United States	Hoffmann-La Roche and Astellas Pharma US
TAS-102	—	Colorectal cancer	European Union	Taiho Pharma USA
Tasigna	Nilotinib	Melanoma	United States	Novartis Oncology
Tasquinimod	Tasquinimod	Prostate cancer	United States, Sweden	Active Biotech and Ipsen
Telcyta	Canfosfamide hydrochloride	Ovarian cancer	United States	Telik
TH-302	—	Soft tissue sarcoma, pancreatic cancer	United States	Threshold Pharmaceuticals and EMD Serono
TH-302	—	Pancreatic cancer, soft tissue sarcoma	European Union	Threshold Pharmaceuticals and Merck Serono
ThermoDox	Doxorubicin	Hepatocellular carcinoma	United States	Celsion
ThermoDox	Doxorubicin	Hepatocellular carcinoma	Japan	Yakult Honsha
Tivantinib	Tivantinib	Hepatocellular carcinoma	United States, European Union	ArQule and Daiichi Sankyo
Tivopath	Tivozanib	Renal cell carcinoma	European Union	AVEO Pharmaceuticals and Astellas Pharma
TK008	—	Leukemia	United States, European Union	MolMed
TKI258	Dovitinib lactate	Renal cell carcinoma	United States	Novartis Oncology
Trametinib/Dabrafenib Combination	Trametinib and dabrafenib	Melanoma	United States, European Union	GlaxoSmithKline
Trastuzumab Emtansine	Trastuzumab emtansine	Breast cancer	Japan	Chugai Pharmaceutical
TS-1	Tegafur, gimeracil and oteracil	Uterocervical cancer	Korea	Taiho Pharmaceutical
TS-1	Tegafur, gimeracil and oteracil	Uterocervical cancer	Singapore	Taiho Pharmaceutical
TSU-68	Orantinib	Hepatocellular carcinoma	Japan	Taiho Pharmaceutical
Tykerb	Lapatinib	Head and neck cancer, breast cancer	United States, European Union	GlaxoSmithKline
Vectibix	Panitumumab	Colorectal cancer	United States	Amgen
Velcade	Bortezomib	Mantle cell lymphoma	European Union	Johnson & Johnson Pharmaceutical Research & Development and Millennium: The Takeda Oncology Company
Velcade	Bortezomib	Mantle cell lymphoma	United States	Millennium: The Takeda Oncology Company
Vidaza	Azacitidine	Acute myelogenous leukemia	European Union	Celgene
Vintafolide	Vintafolide	Ovarian cancer	United States	Merck
Volasertib	Volasertib	Acute myeloid leukemia	European Union	Boehringer Ingelheim
Vosaroxin	Vosaroxin	Acute myeloid leukemia	United States, European Union	Sunesis Pharmaceuticals
Votrient	Pazopanib hydrochloride	Ovarian cancer, renal cell carcinoma	United States	GlaxoSmithKline
Votrient	Pazopanib hydrochloride	Ovarian cancer	European Union	GlaxoSmithKline
Xalkori	Crizotinib	Non-small cell lung cancer	United States	Pfizer
XL184	Cabozantinib	Castrate resistant prostate cancer	United States	Exelixis
Xtandi	Enzalutamide	Prostate cancer	United States, European Union, Japan	Medivation and Astellas Pharma
Yervoy	Ipilimumab	Prostate cancer, squamous non-small cell lung cancer, metastatic melanoma, prostate cancer, small cell lung cancer	United States	Bristol-Myers Squibb
Yondelis	Trabectedin	Ovarian cancer, soft tissue sarcoma	United States	PharmaMar USA and Johnson & Johnson Pharmaceutical Research & Development
Yondelis	Trabectedin	Soft tissue sarcoma	European Union	PharmaMar and Johnson & Johnson Pharmaceutical Research & Development
Zaltrap	Aflibercept	Colorectal cancer	United States	Regeneron Pharmaceuticals and Sanofi US
Zevalin	Ibritumomab tiuxetan	Diffuse large B-cell lymphoma	United States	Spectrum Pharmaceuticals
Zybrestat	Fosbretabulin	Anaplastic thyroid cancer	United States	Oxigene
Zymafos	Palifosfamide	Small cell lung cancer	United States	Ziopharm Oncology

Prying eyes want to know

Drug makers could get a marketing lift by disclosing more clinical trial data.

By Ed Silverman ed.silverman@ubm.com

Earlier this year, the National Institutes of Health ran a workshop to examine the safety of several widely used diabetes drugs called GLP-1 inhibitors and whether a definitive link can be established to acute pancreatitis and pancreatic cancer, which were the subject of a pair of recent studies that generated considerable controversy and raised fresh concerns in the medical community.

The outcome was inconclusive – it remains unclear if FDA will want new studies. But the American Diabetes Association did not wait for the session to end to take a stand. In an unexpected move, the organization called for several drug makers that sell these widely used medications – such as the **Januvia** pill marketed by **Merck** – to release patient-level data from their various studies over the years.

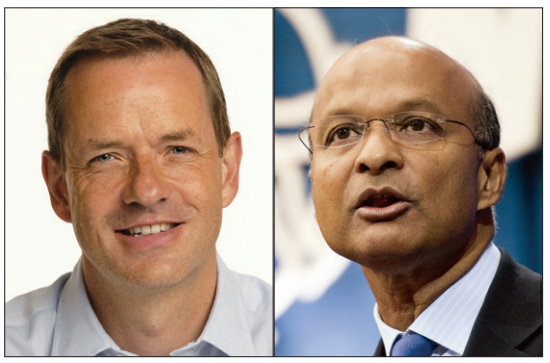
The idea is based on a fairly straightforward notion – researchers should be able to independently review and verify the results of clinical trials or at least adjudicate the findings in order to determine that the results match what was reported by a drug maker. In this way, regulators, physicians, and patients can feel reassured that clinical trials are reliable.

"There's an enormous amount of opinions flying around," says Robert Ratner, the ADA chief medical officer and chief scientific officer. "Our goal is to develop a system in which we can take a look at the data that are available … We want maximal transparency and a maximal degree of data to make rational judgments about the veracity of the data."

But whether the drug makers – which also include **Bristol-Myers Squibb**, **AstraZeneca**, **Lilly**, **Novo Nordisk**, and **Boehringer Ingelheim** – will comply remains to be seen. With the exception of **GlaxoSmithKline**, the pharmaceutical industry has resisted releasing such data over concerns that proprietary information will be compromised and a health scare could ensue if data is misunderstood.

The pharmaceutical industry trade groups – the European Federation of Pharmaceutical Industries and Associations and the Pharmaceutical Researchers and Manufacturers of America – recently released voluntary principles that outline steps drugmakers are willing to take toward transparency. But the effort has been met with a mix of cautious optimism and derision over a series of caveats. As a result, Sense About Science, a charitable trust based in the United Kingdom, is proceeding with an online petition called AllTrials to pressure drug makers to make complete trial data available. Another backer is BMJ, one of the premier medical journals, which also adopted a new policy that studies would not be published so long as a drug maker declines to make data available.

Meanwhile, a battle is under way as drug makers are fighting an effort by the European Medicines Agency, which wants to release more data as part of a new policy toward transparency. The new voluntary principles are, in fact, designed to blunt the EMA changes and also thwart the European Parliament from adopting legislation that also calls for greater disclosure.



Andrew Witty of GlaxoSmithKline and Omar Ishrak of Medtronic are perhaps the only two high-profile CEOs to take a strong position of advocacy for the release of trial data.

Also, **AbbVie** and **Intermune** went to court to block the regulator from responding to Freedom of Information requests from unnamed rivals for trial data on some of their drugs. And the trade groups are lining up patient advocacy groups, which are sometimes funded by drug makers, to lobby members of the European parliament to oppose a bill that would similarly require greater disclosure of trial data.

"EMA's proposed policies on clinical trial information raise numerous concerns for patients," PhRMA Senior VP Matt Bennett says. "We believe it is important to engage with all stakeholders in the clinical trial ecosystem, including patients who volunteer to participate in clinical trials, about the issue. The proposal could risk patient privacy, lead to fewer clinical trials, and result in fewer new drugs."

Such a stance, however, may miss a crucial selling point. By embracing greater transparency, drug makers may be able to convince regulators and physicians that their clinical trial findings can, in fact, be verified independently. In doing so, they would be in a position to more consistently argue that their data is sound. And this could help restore some of the integrity lost during recent safety scandals.

In fact, this posture can have significant marketing potential. A more transparent pharmaceutical industry would be able to argue that its clinical studies have still greater value. This is a sales tool that drug makers simply do not have.

"There are certainly disadvantages to disclosing patient-level clinical trial data," says Keith Vance, a marketing consultant to the pharmaceutical industry and an adjunct assistant professor at the Leonard N. Stern School of Business at New York University. "Chief among them is that the data is frequently 'messy' and difficult to interpret. As a result, it's easy to find 'facts' in patient-level clinical trial data – such as the occurrence of a particular side effect – that arm the critics of pharmaceutical companies.

"But even then, those 'facts' and a causal relationship to the trial drug are unsupported by rigorous analysis. However, in an era where many – lawmakers, patients, even healthcare providers – view the pharmaceutical industry as untrustworthy and guilty of obfuscation (at best) or outright deception (at worst), release of clinical trial data could be a meaningful first step toward changing perceptions for the better."

A recent example in which releasing trial data won praise involved **Medtronic**, which was widely criticized after reports disclosed that doctors with financial ties to the device maker were aware of serious problems with **Infuse**, a bone graft substitute in spinal fusion surgeries. The physicians never disclosed potential health complications in articles in medical journals, but their articles greatly boosted usage, including off-label use. The conflicts not only prompted an investigation by the U.S. Senate Finance Committee, but an entire issue of *The Spine Journal* was devoted to reviewing 13 previously published studies and discovered that side effects were downplayed or omitted. As a result, Medtronic agreed to provide the Yale University Open Data Access Project with $2.5 million in funding for an independent review of patient-level data. Two independent analyses found that the Medtronic product offers little benefit over conventional procedures and may be linked to an increased risk of cancer as well as the possibility of sterility in men. Moreover, both reviews found high levels of reporting bias in the papers that were published by Medtronic, which resulted in underreporting of adverse events.

The effort was heralded as "a historic moment in the emerging era of open science," according to an editorial in the *Annals of Internal Medicine*, which published the two reviews and also noted that nearly half of all clinical trials are never published and many have long delays in publication. Such proclamations vindicated the decision by Medtronic CEO Omar Ishrak, who agreed to fund the review and provide the data as part of an effort to rebuild corporate image. "We recognize that our products and therapies must have the public and medical community's trust," he said at the time that the reviews were published.

This is a point some say has been lost on most drug and device makers, according to Harlan Krumholz, a Yale University School of Medicine cardiologist and advocate for releasing trial data who heads the Yale University Open Data Access Project.

"These companies have a lot to gain with regard to reputation and brand," he says. "Their profile has sunk in the eyes of the American public and among healthcare professionals.

"Despite their good work, they are looked upon with some suspicion in many quarters – largely as a result of what has seemed to be an unending series of episodes of bad behavior that has overshadowed their outstanding work. Data sharing is an opportunity for them to demonstrate their commitment to transparency – and to ensuring that everything that can be known about the benefits and risks of their products is available to scientists to evaluate."

Glaxo CEO Andrew Witty espoused much the same theory after the company paid $3 billion to the U.S. government to settle civil and criminal charges. Besides marketing medicines for unapproved uses, these included withholding clinical trial data for the **Paxil** antidepressant and failing to include safety data in reports about its **Avandia** diabetes pill that were given to FDA. In a bid to restore some confidence in its operations, Glaxo last fall agreed to publish case study reports for all of its medicines once they have been approved or discontinued from development and the results have been published. The drug maker also committed to publishing reports for all approved medicines dating back to its formation, but confidential patient information will be removed.

"We need to take a different approach – one focused on partnership, collaboration, and openness," Witty said in announcing the plan. "By being more open with our clinical trial data, we also hope to help further scientific understanding."

By May, Glaxo created an online system for researchers to request access to patient-level data and released the names of a group of experts who will review requests from researchers seeking to examine trial data.

The only other drug maker to so far walk down this path has been **Roche**, which last spring agreed to make available data from all 74 clinical trials for its **Tamiflu** treatment to a team of Cochrane Collaboration researchers. They had battled for more than two years over requests to obtain trial data in order to verify efficacy results. The drug maker also agreed to widen access more generally for clinical trial information for its medicines.

Most large drug makers have been silent on the issue, preferring to let their trade groups speak for them. The only instance that prompted a response was the challenge by the ADA, which was designed to put them on the spot. "If one company refuses to participate, does this impact the outcome? Yes, it probably would impact to a certain degree," says Ratner, "but it would look awfully bad for that company to refuse when others have [agreed]."

Not surprisingly, the ADA was greeted with caution. Merck committed to working with the organization, while Lilly and Boehringer welcomed "future discussions." AstraZeneca and Bristol-Myers Squibb issued a statement saying they "recognize there can be value in pooling patient level data from trials of agents in a class for the purpose of an independent meta-analysis" and support making "scientifically valid results of a pooled analysis of safety data available to the public and scientific communities through an independent review, and look forward to a discussion" with the ADA.

A more granular response came from Alan Moises, a corporate VP and the global chief medical officer at Novo Nordisk. "The ADA request, I'm interpreting, is really an expedition into what might be available, what sponsors will be able to share with an independent body that the ADA, through some as-yet undefined mechanism, might identify as an arbiter of the data is available," he said. "…We certainly are open to more sharing rather than less sharing, and more than has been shared to date."

The ADA gambit will take time, though, as will the AllTrials campaign. The effort has generated some unfavorable publicity, further underscoring what critics say is either a blind eye or a tin ear when it comes to seizing opportunities to restore confidence in business practices.

"If we've learned anything over the past decade of litigation, it is that the drug industry has repeatedly buried trials and manipulated trials to make their products look better than the raw data would indicate," says Carl Elliott, a professor in the Center for Bioethics and the Department of Pediatrics at the University of Minnesota Medical School. "This is totally understandable; billions of dollars are at stake. But it makes no sense at all for the rest of us simply to trust industry without seeing the data."

By adopting voluntary principles, the industry trade groups hope to silence such criticism, but this may be difficult to accomplish. "In terms of the principles for responsible clinical trial data sharing outlined by the EFPIA and PhRMA, these are to be broadly welcomed, says Carl Heneghan, a director at the Centre for Evidence-Based Medicine at the University of Oxford and a Cochrane Collaboration researcher. "Yet, there are many details that need to be fleshed out to ensure this is little more than just window dressing … This current document does little to move the debate on clinical trial transparency forward. The EFPIA should decide whether they are for the release of clinical trial data, which ultimately benefits patients, or not. The current document is clouded in caveats, which would certainly allow a company to refuse a request, simply because they deemed it not to be in their interest." ■ MEDADNEWS

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By Joshua Slatko joshua.slatko@ubm.com

Responding to Sunshine

By Mary Bennett

On August 1, mandated Sunshine Act data collection began. We've all heard it many times, so those involved should be ready by now, right? Much preparing has (or should have) been done by the pharmaceutical and device industry, physicians, their employers and other involved stakeholders. But weaknesses remain that could lead to reporting mistakes, angry physicians, employer embarrassment and media frenzy. But how prepared is the industry?

SYSTEMS

Industry preparedness appears to be varied, though by now most companies know if they are "applicable manufacturers" bound by the Physician Payment Sunshine Act. As early as February 2012, two-thirds of surveyed life science companies said they were 50 percent to 100 percent ready to identify, gather, compile and report the necessary data.

Some larger manufacturers have even been doing "trial runs" of their systems by gathering and posting their data on secure websites or sending letters so that key physicians receiving payments above a threshold amount can verify the numbers. Smaller manufacturers seem less prepared; some remain in the earliest stages of identifying the physicians for whom they need to collect and report.

What's the cost of noncompliance? Let's not forget that a reporting error by a manufacturer may trigger penalties least affordable by small players – $1,000 to $10,000 per occurrence and up to $150,000 annually. For intentional failure to report, fines can be as high as $100,000 per instance, with an annual cap of $1 million.

So how do organizations create processes to ensure compliance? Do they buy them or build them? That's the question being discussed by most manufacturers today. Data tracking systems for Sunshine can be a massive undertaking for most IT departments, leading many companies to make the decision to outsource solutions. What was once a cottage industry of high tech data capture technology has mushroomed to focus on the tech needs growing out of Sunshine. Very small companies and some others plan to track the data manually, but that's inefficient and mistake prone.

DATA

The long awaited final rules have helped to both clarify some issues and leave other questions unanswered. The regulations are detailed regarding what is included and excluded in the "transfer of value" that must be reported. The Centers for Medicare & Medicaid Services (CMS) have created an internet FAQ page to address related questions. By now, large and some small industry players have identified the universe of physicians with which they contract for services and have identified how those payments must be reported.

It is not too soon for manufacturers to develop their assumptions document. Sunshine permits companies to submit a non-public document outlining the assumptions they used to categorize their physician payments. This will likely be a living document as the process evolves, but it will help internal users approach data input in a uniform way. Good database systems will have this embedded as a foundation element.

TRAINING

While system and data set development have already consumed a lot of manufacturer time, resources and funds, training has been identified as the biggest Sunshine challenge for industry. All tracking systems rely on accurate and thorough data entry by a host of users – e.g. finance, sales, marketing, medical affairs – who must input all required "transfers of value" to a "covered recipient" (physicians, chiropractors, dentists, and others). Without proper training, manufacturers face the inevitable risk of "garbage in, garbage out." And, as noted earlier, those errors can get expensive.

So far, training has covered a spectrum. Some companies have trained heavily on data identification and system entry. The trainees are the people who generate the "transfer of value." Think marketing staff who engage a physician speaker and host a dinner for program attendees; medical affairs personnel who contract with advisory group participants and pay travel costs; sales reps who provide an in-office "Lunch and Learn" for a physician and staff. At the other end of the spectrum, some companies have not yet begun to train.

Smart manufacturers are planning for the second wave of Sunshine – physicians and hospitals caught off guard by the data. Manufacturers who want to get ahead of the game will train employees who are responsible for dealing with the expected barrage of inquiries and complaints from media, physicians, employers and others. When questions and issues are handled badly, it can damage relationships, company reputation and the ability to partner with thought leaders. That ultimately can have a negative impact on patients.

Currently, industry attention is largely focused on the front end of the process. Hopefully, manufacturers will shift their attention, no later than August 1st, to prepare for the impact.

HOSPITALS

Teaching hospitals may be the best prepared for Sunshine because they already know that their top physicians are in high demand and frequently consult for the pharmaceutical/device industry. While large hospital systems have long-standing annual disclosures, there are indications that the disclosure submissions do not receive close scrutiny, or in some instances, are ignored.

Neglected disease approvals up

The annual number of new drug approvals globally to treat neglected diseases has nearly doubled in recent years, with HIV/AIDS and malaria drugs accounting for 60 percent of the most recent approvals, according to research by The Tufts Center for the Study of Drug Development. During an eight year period from 2000 to 2008, an average of 2.6 new drug products, including new molecular entities, vaccines, indications, combinations, and formulations, were approved each year to combat neglected diseases. The number increased to an average of five per year in 2009 to 2012, according to Tufts CSDD.

The analysis, reported in the July/August Tufts CSDD Impact Report, is the latest in a continuous series of studies that track progress in drug development targeting neglected diseases, in addition to patient access to existing products through donation programs.

"We are observing growth in drug development – the annual number of approvals has doubled when we compare the period 2009-2012 to 2000-2008 – but only 25 percent of new approvals are new molecular entities or new vaccines," says Joshua Cohen, Ph.D., assistant professor at Tufts CSDD, who served as principal investigator on the study. "Approximately 60 percent of new approvals target 'Big Three' neglected diseases – malaria, TB, and pediatric indications for HIV. Several diseases, such as Buruli ulcer, Dengue fever, and trachoma, have not seen any new approvals. There are products in development (the number is 16 in Phase III), but again the 'Big Three' dominate, while few drugs in Phase III are targeting lesser-known neglected diseases."

Neglected diseases are typically tropical infections most commonly found in developing countries where the population lacks the income to pay for drug treatments. This lack of purchasing power has dissuaded some drug developers from investing in therapeutics to treat these indications.

"It is important to note that new approvals are a necessary but insufficient condition to improved patient access to pharmaceuticals targeting neglected diseases," Dr. Cohen told *Med Ad News*. "Patients in developing nations often cannot afford new branded products or even older generics. Therefore, they rely on access mechanisms, such as patient assistance programs, which provide free or subsidized pharmaceuticals. We have seen growth in such programs in recent years, and a commitment from pharmaceutical companies to eradicate certain neglected diseases with continued free donations of products targeting neglected diseases, such as leishmaniasis and leprosy."

Although increased approvals may lead to greater access to new medicines, Dr. Cohen believes that policy makers need to ensure that healthcare systems adopt safe, effective, and easy to administer products that are also affordable and accessible to patients. "The important take-home message is that all relevant stakeholders, from the pharmaceutical industry, to product development partnerships, to philanthropic donors must work together to increase the supply of donated or subsidized medicines, and improve the delivery mechanisms to ensure that drugs make it into the hands of those who need them most," he says.

FACTS & FIGURES

Close to **70 percent** of Americans are on at least one prescription drug, and **more than half** take two drugs, according to Mayo Clinic and Olmsted Medical Center researchers. **Twenty percent** of patients are on five or more medications. The most commonly prescribed were **antibiotics**, **antidepressants**, and **painkilling opioids**.

In general, women and older adults receive more prescriptions. Vaccines, antibiotics, and anti-asthma drugs are most commonly prescribed in people younger than 19. Antidepressants and opioids are most common among young and middle-aged adults. Cardiovascular drugs are most commonly prescribed in older adults. Women receive more prescriptions than men across several drug groups, especially antidepressants. Nearly one in four women between the ages of 50 to 64 are on an antidepressant.

Prescription drug use has increased steadily in the United States for the past decade. The percentage of people who took at least one prescription drug in the past month increased from **44 percent** in 1999-2000 to **48 percent** in 2007-08. Spending on prescription drugs reached **$250 billion** in 2009, the year studied, and accounted for **12 percent** of total personal health care expenditures. Drug-related spending is expected to continue to grow in the coming years, according to the researchers.

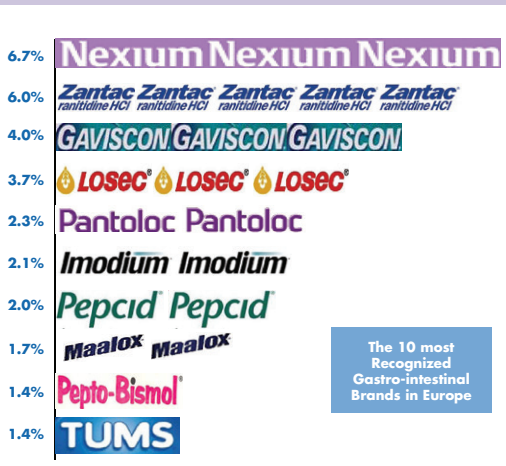
Pharmas tend to focus attention on market research in Phase IIIa to market approval and on health economics and outcomes research from launch to six months post-launch, according to a Cutting Edge Information study. The study, "Launching Pharmaceutical Brands: Formulas for Commercialization Success," found that between market approval and launch, market research and health economics and outcomes research even out, receiving **11 percent** and **10 percent** of the average budget, respectively. Market access categories' financial support lessens from launch to six months post-launch. During that timeframe, health economics and outcomes research becomes the market access priority with **9 percent** of the average total budget, while market research receives only **6 percent**.

This does not necessarily translate into companies following the same patterns across the board when launching products, says David Richardson, research manager, Cutting Edge Information. "There are definitely things that could go in the 'launch playbook' that have to do with gaining approval, earning reimbursement from payers, etc.," he told *Med Ad News*.

Surveyed brands focused on market access throughout the commercialization and launch process, though specific attentions changed from Phase IIIa to post-launch. According to Cutting Edge Information, pharmas must support many different commercialization efforts to ensure a brand's successful launch. During the early stages of commercialization – Phase IIIa to market approval – surveyed companies allocate an average of **17 percent** of their budget to market research. This category is the highest financial priority among market access concerns.

MOST-RECOGNIZED BRANDS

GASTROINTESTINAL



The most-recognized gastrointestinal brand in North America is **Prilosec**. The brand was most recognized by 11.5 percent of physicians in a survey conducted by Brand Institute Inc. during the first quarter of 2013. Prilosec, comprising omeprazole, is marketed by **AstraZeneca** (astrazeneca.com). The drug was first approved by FDA in September 1989 for the short-term treatment of active benign gastric ulcer; for the short-term treatment of erosive esophagitis that has been diagnosed by endoscopy; for the long-term treatment of pathological hypersecretory conditions; to maintain healing of erosive esophagitis; and for acute benign gastric ulcer.

Nexium is the second most-recognized gastrointestinal brand in North America. About 10.1 percent of physicians recognize this brand the most. Nexium, comprising esomeprazole, is marketed by AstraZeneca. The product was first approved by FDA in February 2001 for the treatment of heartburn and other symptoms associated with gastroesophageal reflux disease; to maintain symptom resolution and healing of erosive esophagitis; for the short-term treatment in the healing and symptomatic resolution of diagnostically confirmed erosive esophagitis; and in combination with amoxicillin and clarithromycin for the treatment of patients with *Helicobacter pylori* infection and duodenal ulcer disease.

The third most-recognized gastrointestinal brand in North America is **Pepcid**. About 7.5 percent of physicians recognize this product the most. Pepcid, comprising famotidine, is marketed by **McNeil** Consumer Pharmaceuticals, a division of **Johnson & Johnson** (jnj.com). The product was first approved by FDA in November 1986, and is indicated for the short-term treatment of active duodenal ulcer, as maintenance therapy for duodenal ulcer patients after healing of an active ulcer, for short-term treatment of active benign gastric ulcer, for short-term treatment of gastroesophageal reflux disease, and for treatment of pathological hypersecretory conditions.

The most-recognized gastrointestinal brand in Europe is Nexium. This brand was recognized the most by 6.7 percent of physicians.

Zantac is the second most-recognized gastrointestinal brand in Europe. About 6 percent of physicians recognize this brand the most. Zantac, comprising ranitidine, is marketed by **GlaxoSmithKline** (glaxosmithkline.com) for the short-term treatment of active, benign gastric ulcers and the maintenance therapy for gastric ulcer patients at reduced dosage after healing of acute ulcers; the short-term treatment of gastroesophageal reflux disease; and for endoscopically diagnosed erosive esophagitis and maintenance of healing of erosive esophagitis.

The third most-recognized gastrointestinal brand in Europe is **Gaviscon**. About 4 percent of physicians recognize this brand the most. Gaviscon, comprising sodium alginate, sodium bicarbonate, and calcium carbonate, is marketed in Europe by **Reckitt Benckiser** (rb.com). The product is indicated for the treatment of heartburn and gastrointestinal reflux disease.

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 gastrointestinal drugs. Brandpoll is a marketing tool designed to help clients monitor the competitive marketplace and identify the potential strengths and weaknesses of their brands.

Compliance is usually through the honor system, but if a physician lies or makes an over-the-limit disclosure, it rarely gets caught – or worse, it is tolerated. Recall the chairman of the Psychiatry Department at Emory University who lost his position in 2009 for such a lie only after it was investigated by Senator Grassley. During the prior years, evidence suggests that his behavior was known and tolerated because of the prestige he brought to the university.

We have been told that "seek forgiveness instead of permission" is the way some health care professionals approach outside work in the state systems, despite policies that may limit the amount of their earnings from industry. Imagine the taxpayer reaction to state government-employed physicians making big money through side work for industry. The public will demand explanations. For example, how can physicians earn so much using only vacation time? If consulting fees equal four times their hospital salary, whom is the employer?

The advent of Sunshine is a wake-up call for hospital systems. With the publication of physician payments, hospital systems have an incentive to start reviewing physician disclosures and reconciling them with their policies and the CMS database. Hospitals are reviewing their policies and, if they have no limits or disclosure requirements, they are moving toward requiring both. Their reputations are on the line.

PHYSICIANS

Half of the more than 1,000 physicians surveyed in January 2013 said "they didn't know that the law requires pharmaceutical and medical device companies to track any payments or 'transfers of value' to physicians and teaching hospitals as of August 1, 2013." This is simply another indicator that physicians are arguably the least prepared for Sunshine out of all stakeholder groups.

Once the first set of data is made public by CMS on Sept. 30, 2014, there certainly will be shock waves. In fact, the first ripples will occur when the 60-day physician review/resolution period begins on March 1, 2014. Evidently, at least half of the physicians will be surprised and maybe angered. At least some of them will dispute the data. It may be a payment attributed to the wrong "Dr. John Smith" because of a faulty NPI. It may be what looks like a minor quibble (e.g. "I came to the $50 meal but only for dessert, so I should be assigned less than $50.") It could be something more fundamental, like ignorance of the rules (e.g. "Why can't you write the check for my consulting work to my practice instead of me?") The industry needs to be ready with proper responses.

After the first ripples, many physicians will scramble to register with CMS so that they can receive updates and notifications about the information that is reported. The physicians will get educated on Sunshine and start reconciling past income with what is projected to appear on the public website. The most prepared physicians will want to create a talk track or handout explaining their payment data to patients who ask. Physicians will then likely want to open dialogue with their industry partners to determine the impact of future payments on reporting and conduct some serious reassessment of those relationships. Next up will be discussions with their office managers to set up a tracking system for reportable transfers of value.

IMPACT

Looking into a crystal ball, here are our top predictions for the Sunshine Act one year from now:

Look for community, government and teaching hospitals to implement more rigorous policies dealing with physician conflicts of interest, outside consulting and disclosure. And within a year, those entities will be diligently reviewing the disclosures and comparing them to the posted CMS data. They will step up enforcement of their policies.

There will be an initial retraction to physician participation in industry engagements. In a March 2013 survey of over 1,000 physicians, "43 percent said inaccurate reporting would adversely affect their interactions with industry and 21 percent said they would sever their relationship with a company that reported incorrect information." We will see physicians opt out in small and big ways – e.g. "Don't bring food to my office"; "I will not consult or be a speaker because I don't want to deal with questions from patients and other stakeholders." It will be more difficult for industry to engage key opinion leaders and, sadly, to obtain important medical opinion on drugs and devices.

The temptation will be stronger for industry to conduct "cost/benefit" analyses when engaging physician partners due to easy access to the cost data. The industry must be vigilant to conduct any analysis in aggregate and to avoid including non-promotional dollars spent. While it is important for manufacturers to understand how they spend their money, misuse of the data is inevitable. Watch for some of these situations to hit the news.

A few stubborn states will continue to require separate and distinct reporting at the state level, further adding to the reporting burden.

Federal and state government agencies will regularly consult the data to uncover investigation opportunities. The IRS may start auditing physician tax filings once they see the posted data. The DOJ will be looking for potential violations of the Anti-Kickback Statute (AKS), where payments may be seen as inducements to prescribe products. And if a claim is submitted to a federal healthcare program for payment of items prescribed in violation of AKS, the False Claims Act could be implicated. We will see cases brought that link Sunshine to both of these laws.

Insurance companies will use the CMS database to counter physician complaints that they are not making enough money from patient insurance reimbursement.

There will be a flurry of headline activity, TV news shows, embarrassment, anger and frustration when the data is first disclosed, but it will die down as CMS and industry work the kinks out of the process and physicians become Sunshine-savvy. The Sunshine Act will take its place among the myriad healthcare laws. The new transparency will build trust between industry, the providers and the public. It will become another risk area routinely overseen by drug and device manufacturers' compliance programs.

Mary Bennett is a registered pharmacist and a VP in the ethical leadership group at NAVEX Global, a compliance consulting company.

By Joshua Slatko joshua.slatko@ubm.com

Cloud gathering in healthcare

The healthcare industry is looking to cloud computing as a means to improve the quality of services while reducing costs, according to new research by Frost & Sullivan. Specifically, the mature healthcare IT market needs a solution to grow revenue. The workflows are being streamlined and made accurate by solutions such as picture archiving and communication systems, radiology information systems, healthcare information systems, and clinical information systems. Despite this, the market needs solutions that integrate these technologies, enabling all relevant patient and imaging data to be available at one spot and yet accessible across various locations. This type of enterprise-wide data sharing can help healthcare service providers increase efficiency at nominal expenditure.

Cloud computing is quickly expanding into a key enabler for enterprise-wide solutions, Frost & Sullivan analysts say. The appropriate implementation of cloud computing technologies can help European healthcare providers improve the quality of medical services and the efficiency of operations, share information across geographic locations, and manage expenditures. The concept can be applied in a variety of ways, including data storage and data loss prevention, maintaining patient information records, and authorized sharing of information. For instance, recorded patient information may need to be shared beyond hospital boundaries during an emergency where time is a crucial factor. This can be done quickly and efficiently by providing authorized access to this information on the cloud.

"Healthcare IT market in Europe has been defined as mature, indicating high installed base and increasing level of market saturation," says Frost & Sullivan Healthcare Analyst Raghuraman Madanagopal. "With countries in Western Europe already having a PACS market penetration of about 70 percent, the market is mostly driven by replacement of legacy systems and associated services and upgrades."

Risk of data loss is also a major concern for most healthcare providers, as it has a crucial impact on the operational efficiency of hospitals. Cloud computing provides extra safety in reducing the risk of data loss, by regularly upgrading itself and improving protection standards. Upgrades occur without any downtime and real time access is not impacted by this, therefore ensuring the 24/7 accessibility required by healthcare providers.

"With most of the European market being driven by replacements, and an increasing demand for enterprise-wide solutions and remote access of patient data across locations, cloud computing provides healthcare institutions with an opportunity to meet these needs," Madanagopal told *Med Ad News*. "Globally, it is expected that the market for cloud computing in healthcare is expected to grow at a CAGR range of 18 percent to 20 percent over the next 7 years. The trend is expected to be slightly lower in Europe owing to the effects of the Eurozone crisis and different priorities across European nations, but, as the freedom to invest improves for the hospitals, cloud computing is expected to grow on the similar lines in Europe."

Cloud computing implementation is, however, in its early stages, and a few restraining factors still exist, such as security and compliance concerns, shortage of qualified personnel to shift data from hardware to the cloud, and poor broadband penetration or low internet speeds in many parts of Europe.

"The most important restraining factor is the risk it poses to data protection," Madanagopal says. "Though cloud providers are coming up with innovative solutions that guarantee data protection, the acceptance for the technology in some countries is still bleak. With implementation of SaaS service and other services that provide access to data only to authorized personnel, the fear of unauthorized leak of data can be wiped out. A better awareness needs to be created among users regarding various compliance and security regulations to help a smooth implementation of cloud computing."

Another major restraining factor is the shortage of trained/qualified personnel who can work with cloud as a mode of data storage. "As cloud computing begins to be implemented, technical training must be provided to hospital personnel to make best utilization of the technology to gain maximum benefits," Madanagopal says.

FACTS & FIGURES

A study by Alliance Life Sciences Consulting Group has found that physicians have become comfortable with e-prescribing, and e-prescribing adoption among doctors has grown year-over-year for the past five years, with a **25 percent** increase from 2011 to 2012.

"E-prescribing has now achieved mainstream status, and drug companies can focus attention on their brands at the point of prescription by communicating relevant messages about the brand, copay cards, patient education and other information," says Dilip Phadnis, director of Syndicated Studies at Alliance. "At the same time, pharmacy benefit managers are sending messages about the cost of brands, formulary status and availability of less expensive alternatives."

With the consistent uptake of e-prescribing by doctors, pharmaceutical companies need to fully understand all of the influences surrounding e-prescribing so that they can take appropriate measures to generate adequate consideration from the e-prescriber.

"More specifically, the study found that physicians often use copay cards obtained through e-prescribing, are open to sample vouchers delivered via the platforms, and would allow advertising to help offset the cost of the systems," Phadnis says.

Study results document that when it comes to prescribing habits, a majority of physicians – about **80 percent** – have made their decision about what drug they are prescribing before entering an e-prescribing system.

"But it should be noted that about **16 percent** of the time, that decision changes after obtaining information from the system – a significant percentage that can impact brand sales," says Phadnis.

Remote monitoring system approved by FDA

The Ambio Remote Health Monitoring System, a wireless remote health and activity monitoring tool developed by Ambio Health, a healthcare technology company specializing in health monitoring systems, has received Class II FDA Clearance 510(k). The company will be demoing the product, which can track health information for patients with high blood pressure, heart disease, and diabetes, at the 2013 American Association of Diabetes Educators Annual Meeting, held from August 7-10, 2013, at the Pennsylvania Convention Center in Philadelphia.

"Our goal at Ambio is to enable individuals to take health readings at home and get connected to health care providers, loved ones and caregivers who may not be able to visit every day," says Kevin Jones, CEO of Ambio Health. "We are very pleased to have realized the important milestone of FDA 510(k) clearance so quickly as it means we will be able to make this product readily available to those who need it."

The Ambio Remote Health Monitoring System was launched in January 2013 at the Consumer Electronics Show and named as one of *eWeek*'s "10 Health and Fitness Tools To Track Exercise, Chronic Conditions."

Ambio's remote monitoring system offers patients home health readings that are automatically logged and can be viewed by family members and caregivers from the secure, web-based Ambio Care Portal. Readings are also available to healthcare providers for the regular monitoring of patient health. The system offers the ability to set individualized alert levels and notifications of exception conditions, as well as individualized reminders for readings and medications that can be sent to the patient via telephone call, text message, or email. Patients can invite family and professional care partners to join their "care circle" – which allows those providing support to the patient to access the data and view results. Members of the care circle can also set up reminders for the patient to take readings and medications, as well as create a points and rewards system for achieving targets.

The system's price starts at $49.97 for a single device, which includes a wireless glucose meter, and the user then pays an annual subscription that is the equivalent of $4.99 per month. Additional devices with wireless connectivity include a blood pressure meter and a weight scale and can be added a-la-carte. The system is plug-and-play with just a broadband internet connection required to work, and has a range of about 5,000 square feet.

"Industry studies show that 90 percent of seniors aged 65 and up would like to 'age in place,' but since most of them have chronic diseases, family members are concerned about their health status, especially when they are not able to visit every day," Jones says."Surveys show that a large percentage of seniors aged 65 and up and their families would use remote health monitoring if made affordable. In addition, numerous studies have shown that remote health monitoring reduces expensive hospitalizations and ER visits for chronic diseases such as heart disease, lung disease and diabetes.

The Ambio Remote Health Monitoring System includes a the web-based Ambio Care Portal, Ambio Scale with wireless connectivity, Ambio Wireless Connectors for blood glucose and blood pressure meters, and Ambio Gateway; Motion and Door/Window Sensors will be available soon as part of the Ambio Activity Monitoring System.

However, most remote health monitoring solutions can only be cost-justified for those most at risk of hospitalization."

According to the PricewaterhouseCoopers' Health Research Institute "Healthcare Unwired" report, 88 percent of physicians would like their patients to be able to track and/or monitor their health at home, with the greatest interest in monitoring weight, blood sugar and vital signs (blood pressure, heart rate respiratory rate). The American Heart Association recommends home monitoring for all people with high blood pressure to help the healthcare provider determine whether treatments are working.

Ambio was founded in 2011 by Jones and Alden Stevens. Jones was a partner in Accenture, the global IT consulting company, and worked with clients in consumer electronics, software, telecommunications and distribution. Stevens was chief information officer of Reynders, Gray & Co., Inc. an investment management company in New York.

"We founded Ambio because we saw that chronic diseases like diabetes and hypertension affect tens of millions of people in this country and are drivers of a majority of health care costs in the United States, and we knew we could develop an innovative solution for the chronic disease and the related 'aging in place' markets," Jones says. "We saw how remote patient monitoring can be used to improve how healthcare is delivered, but that existing solutions were much more expensive and complex than they needed to be. We endeavored to create a solution that was so affordable that it would be cost beneficial to use with the majority of people with chronic diseases, while at the same time being simple, safe, reliable and secure."

AdAgencyUpdate

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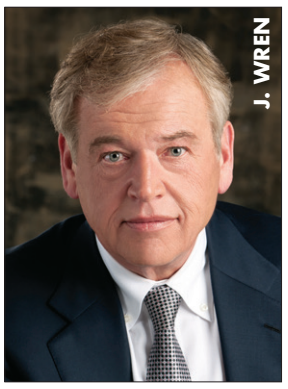
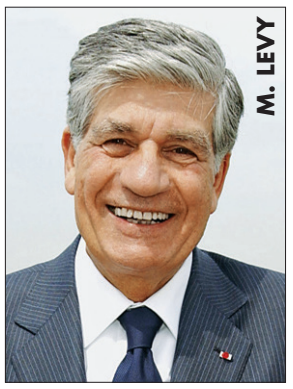
Omnicom, Publicis to combine





Omnicom Group Inc. and Publicis Groupe SA have signed a definitive agreement for a merger of equals, creating the world's largest company in communications, advertising, marketing, and digital services, with combined 2012 revenue of $22.7 billion. Based on closing prices on July 26, 2013, Publicis Omnicom Group will have a combined equity market capitalization of about $35.1 billion. The merged group of more than 130,000 employees, network leaders say, will be exceptionally well positioned to serve clients' evolving needs, helping them to build their brands and grow their businesses in the rapidly changing communications landscape.

The combination, which has been unanimously approved by the boards of both companies, brings together an extensive portfolio of agencies offering clients industry-leading talent across many disciplines and geographies. Publicis Omnicom Group will include such agency brands as BBDO, Saatchi & Saatchi, DDB, Leo Burnett, TBWA, Razorfish, Publicis Worldwide, Fleishman-Hillard, DigitasLBi, Ketchum, StarcomMediaVest, OMD, BBH, Interbrand, MSLGROUP, RAPP, Publicis Healthcare Communications Group, Proximity, Rosetta, CDM, ZenithOptimedia and Goodby, Silverstein & Partners, among others

"The communication and marketing landscape has undergone dramatic changes in recent years including the exponential development of new media giants, the explosion of Big Data, blurring of the roles of all players, and profound changes in consumer behavior," says Maurice Lévy, chairman and CEO of Publicis Groupe. "This evolution has created both great challenges and tremendous opportunities for clients. We conceived this merger to benefit our clients by bringing together the most comprehensive offering of analog and digital services. Equally important, it will offer our talented people new avenues for growth and success at the crossroads of strategic intelligence, creativity, science and technology."

Publicis Omnicom Group has been structured with balanced corporate governance consistent with the spirit of a merger of equals. The two legacy CEOs will lead the company as co-CEOs through an initial integration and development period of 30 months, following which Mr. Lévy will become non-executive chairman and John Wren of Omnicom will continue as CEO. The company will have a single-tier board with 16 members, consisting of the two co-CEOs and seven non-executive directors from each company.

For the first year following the closing of the transaction, Bruce Crawford, currently Omnicom chairman, will be the non-executive chairman of Publicis Omnicom Group. He will be succeeded by the current Publicis Groupe chairperson, Elisabeth Badinter, as non-executive chairperson for the second year following the closing of the transaction.

The transaction is expected to create significant value for shareholders. The new company's broader portfolio of agencies and services and deeper geographic footprint will allow the combined company to accelerate revenue growth and create operating synergies. The future scalability and internal synergies of the combined company are expected to generate efficiencies of $500 million.

The transaction is a cross-border merger of equals under a holding company, Publicis Omnicom Group, in The Netherlands. The Group's operational head offices will continue to be based in Paris and New York. The merger is expected to be tax-free to the shareholders of both companies. The transaction has been structured so that the shareholders of Publicis Groupe and Omnicom, after special dividends, will each hold about 50 percent of the equity of Publicis Omnicom Group. Publicis Groupe shareholders will receive one newly issued ordinary share of Publicis Omnicom Group for each Publicis Groupe share they own, together with a special dividend of €1.00 per share. Omnicom shareholders will receive 0.813 newly issued ordinary shares of Publicis Omnicom Group for each Omnicom share they own, together with a special dividend of $2.00 per share. In addition, Omnicom shareholders will receive up to two regular quarterly dividends of $0.40 per share if declared and the record date occurs prior to closing.

Publicis Omnicom Group is expected to be listed on the NYSE and Euronext Paris, traded under the symbol OMC, and to be included in the S&P 500 and CAC 40. The transaction is subject to approval by the shareholders of both companies as well as numerous regulatory approvals. It is expected to close in the fourth quarter of 2013 or the first quarter of 2014.

"Both Maurice and I believe this new company reflects our vision of retaining the best talent, attracting an incredible roster of clients and leading innovation," Mr. Wren says. "Omnicom and Publicis Groupe are reshaping the industry by setting a new standard for supporting clients with integrated messaging across marketing disciplines and geographies. This combination will enable us to leverage the skills of our exceptionally talented people, our broad product offering, enhanced global footprint, and tremendous roster of global and local clients. In short, we believe this is a merger that will set our new company on a path to accelerated growth, with long-term benefits for clients, employees and shareholders."

Cost, expectation mismatch for insurance: Harte-Hanks study

A significant gap may exist between the cost of health insurance and what consumers may be willing to pay in the new ACA environment, according to new research by the Agency Inside Harte-Hanks. The agency's 2013 Consumer Health Care Market Report analyzes consumer awareness and attitudes toward the upcoming Affordable Care Act and explores the implications for health plan marketers who need to understand, segment, and engage a new, uncharted healthcare market.

As the customer engagement agency of Harte-Hanks, The Agency Inside surveyed more than 600 consumers about factors such as motivation, channel consumption, affordability, and the likelihood to purchase. Participants were screened to ensure they were uninsured, subsidy-eligible, between the ages of 18 and 64, and influential in decisions about healthcare coverage. The research weighs the data by state to approximate the proportion of the uninsured as per the U.S. Census, and respondents represented a cross section of individuals and families.

The analysis showed that two consumer segments appear to be the most attractive to insurers among the subsidy eligible and uninsured: adults who rate their health, and that of their family members, as good, and young adults between the ages of 18 to 39. According to Harte-Hanks' researchers, both of these key segments need education on the Affordable Care Act, are uniquely motivated, and will require different marketing approaches in terms of content and channels.

"Working with our data partners and clients, we have identified publicly available data and predictive models that have been verified against actual client usage data to identify the desirable segments of the uninsured population," says Scott Overholt, VP, healthcare markets, The Agency Inside. "Our strategy is to help focus marketing dollars to target those segments and the individuals within them directly, one to one. This is needed in a largely unknown healthcare marketing environment where all insurers will be competing for the same desirable uninsured consumer segments."

According to the study, uninsured participants who reported either themselves or their families as healthy are familiar with health insurance, as many of them have carried health insurance coverage in the past. More than two-thirds of this group, though, do not have health insurance for their children. In addition, these participants are more likely to be educated, and, when compared to those that are in poor health, they are nearly twice as likely to have a college or graduate degree. They are more likely to be employed full-time; are less likely to take prescription medications; are pessimistic about the Affordable Care Act; seek specific characteristics in a health insurance company; and are more likely to talk with someone to research health insurance companies.

"Right now, the only things most people know about the law are politically motivated arguments for the past three years, most of which has little to do with consumers, or even with health itself for that matter," Overholt told *Med Ad News*. "Health plans are putting a lot of energy and effort into education before the products are even available, and this is new for this industry. Insurers are setting up online centers they are driving (or will drive, depending on where they are in their plan) people to through all channels. On those digital destinations, they are using video to explain the 'what's in it for you, the consumer' to help consumers get a better understanding of the individual mandate and the value proposition of the insurer. In addition to the general education around the program, another set of challenges are the uninsured segments that are not English-fluent; do not have their own internet connectivity; and do not have bank accounts. They require separate, specialized outreach."

Moving forward, the survey validates what The Agency Inside members already knew, according to the report: Those uninsured with the lowest quality of health will be eager to secure health insurance. The takeaway message for insurers, researchers say, is that they are bound to acquire a certain percentage of people that are not healthy into their membership. To help mitigate this risk, insurers should focus on identifying and attracting the younger and healthier consumer segments. Health insurers should focus efforts on the use of tested and proven targeted marketing strategies and tactics to find and attract the most desirable people to their plans.

"First, insurers need to identify the desired targets, then understand them, and then craft the message and offer to appeal to these desirable uninsureds," Overholt says. "Using predictive models we can identify those consumers likely to be healthy, or interested in maintaining good health, based on some defining characteristics. Demographic and lifestyle information can be added to help with messaging relevance. For a simple example, people with children buy health insurance for a different set of reasons than those without children. In these campaigns, insurers are selling something they hope consumers won't use and the consumers may not think they really need. This is one of the hardest marketing challenges we've ever seen in healthcare, or actually, just about any markets. What can we do? Insurers need to convince the right consumers of the value of their healthcare plan. And that is done through relevant messages in the channels – the multiple channels, in the case of younger uninsured -- consumers choose."

Although healthcare insurance providers may now have a better understanding of their new audience, this does not necessarily mean that they have gained a good and accurate comprehension, Overholt told *Med Ad News*. "Insurance providers have spent a lot of resources, to their credit, trying to achieve some degree of certainty about consumer characteristics, motives and probable behavior," he says. "But there's no history with these products, prices or sales channels, so there are no hard facts. They won't know what happened, and who they got signed on until campaigns are launched and we see the results. After the initial enrollment, analytics will become very important to understand the new customer base, map its health risk profile, and adjust strategies for the next round of product pricing and marketing."

AGENCY PEOPLE ON THE MOVE

The CementBloc

Dan Sontupe is promoted to executive VP of payer strategy and market access, The CementBloc (thecementbloc.com). Prior to joining the agency, Mr. Sontupe was director of client services at Ogilvy CommonHealth Payer Marketing. **Greg Williams** is named VP of the payer strategy team, and **John Knutila** becomes director of content strategy.

GA Communication Group

Ron Bieletzky becomes senior art director, GA Communication Group (gacommunication.com). Mr. Bieletzky was an art director at Topin & Associates and Corbett. **Jean May** is named producer. Ms. May was a project director at CAHG. **Lauren Goodwin** becomes project manager. Ms. Goodwin was a marketing assistant at Comply Enterprises. **Ellen Life** is appointed senior copywriter. Ms. Life was a senior copywriter at Plan B and TMP Worldwide. **Maggie Bronny** becomes the agency's first email specialist. Ms. Bronny was a brand manager for IF Marketing. **Syed Ahmed** is named senior copywriter. Mr. Ahmed was a lead writer at AbelsonTaylor.

Pacific Communications

Tim Brennan is named art supervisor, Pacific Communications (pacific-com.com). Mr. Brennan was an art director at AbelsonTaylor

Rosetta

Nikki Muntz is appointed partner, healthcare business development, Rosetta (rosetta.com). Ms. Muntz was VP of business development at Cell Division. **Eileen O'Brien** becomes associate partner, paid, owned, and earned media. Ms. O'Brien was director of search and innovation at Siren Internactive.

Sudler & Hennessey

David Cherry is promoted to chief digital officer in the United States, Sudler & Hennessey (sudler.com). Mr. Cherry has been with Sudler since 2009; before that he was VP, marketing technology at Wunderman. **Joe Gattuso** is named executive VP, director of strategic planning. Mr. Gattuso was executive VP, chief strategic officer at Ogilvy CommonHealth. **Chris Duffey** and **Greg Lewis** have both returned to Sudler, Mr. Duffey as senior VP, group creative director and Mr. Lewis as senior VP, management supervisor in the Sentrix division. Mr. Duffey returns to the agency from Draftfcb/NeON; Mr. Lewis was chief marketing officer at DKI. **Richard Veal** is appointed senior VP, strategic planning. Mr. Veal was VP, practice leader, oncology marketing at Digitas Health.

Andrew Kaufman becomes senior VP, strategic planning. Mr. Kaufman was art supervisor at Juice Pharma. **Ed Infurna** is named senior VP, account management. Mr. Infurna was at CDM. **John Donohue** becomes VP, director, editorial services. **Mark Davis** is appointed senior VP, digital strategist. **Chris Watson** becomes senior VP, creative director, Sentrix. Mr. Watson was executive creative director, Harrison & Star. **Thomas Culhane** is named senior VP, management supervisor. Mr. Culhane was senior VP group account supervisor, Juice Pharma. **Tom Sudovar** and **Laura Torres** are hired as VP account group supervisors. Ms. Torres was group account supervisor at Rapp. **Eric Hannula**, **Tom Finnerty**, and **Brian McIntosh** are hired as VP associate creative directors. Mr. Finnerty was group art supervisor at DDB Remedy. **Denise Ficano** is promoted to senior VP, group creative director. **Jane Ma**, **Karyn Ruff**, and **Mike Sampar** are promoted to VP group account supervisor. **Mark Walano** is promoted to VP, associate creative UX director. **Brenda O'Connor** is promoted to VP, associate director HR. **Kimberly Shah** is promoted to VP senior speaker bureau manager and **Vincent Astatigno** is promoted to VP speaker bureau manager in the IntraMed medical education division.

inVentiv adds MedCom offices

inVentiv Health has announced that its medical communications business has opened two new offices in Tokyo and New York, creating what network leaders call the industry's largest global network of experts in peer-to-peer medical and scientific communications.

In opening the two new offices, inVentiv Medical Communications expands its existing team of 180 scientists, writers, communications experts, and Ph.D.'s in offices across North America, Europe, and Asia. iMC has been expanding its global footprint in response to client demand for its expertise, and already has offices in London, Munich, Paris, Shanghai, Dallas, and the Philadelphia area.

Nearly all inVentiv Medical Communications personnel hold Ph.D.'s or other advanced degrees. The team includes oncologists, hematologists, neuroscientists, biologists, pharmacists, medical writers, program managers, strategists, and specialists in market access.

"With this level of expertise, we are able to help clients influence change within clinical and payer audiences," says Elaine Ferguson, global managing director of iMC. "Now, with these new offices, we are everywhere our clients need us to be, providing scientific rigor and value- based communications solutions that are the best in the business."

"inVentiv Medical Communications bridges the gap between clinical trials and the commercialization of a product," says Paul Meister, CEO of inVentiv Health. "This type of sophisticated support has never been more important in facilitating access to products because market access today is about more than just the cost of a drug."

The new staff members in New York City were formerly part of Noveida Health. John LaPolla, who will lead the New York team, holds degrees in microbiology from Cornell University and in biochemistry from Mount Sinai Medical Center. For 14 years, Mr. LaPolla has specialized in oncology and chronic pain, as well as cardiometabolic and psychiatric disorders. He has also worked in market access and developed technology platforms for some of the world's largest pharmaceutical companies, as well as for biotech startups.

In Tokyo, iMC will be led by Aya Tokaji as director of scientific services. The Tokyo team will work alongside iMC's China office which won a contract in July to provide a global pharmaceutical client with assistance in understanding China's oncology landscape and support at an upcoming medical meeting on oncology.

"At inVentiv, medical communications isn't an afterthought as it is at other communications firms. Rather, it is absolutely integral, a core capability and built into everything we do," Ferguson says. "For companies wanting to accelerate time to market, the sophisticated medical communications we can provide has become mission critical."

Cadient launches updated analytics platform

Cadient Group has unveiled the next generation of its insights and analytics solution Reveal. The solution is a proprietary SaaS business intelligence solution that is engineered to simplify the data analysis and interpretation process for key decision makers in a company. According to Cadient Group leaders, Reveal allows businesses to gather brand and competitive multichannel data—including social, web, advertising, mobile, and search—while enabling users to democratize and socialize key findings within an organization.

Some of the key enhancements in the latest Reveal release include how insight authoring now has an "attachment" feature that provides supporting details with an observation as well as a new resource library that offers a searchable, central repository for teams to share saved reports, insight attachments, or documents of any kind. In addition, the latest release of Reveal can recognize when new insights are available with visual cues on data visualizations that have recent observations posted.

"Reveal focuses on marketing channels including Websites, social media outlets (Facebook, Twitter, YouTube), mobile (mobile websites and apps), advertising (offline, banner ads, emails, and paid search), and search," says Bryan Hill, chief technology officer at Cadient Group. "The data available within these channels includes metrics and information on competitive properties, allowing marketing teams to gain a comprehensive view of how their marketing campaigns are working in real-time and relative to the competition. Additional data sources, such as eDetailing data and SFA/CRM data, as well as external sources from providers like Data.gov can be integrated through the Reveal data exchange."

Cadient's REVEAL is a proprietary SaaS business intelligence solution engineered to simplify the data analysis and interpretation process for key decision makers in a company.

The Reveal console is vital to the present day business world, Hill says. "The system of gathering, analyzing, and making use of data in business today is broken," he told *Med Ad News*. "Systems for collecting data as well as the people who monitor, analyze, and make decisions based on the data are separated either due to technical or organizational differences. Cadient saw an opportunity to make things simpler - bring all the data together in one place, focus on the metrics and data that matter, visualize the data in a way that folks outside the analytics team could make sense of it and provide access to key-stakeholders from the cubicle all the way to the board room."

PeopleontheMove

By Joshua Slatko joshua.slatko@ubm.com

Lechleiter returns to Lilly

Eli Lilly and Co. has announced that **John C. Lechleiter**, Ph.D., has returned to his duties as chairman, president, and CEO. Dr. Lechleiter had been on medical leave since his scheduled surgery for a dilated aorta on May 13, 2013. His surgery and recovery were successful and he has been cleared by his personal physician and the company's employee health services physician to return to full-time work.

"I am overwhelmed and humbled by the tremendous support and well-wishes I have received from my friends and fellow Lilly colleagues around the world," Dr. Lechleiter says "I return to Lilly with renewed energy and enthusiasm, along with a new perspective on health and wellness and the critical importance of new medicines in advancing patient care. I want to thank and acknowledge Derica Rice for the important role he played during my absence, as well as

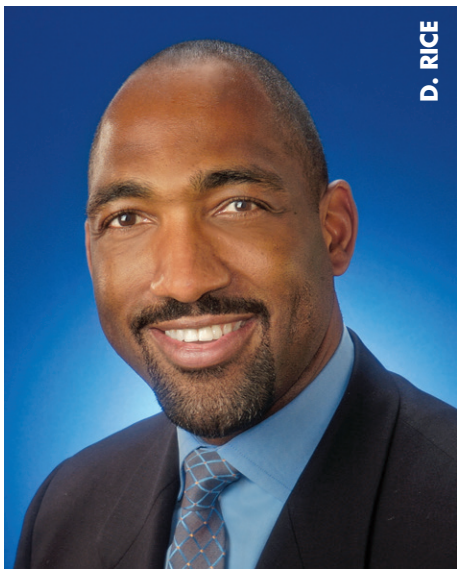

J. LECHLEITER

Ellen Marram for her leadership of the Lilly board."

Derica Rice will continue in his role as executive VP, global services and chief financial officer. Rice had assumed the additional role of acting CEO during Lechleiter's medical leave. **Ellen Marram** will continue in her role as the board's lead independent director after serving as acting chairperson of the board of directors during Dr. Lechleiter's medical leave.

Dr. Lechleiter has served as president and CEO of Lilly since April 1, 2008. He became chairman of the board of directors on January 1, 2009. He first joined Lilly in 1979 as a senior organic chemist in process research and development.

Mr. Rice was promoted to executive VP, global services and chief financial officer, effective January 1, 2010. Before becoming Lilly's CFO in 2006, Mr. Rice had been VP and controller since July 2003. He first joined the company in 1990 as an international treasury associate.


D. RICE

Ms. Marram is president of the Barnegat Group LLC, a company that provides business advisory services. She has been a member of the board of directors of Lilly since 2002 and was elected lead independent director effective April 2012.

PHARMA

■ **Dilip Shanghvi** is named chairman of the board of directors, Taro Pharmaceutical Industries. Mr. Shanghvi was previously board chairman from September 2010 until his resignation from the board in April 2012. Additionally, **James Kedrowski** has retired as the company's interim CEO, and **Kal Sundaram** has been named new CEO. Mr. Sundaram became a member and chairman of Taro's board of directors in April 2012; before that, he was CEO of Sun Pharmaceutical Industries Ltd. from April 2010 to April 2012. Taro (taro.com) is a multinational, science-based pharmaceutical company, dedicated to meeting the needs of its customers through the discovery, development, manufacturing and marketing of the highest quality healthcare products.

■ **Don DeGolyer** is named chief operating officer, pharmaceuticals, Endo Health Solutions Inc. Mr. DeGolyer was president and CEO of Sandoz Inc., the generic division of Novartis. Endo (endo.com) is a U.S.-based specialty healthcare company with four business segments that are focused on branded and generic pharmaceuticals, devices, and services.

■ **Simon Lowth** will step down from his role as chief financial officer of AstraZeneca at the end of October to become chief financial officer of the BG Group PLC, a natural gas company. AstraZeneca (astrazeneca.com) is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection, and neuroscience diseases.

■ **Maggie FitzPatrick** is appointed chief communications officer and VP of public affairs and corporate communication, Johnson & Johnson. Ms. FitzPatrick was chief communications officer at Cigna. Johnson & Johnson (jnj.com) is one of the world's largest pharmaceutical, biologics, diagnostics, medical device, and consumer health companies.

■ **Dr. Michael Grund** becomes managing director of Merck Korea, an affiliate of Merck KGaA. Dr. Grund succeeds **Juergen Koenig**, who becomes president of Merck Russia. Merck KGaA (merck.de) is one of the world's leading providers of innovative pharmaceuticals, life science tools, and cutting-edge performance materials and technologies.

BIOTECH/BIOPHARMA

■ **Dr. Mathias P. Schlichting** steps down as chairman of the supervisory board of Mologen AG for health reasons. The remaining members of the board have nominated **Stefan ten Doornkaat** to serve as Dr. Schlichting's successor until the company's ordinary annual general meeting in 2014. At that meeting the board members and Mr. ten Doornkaat intend to elect **Gregor Kunz** as the new chairman of the board. Mologen (mologen.com) is a biotechnology company headquartered in Berlin that specializes in the research and clinical development of innovative drugs in the fields of oncology and infectious diseases.

■ **Krishna Polu**, M.D., is appointed to the newly created position of chief medical officer, CytomX Therapeutics Inc. Dr. Polu previously served as VP, clinical development at Affymax Inc. **Debanjan Ray** is promoted to VP, business development and alliance management. Mr. Ray joined the company in August 2011 as senior director, head of business development. CytomX (cytomx.com) is a biotechnology company developing the next generation of highly targeted antibody therapeutics.

SPECIALTY PHARMA

■ **Chad E. Beyer** is named president and CEO of Promentis Pharmaceuticals Inc. Mr. Beyer was the founder of Solomon Therapeutics, a consulting company. Promentis (promentispharma.com) is a drug-development startup developing treatments for schizophrenia and other central nervous system disorders.

■ **Brian J. G. Pereira**, M.D., is appointed president and CEO, Visterra Inc. Dr. Pereira was president and CEO of AMAG Pharmaceuticals from 2006 to 2011. He replaces **Steven Brugger**, who has left the company to pursue other opportunities. Visterra (visterrainc.com) discovers and develops novel antibodies for the prevention and treatment of infectious and other major diseases.

■ **Wilson W. Cheung** becomes chief financial officer and senior VP, finance, SciClone Pharmaceuticals Inc. Mr. Cheung was chief compliance officer, Asia Pacific, for Velti Plc. SciClone (sciclone.com) is a U.S.-based, China-focused specialty pharmaceutical company with a product portfolio of therapies for oncology, infectious diseases and cardiovascular, urological, respiratory, and central nervous system disorders.

■ **Jan Fagerberg**, M.D., Ph.D., is appointed chief medical officer, ISA Pharmaceuticals B.V. Dr. Fagerberg was VP global development and managing director of Amgen Research for Amgen. **Jens Hennecke** becomes chief business officer. Mr. Hennecke was senior VP, business development, at Micromet Inc. **Ronald Loggers** will step down from the company's board of directors to become acting CEO. Mr. Loggers has been on the board since 2009 and is managing director at Multifund B.V. **Gerard Platenburg** is promoted to chief operating officer. Mr. Platenburg joined the company in 2009. ISA (isa-pharma.com) is an immunotherapy company developing rationally designed, fully synthetic therapeutic vaccines against cancer and persistent viral infections.

■ **Hagop Youssoufian**, M.D., is named executive VP, research and development, Progenics Pharmaceuticals Inc. Dr. Youssoufian was president, research and development and chief medical officer at Ziopharm Oncology. Progenics (progenics.com) is developing innovative medicines for oncology, with a pipeline that includes several product candidates in late-stage clinical development.

■ **Carol Satler**, M.D., Ph.D., is appointed senior VP of medical and scientific affairs, AMAG Pharmaceuticals Inc. Dr. Satler previously served in executive clinical development and medical affairs roles at Pfizer, Sanofi, Forest Labs, and Millennium. **Amit Verma** becomes VP of marketing. Mr. Verma was global commercial lead for Jevtana at Sanofi. AMAG (amagpharma.com) is a specialty pharmaceutical company that markets Feraheme and MuGard in the United States.

■ **Steven E. Benner**, M.D., steps down as senior VP, chief medical officer, and chief compliance officer, Cell Therapeutics Inc., for personal reasons. **Nancy Boman**, M.D., Ph.D., currently senior VP, clinical development and regulatory affairs, assumes interim responsibility for the oversight of Cell Therapeutics' ongoing and planned clinical trials of compounds for the treatment of blood cancers. The company has engaged a search firm to assist in an external search for a new chief medical officer and will appoint a new chief compliance officer. Cell Therapeutics (celltherapeutics.com) is a biopharmaceutical company committed to the development and commercialization of an integrated portfolio of oncology products aimed at making cancer more treatable.

■ **Hege Hellstrom** is appointed VP and head of commercial for Europe, Middle East, and North Africa, Sobi. Mr. Hellstrom spent more than a decade at Baxter and 10 years at Genzyme. **Rupert Haynes** becomes head of global commercial operations, therapeutic area inflammation. Mr. Haynes joins Sobi from UCB, where he was responsible for that company's marketing excellence program. Sobi (sobi.com) is an international specialty healthcare company dedicated to rare diseases.

SERVICE SUPPLIERS

■ **Ruth Woodrow** is promoted to director, Insight Research Group. Ms. Woodrow joined the company two years ago from Synovate Healthcare. Insight (insightrg.com) is a UK-based consultancy established in 1983 that specialises in providing market research to the healthcare sector.

■ **John Robinson** has been named VP of payer research for the Healthcare Insights team, MarketVision Research. Mr. Robinson was senior director at Genactis. MarketVision (mv-research.com) is a full-service marketing research firm with offices in Cincinnati, Chicago, Dallas, Cleveland, Los Angeles, New York, and Philadelphia.

■ **Betty Michelson** becomes sales solution executive, IMS-Appature Inc. Ms. Michelson was VP, business development for Informed Medical Communications. IMS-Appature (appature.com) is a Seattle-based technology company that provides a cloud-based marketing software platform, Appature Nexus, designed exclusively for healthcare and life sciences companies.

■ **Ivan Oransky**, M.D., is named VP and global editorial director for MedPage Today, Everyday Health Inc. Dr. Oransky was exeutive editor, Reuters Health, and independently blogs at Retraction Watch. MedPage Today is a medical news organization serving healthcare professionals; Everyday Health is a digital health and wellness company that attracts more than 40 million people monthly through its Websites, mobile applications, and social media presence.

■ **Tracy Naden** becomes managing director, Allidura Consumer, a Chandler Chicco company. Ms. Naden was managing director, consumer, for Twist Marketing. Allidura (chandlerchiccocompanies.com) is a health and wellness communications agency that specializes in creating enduring alliances between brands and those that influence them.

National service – obligation? Or putting some skin in the game?

By Sander A. Flaum

HOW DO YOU FEEL about compulsory military service?

Personally, I have no reservations about the draft. I joined the ROTC at Ohio State and learned much about leadership during my years of military service. I'm a veteran, and I think everyone would profit from some time in our country's uniform.

That's why I was so struck by a wonderful essay in the *Wall Street Journal* by General Stanley McChrystal, the former commander of U.S. and international forces in Afghanistan. He advocated a universal national service program that would offer the opportunity for civic duty to all young Americans.

This is not a new idea. The concept was floated in the 1960s during the Kennedy Administration and then again by President George W. Bush. In 2006, Charles Rangel, congressman from New York, sponsored a bill calling for two years of mandatory service – military or otherwise – from all U.S. citizens between 18 and 54.

From many, the knee-jerk reaction was: "You've got to be kidding!" "What about 18-year-old single mothers?" "How much will it cost? " "Slave labor!" "Unconstitutional!"

I imagine you already have a gut reaction.

McChrystal himself acknowledges the problems. We can barely afford to keep the Navy, Army, Marines, and Air Force solvent as it is. The chance that Congress will pass any new program that entails feeding, clothing and housing an entire generation of young people is about as close to zero as you can imagine.

But even as you dismiss the prospect of seeing millions of uniformed 18 to 22-year-olds, we can't ignore McChrystal's insight. An entire generation of Americans is growing up with minimal exposure to the concept of national service as a part of citizenship.

Service is not about "giving back." That's what you do when you're grown up – donating to your college, taking part in a community clean-up, or serving meals at a Ronald McDonald House.

National service is about how young adults can pay their dues for the right to call themselves an American. It doesn't need to be in the armed forces; it can be by volunteering for programs like the Peace Corps, Teach for America, and AmeriCorps. Performing national service means transitioning from a life that's been about "me" to working for a greater good.

But here's the problem. Far more people apply for these national programs than can be accepted. With 150,000 applicants and only 4,000 openings yearly, the Peace Corps is more selective than Harvard. AmeriCorps has 80,000 positions, yet receives more than half a million applications.

It's not that this new generation doesn't want to contribute; there just aren't enough slots to go around. Here's the greatest, arguably the most innovative country in the world, stumped about how to offer new generations the opportunity to serve.

That got me to thinking about the draft. The Selective Service System is still very much alive. It even has a Web site: www.sss.gov. Although no one is being drafted today, virtually all 18-year-old males must register. In times of national need, the SSS has the power to conscript people through a lottery based on date of birth.

So here's a modest proposal.

Let's amend the Selective Service Act to include all 18-year-old Americans, men and women. Reinstate the draft; but on a very modest level, just enough to fill the needs of a new federal Domestic Action Corps, intended for nonmilitary service. The size of the program would be in line with what we can afford – 50,000? 100,000? Let the bean counters decide. DAC troops would serve in myriad ways – helping in national disasters, counseling in poverty areas, working as teaching assistants, or maintaining infrastructure.

As our economy improves and the deficit shrinks, we might be able to enlist more people. Sure, it's only a drop in the bucket, but what's exciting is that ALL 18-year-old Americans would have the chance to be called up. They would still have to pass a physical examination and some would have clear exemptions. In reality, very few would be called (maybe 1 in 365), but everyone would know of someone who had been called up.

Giving everyone an opportunity to serve would take high-level volunteerism out of the domain of the elite, where it is now (over 90 percent of Peace Corps members are college grads), and return it to all of us. With a peacetime "Draft" for non-military service, all young people would have the opportunity to put some skin in the game – that is, ante up the price of admission for being a citizen.

And as a vet, that's an idea I could salute.

MEDADNEWS

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August 2013

5:47 PM Monday—Agency receives RFP

7:31 PM Tuesday—Still searching for an oncology "consultant" for the pitch

Subject: Urgent need!

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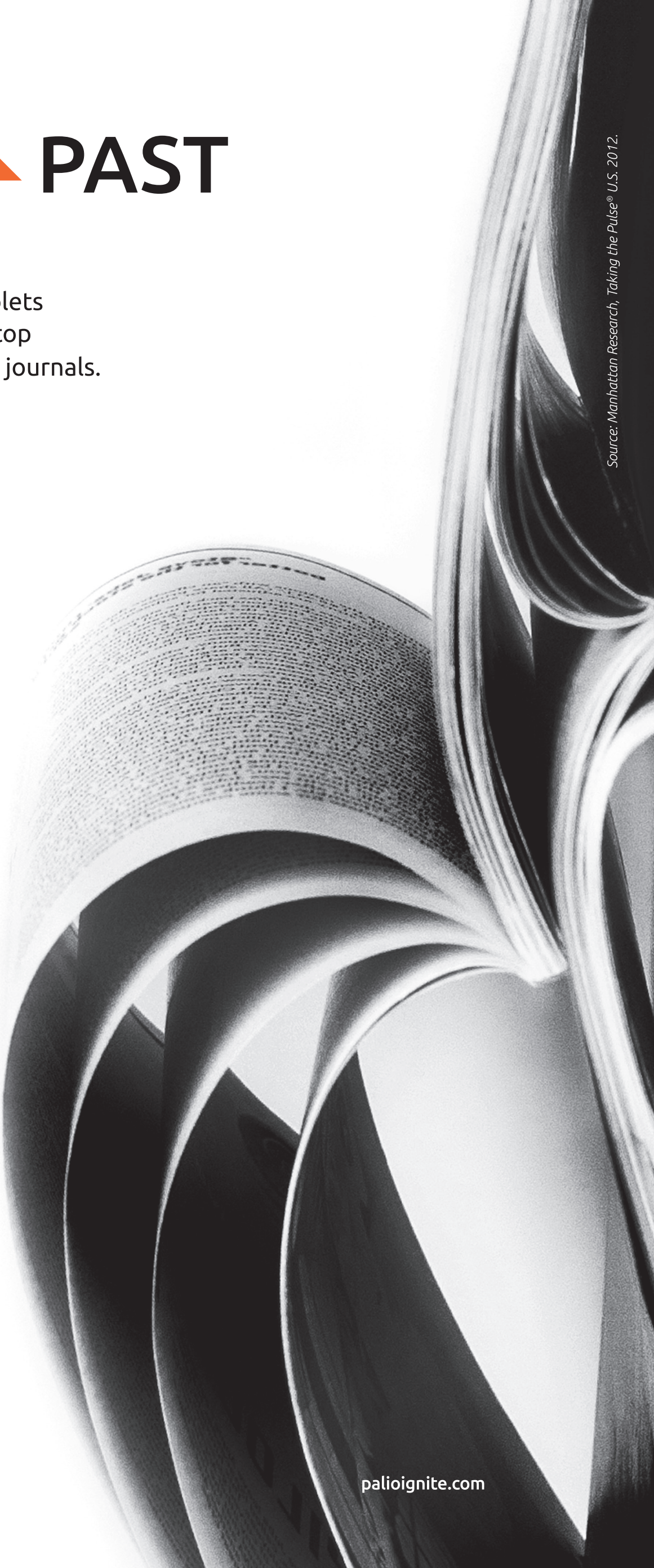

Source: Manhattan Research, Taking the Pulse® U.S. 2012.

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