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MPANIES

WTH PROSPECTS

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2011 saw the completed acquisitions of two top 10 biotechnology players: Genzyme Corp. (bought by pharma giant **Sanofi** SA) and Cephalon Inc. (purchased by generic leader **Teva** Pharmaceutical Industries Ltd.) In 2012, some biotech companies of smaller stature than Genzyme and Cephalon have been the target of acquisitions.

For example, in May 2012 **Human Genome Sciences** Inc. (HGS) said its board was fending off unsolicited takeover bids from **GlaxoSmithKline**. The London-based pharma behemoth made an unsolicited takeover bid valued at nearly $2.6 billion for the Rockville, Md.-based company. Reportedly, HGS' holdings will be diluted if any company attempts to obtain 15 percent or more of its stock without board approval.

Human Genome Sciences generated 2011 revenue of $131 million. The two companies share sales of the injectable lupus treatment **Benlysta**.

Also in May, **Hadasit** Bio-Holdings announced that **Thrombotech**, a portfolio company of which Hadasit holds a 24.8 percent stake, signed a merger deal with **D-Pharm**. Hadasit is a publicly traded portfolio of biotech companies based on intellectual property developed and owned by Hadassah University Hospital, Israel's foremost medical research center. D-Pharm is a clinical-stage, technology-driven biopharma company developing proprietary products for treating CNS disorders.

Hadasit Bio-Holdings will hold 15 percent of D-Pharm, which will issue rights for a sum of 11.5 million NIS (~$3 million). Of that amount,

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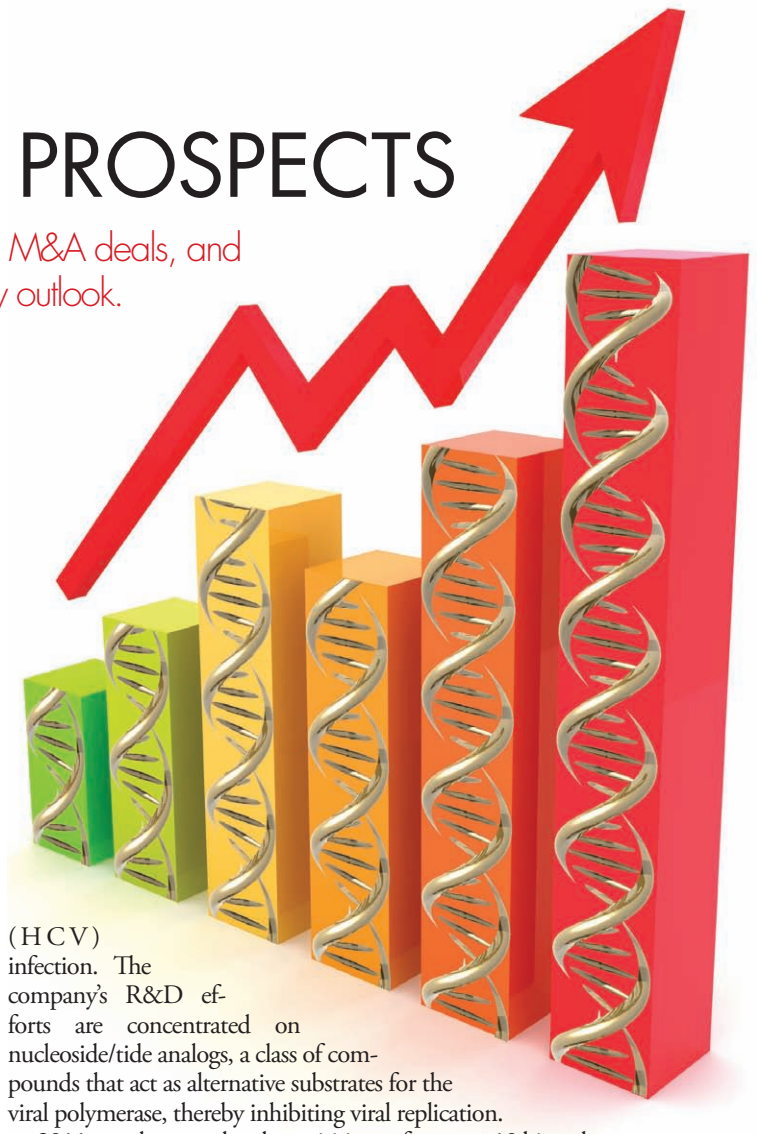
21ST ANNUAL REPORT

TOP 100 BIOTECHNOLOGY COMPANIES

STRONG GROWTH PROSPECTS

Projected increases in the amount of product approvals, M&A deals, and IPOs during 2012 have generated a promising industry outlook.

By Andrew Humphreys andrew.humphreys@ubm.com



The top 100 public biotechnology companies profiled in this annual special report generated 2011 revenue of $94.58 billion, compared to $92.08 billion during 2010, representing a 2.7 percent year-over-year increase. In terms of research and development, the top 100 revenue-generating biotech companies spent roughly $25.42 billion, down 1.7 percent from an R&D expenditure of about $25.87 billion for 2010. On the employee front, the top 100 companies of 2011 had a collective work force of more than 86,756, a 2.9 percent improvement compared to 84,274-plus staff members during the previous calendar term.

In February 2012, the Biotechnology Industry Organization (BIO) CEO & Investor Conference that included 1,200-plus industry leaders highlighted survey data indicating a strong level of optimism for the biotech sector. Part of this optimism stems from the anticipation that 2012 will be a strong year in terms of an upswing in U.S. regulatory approval of new biotech medicines as well as increased M&A activity.

"The BIO CEO & Investor Conference synthesized the overall mood within the industry of momentum and progress with recent approvals and increased M&A activity, and optimism for the year ahead," says Alan Eisenberg, executive VP of emerging companies and business development for the Biotechnology Industry Organization.

The study also revealed that a majority of investors (56 percent) still believe this is a good time to invest in biotechnology, particularly with early-stage companies and those concentrated on autoimmune disease and oncology. The data showed that investors expect a marked increase in biotech IPOs during 2012.

MERGER AND ACQUISITION ACTIVITY

Biotech M&A activity increased during the past 10 years, according to Deal Search Online, an Irving Levin Associates M&A database. Also, for 2011, deal volume and dollars committed remained strong. Though 2011 did not surpass 2009's decade-high 193 deals, buyer confidence remains and the average price per deal increased, Deal Search Online data show.

According to Deal Search Online, **Gilead** Sciences Inc.'s $11 billion acquisition of Pharmasset Inc. was the largest biotech transaction of 2011. First announced in November 2011, the deal was completed in January 2012 with Pharmasset becoming a wholly owned subsidiary of Gilead. Based on 2011 revenue, Gilead ranks No. 3 among public biotech companies.

Located in Foster City, Calif., Gilead is a biopharma company that discovers, develops, and commercializes innovative therapeutics in fields of unmet medical need. The company's mission is to advance the care of patients suffering from life-threatening diseases around the globe. Gilead has operations located in North America, Europe, and Asia Pacific.

Pharmasset is a clinical-stage pharma entity dedicated to discovering, developing, and commercializing novel drugs to treat viral infections. Pharmasset's main focus is the development of oral therapeutics for treating hepatitis C virus (HCV) infection. The company's R&D efforts are concentrated on nucleoside/tide analogs, a class of compounds that act as alternative substrates for the viral polymerase, thereby inhibiting viral replication.

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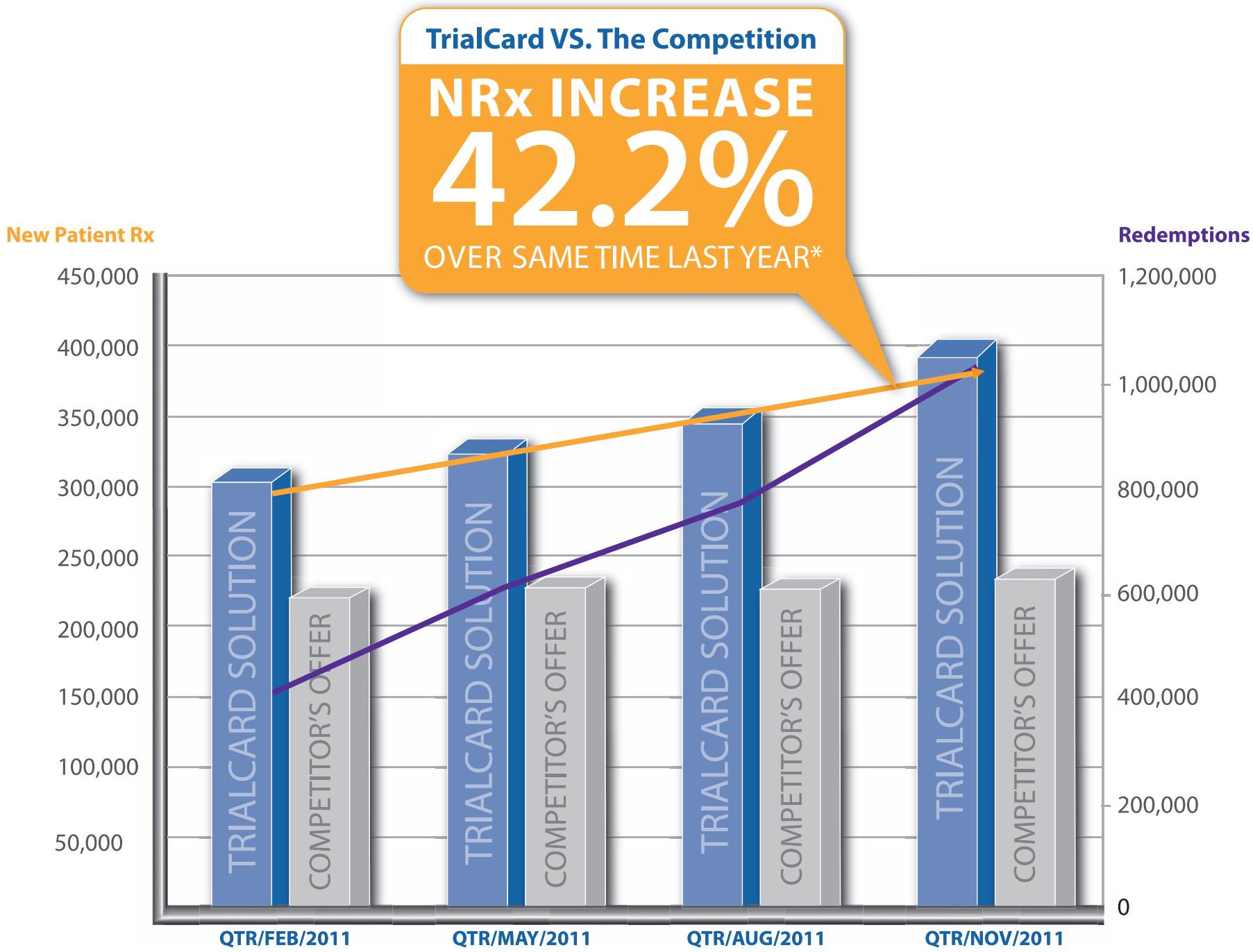

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tothepoint

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

On all regions of the healthcare map, we struggle to see the future, to plan and strategize and guess how it will all turn out. And we are generally wrong.

In pharma, as with any field of human endeavor, many if not most consequences are unintended. Cancer research led to the development of Preparation H. The APPROVe study of Vioxx, intended to evaluate the drug's efficacy for treating colorectal polyps, instead found a link to increased rates of adverse cardiovascular events and led to perhaps the most financially disastrous market withdrawal the industry has ever seen. DTC advertising – or so some researchers assert – can lead to distractions in the exam room and unnecessary prescribing, which in turn can be damaging to a brand's reputation for efficacy. And the list goes on. On all regions of the healthcare map – drug development, marketing, regulatory, academics, medical practice – we struggle to see the future, to plan and strategize and guess how it will all turn out. And we are generally wrong.

The latest examples of this universal truth can be found throughout this month's issue. According to a study discussed on page 30, doctors whose access to pharmaceutical sales representatives is limited can take more than four times longer to change prescriptions based on new information than their peers who have more frequent contact, whether that new information is positive or negative. Another article on the same page relates the findings of a study suggesting that when an FDA communication about a prescription drug is widely reported in the news media and is not related to a safety issue or accompanied by clear guidelines about how to apply the information, the resulting confusion can significantly reduce overall rates of treatment.

Unintended consequences are not universally negative, of course. As Chris Truelove writes in "Beyond birth control" (see page 24) the genericization of birth control drugs has forced companies with women's health portfolios to expand their horizons by exploring the use of these drugs for other indications, particularly focusing on the therapeutic needs of older women. This accident of fate and timing, one would hope, may lead to two unplanned but decidedly positive outcomes: the availability of new treatments targeting the health needs of older women that were previously underserved, and bigger bottom lines for those companies that successfully pursue such treatments.

The field of continuing medical education could be its own little case study for unintended consequences. As Ed Silverman discusses in "The price of an education" (see page 26), the ongoing campaign to keep industry money out of CME is succeeding, to the tune of a more than 30 percent drop in company support for CME activities between 2007 and 2010. Lovely, if you are a believer in the malign influence of industry dollars – but during the same period, the total number of available CME activities also dropped by 27.8 percent, which means doctors have fewer opportunities to take needed courses to keep up their licenses – not necessarily the best result for the public health. On top of that, CME funding has to come from somewhere, and that somewhere may end up being physicians' pockets, another end result that can't be expected to build a more educated pool of doctors.

Avoiding unintended consequences in patient adherence programming is the goal of "The patient journey, re-envisioned" (see page 23), a contributed piece from three of our friends at IMS Consulting and another at TRiG (The Research Intelligence Group). The authors argue that drug marketers must modernize their processes for tracking and responding to the patient journey, accumulating useful data about patients using multiple research strategies and methods and responding dynamically to changes in the marketplace from the earliest days of drug development through to product maturity and beyond. In the past, most companies based their ideas of the patient journey on primary research with physicians – but grounding one's strategy on the perception of physicians, rather than the reality of actual patient behavior and emotion, can lead to some very unpleasant unintended consequences, like wasted market research dollars and non-adherent patients.

Perhaps my very favorite quotation in the New Testament is from Saint Paul's Epistle to the Corinthians, 1 Corinthians 13: "For now we see as through a glass, darkly." Paul was referring (I think) to how humans perceive the Divine Will, but the sentiment can be applied to any attempt we make to see beyond the limits of our own fragile perceptions. In pharma, as anywhere, it is wise to remember that we all are seeing as through a glass, darkly.

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This month on PharmaLive.com

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MedAdNews insider

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Featuring **F. Randy Vogenberg**, Ph.D., principal, Institute for Integrated Healthcare and co-founder, Bentelligence; **Gregg Judd**, principal, Benefits Information Group and co-founder, Bentelligence; and **Ed Silverman**, editor, Pharmalot, Editor-at-Large, *Med Ad News* and *R&D Directions*

Webcast begins June 28th at 1:00PM ET

Please visit PharmaLive.com/webcasts for more details.

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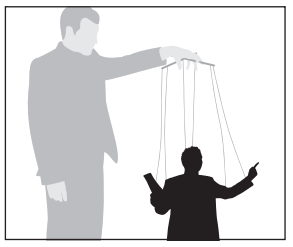

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Sander Flaum is tired of reading about how industry R&D is about to improve; if we expect the U.S. biomedical industry to stay in front, FDA has to modernize, too.

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DotPharma

BUILDING AN EFFECTIVE ECOSYSTEM FOR PATIENTS AND PHYSICIANS

The rapid growth in accessing health-related information online is compelling pharma marketers to create ecosystems" that allow patients and physicians access to compelling, relevant content across a variety of touchpoints on their own terms and timeline.

DEAR JANET: WHAT DOES THE FDA REALLY DO?

In its most recent bid to appear attentive and transparent, FDA has launched a new online form allowing users to ask questions of Janet Woodcock, the director of the Center for Drug Evaluation and Research.

RESPONSIVE DESIGN: A MARRIAGE OF ADAPTABILITY AND SIMPLICITY

Rather than building separate Websites for traditional and mobile users, marketers can use responsive design principles to build a single site that can adapt to display on any number of devices.

PLAVIX CAUSES BUZZ MORE WAYS THAN ONE

The end of patent protection for Plavix, plus the appearance of a judicially-required book about a botched patent deal for the drug, gave Bristol-Myers Squibb a more than 50 percent social media buzz bounce in mid-May.

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WHAT'S IN PRINT

THE PATIENT JOURNEY, RE-ENVISIONED
A NEW JOURNEY OF DISCOVERY

The rise of social networking has given patients an electronic avenue for practicing "peer-to-peer healthcare," the tendency of patients to "lend a hand, lend an ear, lend advice," using the speed and scale of the Internet. Companies can gain more systematic insight into conversations conducted in social media through data aggregator companies, which scan social media key words and then code and analyze them for trends.
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GUIDE TO INTERACTIVE SERVICES

Leaders from FingerPaint Marketing, Flashpoint Medica, and MMS Inc. discuss their agencies' digital strategies and offerings.
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MICROSOFT KINECT: A RISING TREND IN HEALTHCARE ENGAGEMENT

Microsoft's Kinect and other gestural interfaces have significant potential to impact the way both healthcare professionals and consumers interact with brands and with each other.
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about 5.4 million NIS has been committed to by Clal Biotechnology.

Thrombotech's lead product, **THR-18**, is designed to improve the safety and efficacy of tPA – an available treatment for ischemic stroke patients – by significantly reducing life-threatening side effects. A Phase IIa study will be used to establish THR-18's safety in treating these stroke victims. Thrombotech has started the Phase IIa trial in various locations in Israel (Hadassah, Ichilov, and Wolfson hospitals). Other sites are expected to open soon in Europe and the United States.

Biotech leader **Amgen** Inc. in April 2012 announced its acquisition of KAI Pharmaceuticals. Amgen, of Thousand Oaks, Calif., generated 2011 revenue of $15.58 billion. Privately held KAI is located in South San Francisco. The purchase price is $315 million in cash.

KAI's lead product candidate is **KAI-4169,** which is undergoing Phase II studies. The novel agent is being initially studied for treating secondary hyperparathyroidism (SHPT) in patients with chronic kidney disease (CKD) who are on dialysis. SHPT, a component of CKD mineral and bone disorder (MBD), is a common and serious complication for CKD patients on dialysis. The innovative experimental therapy is administered intravenously at the same time that the patient is undergoing dialysis. The vast majority of CKD patients on dialysis are affected by SHPT, a component of CKD-MBD, which can result in serious consequences. Amgen has acquired global rights to KAI-4169 except for Japan.

In January 2012, Amgen agreed to purchase the biotech entity Micromet Inc. for $11 per share in cash. The deal valued Micromet at $1.16 billion. Founded in Germany, Micromet's R&D center is located in Munich. The company's headquarters is based in Rockville, Md. Micromet was listed as a top 100 biotech company (No. 73) in last year's *Med Ad News* biotech special report based on 2010 revenue.

The acquisition includes **blinatumomab**, a Bispecific T cell Engager (BiTE) antibody in Phase II trials for acute lymphoblastic leukemia (ALL). Blinatumomab is additionally being studied for treating non-Hodgkin's lymphoma (NHL). The drug compound may have uses for other hematologic malignancies.

POTENTIAL BLOCKBUSTERS AND INNOVATIVE DRUGS IN THE PIPELINE

The biotech pipeline is crowded with a new wave of possible billion-dollar brands and one-of-a-kind products expected to gain regulatory approval in 2012 or 2013.

This year kicked off with the U.S. FDA approval of a long-awaited diabetes drug, **Amylin** Pharmaceuticals Inc.'s **Bydureon**. This is the first once-weekly treatment for type 2 diabetes, the most common form of diabetes. Amylin's partner **Alkermes** Inc. developed the extended-release technology for Bydureon.

Bydureon is an injectable, extended-release form of Amylin's older and market-successful diabetes product **Byetta**, which is injected twice per day. Byetta and Bydureon have the same active chemical, exenatide. Bydureon is designed to help the body produce more insulin, which can reduce high blood-sugar levels.

Amylin and previous partner **Eli Lilly** and Co. filed Bydureon for U.S. marketing clearance during May 2009. FDA regulators did not approve the medicine, asking in March 2010 for more info regarding the medicine's prescribing label and the companies' risk-management plan to ensure the drug's benefits would outweigh its risks. Amylin and Lilly provided the requested info, but during October 2010 the regulatory agency declined to approve Bydureon again. FDA requested a new study to test the effect of a high dose of Bydureon on heart rhythm, which was accomplished. Meanwhile, the Amylin and Lilly partnership mutually came to an end during November 2011 with full responsibility for the global development and commercialization of exenatide transitioning to Amylin.

Some industry analysts have projected that Bydureon annual sales could approach $2 billion before 2020, though the drug will compete in a crowded marketplace with other new medicines on the horizon.

Another potential blockbuster medicine approved by FDA in January 2012 was **Erivedge** (vismodegib). The drug's first approval was for the treatment of adults with metastatic basal cell carcinoma, or with locally advanced basal cell carcinoma that has recurred following surgery or who are not candidates for surgery, and who are not candidates for radiation. The first-in-class hedgehog-pathway inhibitor is part of a development program between the biotech companies **Curis** Inc and. **Roche/Genentech** Inc. The hedgehog signaling pathway plays a significant role in regulating proper growth and development during the early stages of life and becomes less active in adults.

Erivedge is the first FDA-approved drug for people with advanced forms of the most common skin cancer. Individuals with advanced basal cell carcinoma have tumors that have spread to other areas of the body (metastasized), or can become disfiguring and invade surrounding tissue (locally advanced). In these instances, the disease cannot be treated with surgery or radiation. Advanced basal cell carcincoma often leads to severe deformity or impaired function of the affected organs.

The medicine is being commercialized by Roche and Genentech via a collaboration deal between Curis and Genentech. Some analysts expect the drug to exceed $1 billion in yearly sales for advanced basal cell carcinoma alone. Erivedge is also being developed in Phase II trials for operable basal cell carcinoma and is undergoing studies for other indications.

During May 2012, **Biogen Idec** Inc. announced that U.S. and EU regulatory authorities have accepted the company's marketing applications for **BG-12** (dimethyl fumarate). The oral therapeutic candidate is intended for treating multiple sclerosis (MS). The Food and Drug Administration accepted Biogen Idec's New Drug Application for BG-12 and granted the Weston, Mass.-based company a standard review time line. The European Medicines Agency (EMA) validated the Marketing Authorisation Application (MAA) for review of BG-12 in the EU.

The investigational oral therapy is the only currently known investigational compound for treating MS that has experimentally shown activation of the Nrf-2 pathway. Biogen Idec's regulatory applications for the compound were based on a comprehensive clinical-development program in which BG-12 showed significant reductions in MS disease activity coupled with favorable safety and tolerability in two pivotal Phase III studies.

Ocriplasmin may represent the first non-surgical treatment for vitreomacular adhesion. The drug is being developed by **ThromboGenics** NV, which concentrates on innovative ophthalmic medicines. The Belgium biopharma company in April 2012 refiled a Biologics License Application (BLA) with U.S. regulators for ocriplasmin intravitreal injection, 2.5 mg/mL, for treating symptomatic vitreomacular adhesion (VMA) including macular hole.

During February 2012, FDA indicated that it intended to assign a priority-review designation to the original BLA filing for the same indication submitted in December 2011. The U.S. regulatory agency grants priority-review designation to products that may offer major advances in treatment, or provide a treatment where no adequate therapy exists. FDA has a goal of completing priority reviews within six months. The EMA is reviewing ThromboGenics' MAA for ocriplasmin for the same indication.

"The resubmission of the BLA filing is a significant step in our strategy to commercialize ocriplasmin in the U.S., if approved," says Dr. Patrik De Haes, CEO of ThromboGenics. "Gaining priority-review designation for ocriplasmin, as anticipated, would further validate the potential of this novel pharmacological drug in treating symptomatic VMA including macular hole. Following our recent commercialization agreement with Alcon for the non-U.S. rights to ocriplasmin and our successful fundraising, we are well positioned to invest in building a first-class commercial organization in the U.S. and to realize the full global potential of ocriplasmin."

AMR-101 is awaiting FDA marketing clearance for treating high triglycerides. The prescription-grade omega-3 fatty acid is being developed by **Amarin** Corp., a late-stage biopharma company concentrated on improving cardiovascular disease treatment. FDA has assigned a Prescription Drug User Fee Act (PDUFA) date of July 26, 2012, for the targeted completion of its review of the drug in the treatment of patients with very high triglyceride levels.

If that indication is FDA-approved, the Ireland-based company plans to separately seek approval for use of AMR101 in treating patients with high triglyceride levels who are additionally on statin therapy for elevated LDL-C levels. Amarin's cardiovascular programs capitalize on the company's expertise in the area of lipid science and the potential therapeutic benefits of essential fatty acids in treating cardiovascular disease.

Tasquinimod is being jointly developed by France's **Ipsen** Group and Sweden's **Active Biotech** AB. The oral compound quinoline-3-carboxamide derivative binds to a molecule called S100A9. The drug has shown antiangiogenic, anti-metastatic, and immunomodulatory properties. The development of tasquinimod is initially concentrated on treating advanced metastatic castration resistant prostate cancer.

In June 2012, Active Biotech and Ipsen presented overall survival data from the tasquinimod Phase II trial in chemotherapy-naive metastatic castrate resistant prostate cancer (CRPC) at the American Society of Clinical Oncology meeting in Chicago. Tasquinimod demonstrated encouraging overall survival improvement in castrate resistant prostate cancer.

"Men with metastatic CRPC in this trial were unexpectedly found to have prolonged survival times beyond that previously reported in this patient population, despite a high fraction of patients with liver and lung metastases," wrote principal author Andrew Armstrong, M.D., assistant professor of medicine and surgery at Duke University and the Duke Prostate Center. "We also found that despite initial imbalances in baseline characteristics, the improvements in progression-free survival with tasquinimod may translate into improvements in overall survival, and, if confirmed in the ongoing Phase III trial, suggests

Methodology

To be included in this biotechnology report, companies have to be publicly traded; have to research and develop human therapeutics deriving from a naturally occurring substance or a biological substance – either human, animal, or plant; have to apply genetic engineering or recombinant DNA technology; and their therapeutic products have to be intended for sale through prescription.

Companies considered for this report are involved in genetic technology, molecular biology, structural chemistry, and/or rational drug design. In addition to researching and developing human therapeutic products, some companies market therapeutic products and others market diagnostic and agricultural products. Excluded from this report are companies that are dedicated entirely to developing assay technologies, high-throughput screening technologies, biotechnology testing equipment, or naturally derived OTC products.

The companies included in this special report have been ranked based on revenue generated in calendar-year 2011 or fiscal-year 2011.

To be considered for the rankings, companies must publish their financial information. For companies reporting on a fiscal year, available figures from the most-recent fiscal year as of this magazine's press time are used. Companies that were successfully acquired during calendar-year 2011 are excluded from this year's rankings. The information in this report was gathered from company-provided documents, including annual reports, Form 10-Ks, quarterly reports, and press releases.

For biotech companies with non-U.S. headquarters, *Med Ad News* used year-end average exchange rates provided by the Federal Reserve Board to convert financial figures to U.S. dollars. The conversions were made for the purposes of convenience and comparison only.

So that the percentage change in financial information reflects the actual increase or decrease in the company's home-country currency, *Med Ad News* used a constant rate of exchange for 2011 and 2010, reflecting the increase or decrease reported by the non-U.S. company.

For certain non-U.S. companies that reported financial figures in U.S. dollars, those figures were used by *Med Ad News* editors rather than the year-end average exchange rates from the Federal Reserve Board to convert local currencies.

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Prototype shown with optional equipment. Production model may vary. [1]Based on Vincentric's 2011 Best Fleet Value in America analysis, mid-size sedan segment. [2]Vehicle's projected resale value is specific to the 2012 model year. Excludes Camry Hybrid models. For more information, visit Kelley Blue Book's kbb.com. Kelley Blue Book is a registered trademark of Kelley Blue Book Co., Inc.[3]MotorIntelligence.com, CY 2002-2011 sales, includes Camry Solara. [4]Do not rely exclusively on the Blind Spot Monitor to determine if a lane change is safe. Always look over your shoulder and use your turn signal before changing lanes. There are several limitations to the function, detection, range and clarity of the monitor. For a complete list of limitations and directions regarding use of the monitor, please see the *Owner's Manual*. [5]Available on XLE and Hybrid XLE models only.

that tasquinimod may have an important role in the future treatment of men with CRPC."

BIOPHARMA CORPORATE VENTURE INVESTMENT LEADS TO MORE DEALS, ACQUISITIONS, AND IPOS

According to research from Burrill & Co., therapeutic companies that attract investment from corporate venture arms are more likely than other venture-backed entities to enter licensing deals, be acquired, or complete an initial public offering. Pharma companies, searching for new ways to access promising early-stage technologies, increasingly look to venture investments in an effort to gain insight and access.

"Our analysis shows that companies that were able to attract the participation of a corporate venture fund had a significantly greater likelihood of providing an exit for its investors," says G. Steven Burrill, CEO of Burrill & Co., a diversified worldwide financial services company concentrated on the life-sciences arena. "The ability to attract corporate venture capital is a validation for companies that secure those investments."

Published in the June 2012 edition of The Burrill Report, the analysis examined all therapeutics venture investments made between Jan. 1, 2000, and year-end 2011 in the S&P Capital IQ database. A total of 2,907 companies received disclosed venture capital funding via 5,100 rounds of financing in that time frame. Of that group, 9.9 percent (286 companies) received funding in part from a corporate venture fund.

Of the companies receiving corporate venture funding from 2000 through 2011, 24.5 percent (70 companies) were acquired, versus 14.4 percent (380 companies) for those that did not gain funding from a corporate venture investor. But according to Burrill, though having corporate venture funding was a greater predictor of an eventual acquisition, it was not because the parent of the corporate venture fund was likely to buy the company. Only 8.6 percent, or six of the corporate venture funded companies that were eventually purchased, were acquired by the parent of that corporate venture arm.

Companies that received corporate venture funding were additionally far more likely to enter into licensing or collaboration deals. A total of 139 companies (48.4 percent) that received corporate venture funding during 2000-2011 entered into at least one licensing/collaboration pact. 782 non-corporate venture funded companies (29.9 percent) entered into licensing/collaboration deals during the past 12 years. "Though it's unclear from the research, that may reflect that having corporate venture funding helps guide companies to work on projects that are of higher interest to potential acquirers," Mr. Burrill says.

Corporate venture funding was additionally a greater predictor of an eventual company IPO. Thirty-five corporate venture backed companies (12.2 percent) successfully completed IPOs, versus 205 companies (7.8 percent) that did not receive corporate venture backing. According to the analysis, there was not a significant difference between the two groups in terms of the time from first venture funding to an M&A or IPO for the companies in the analysis that attained exits. The companies backed with corporate venture capital achieved exits at an average pace of four years versus four years and three months for non-corporate venture backed companies.

Burrill's Biotech 2012 annual report notes that corporate venture investing in life sciences has increased steadily during the past few years, accounting for about 20 percent of life-sciences venture investment in 2011. With many traditional venture capitalists concentrating on later-stage agreements, corporate venture funds have helped fill a gap in earlier-stage funding.

VENTURE CAPITAL DOWN IN FIRST-QUARTER 2012

Venture capital funding in the life sciences sector, which includes the biotechnology and medical device arenas, declined 22 percent during first-quarter 2012 versus the previous quarter, according to a PricewaterhouseCoopers U.S. report (which included data from the PricewaterhouseCoopers LLP/National Venture Capital Association MoneyTree Report, based on data from Thomson Reuters).

Venture capitalists invested $1.5 billion during the first quarter, the lowest level since fourth-quarter 2010. Deal volume decreased too, falling 11 percent from 4Q 2011 to 171 deals. Dollars invested into life sciences companies during first-period 2012 dropped off 8 percent compared to 1Q 2011. The amount of deals decreased 12 percent from the $1.6 billion invested in 195 deals during the first three months of 2011.

For every sector, venture capitalists invested $5.8 billion in 758 deals during first-period 2012, declining 19 percent in dollars invested and dropping off 15 percent in deals, versus $6.7 billion going into 861 deals during first three months of 2011. The life sciences share of total venture capital dollars invested was at 26 percent in first-quarter 2012, falling one percent compared to fourth-quarter 2011.

"Venture capitalists remained cautious during the first quarter after a lackluster fourth quarter in the public markets, as evidenced by the shift from investing in earlier stage companies to a focus on later stage companies in Q1," says Tracy T. Lefteroff, global managing partner of the venture capital practice at PwC.

In 1Q 2012, biotechnology represented 53 percent of funding and medical devices accounted for 47 percent of dollars invested. In comparison, in fourth-quarter 2011 biotechnology claimed 73 percent of investment in the sector and medical devices represented 27 percent.

Biotechnology investing dropped off by 43 percent in dollars and 14 percent in deals, with $780 million going into 99 transactions. Despite the decline, biotechnology ranked No. 2 in terms of overall dollars invested, second only to the software industry. Year-over-year, biotech investments fell by 18 percent and deals decreased 9 percent, with $949 million going into 109 transactions in first-period 2011.

"A more active M&A market may be the reason that the biotech industry experienced a

decline in investing in Q1, as VCs saw more of their portfolio companies experience exits during the first quarter," Ms. Lefteroff says. "While on the surface, the jump in dollars invested in the medical device industry during Q1 may seem surprising given the 22 percent drop in life sciences funding overall, a deeper dive shows that companies in the later stage of development accounted for more than half of the investments in this industry."

Two of the seven biotechnology subsegments generated growth during 1Q 2012 year-over-year. Dollars invested in the biosensors and biotech industrial subsegments increased 599 percent and 14 percent compared to 1Q 2011. Funding for all other subsegments declined during the first quarter of 2012. The human biotechnology subsegment captured the largest share in first-period 2012 with $621 million going into 67 deals and remained flat year-over-year in dollars and transactions.

BIOSIMILARS APPROVAL PATHWAY PROGRESS

FDA in February 2012 released the regulatory agency's long-awaited guidance to assist in the development and approval of biosimilar drugs for the U.S. marketplace. Biosimilars have yet to be cleared for marketing in the United States because of their complex nature and the lack of a formal regulatory approval process for them. Biosimilars are derived from large complex bio-molecules, making their duplication much more difficult than small-molecule generics. FDA's draft guidance requests clinical and lab studies to prove that a drug manufacturer's versions of biological drugs are highly similar to the original products. The U.S. regulatory agency reportedly requested a 17 percent increase in FDA's 2013 budget, of which a significant amount would be directed at reviewing generic drugs and biosimilars.

U.S. regulators are looking to bridge European data for biosimilars, as significant clinical-trial info already exists in that marketplace. At least 16 biosimilars have been approved by the EMA compared to no formal biosimilar drug filings in the United States.

Patent expirations of biologics are anticipated to result in the European launch of several new biosimilars and help drive that marketplace. According to Frost & Sullivan analysis, the biosimilars market is expected to grow from $172 million during 2010 to $3.99 billion in 2017 for a compound annual growth rate (CAGR) of 56.7 percent. This analysis covers the existing biosimilars segments (erythropoietin, granulocyte colony stimulating factors, and human growth hormones) and emerging biosimilars segments (monoclonal antibodies, insulin, and interferon – alpha and beta).

"The expiration of patents and other intellectual property rights of biological innovators over the next decade opens up opportunities for biosimilars to enter the market and increase industry competition," says Frost & Sullivan Research Analyst Srinivas Sashidhar. "Price reduction strategies will ensure increased adoption among physicians and patients alike, spurring market advancement."

Despite lucrative growth prospects, the necessity for large investments will pose a strong challenge to smaller companies, according to the analysis. Complex production processes, expensive biological and chemical materials, and rigorous clinical studies as well as mandatory safety, efficacy, and quality tests require sizable investments.

"The need for considerable financial outlays will hinder the entry of small biotech firms in particular," Mr. Sashidhar says. "On the other hand, specialty pharmaceutical companies with biotech expertise and financial capabilities are well-positioned to venture into the biosimilars market."

High manufacturing costs represent another major market entry barrier. But viable prospects exist for licensing deals between companies, the analysis notes. To attain market success, companies will need to have strongly integrated R&D, production, sales, and marketing processes.

"Access to sales and marketing capabilities can be achieved through collaborations between pharmaceutical companies and specialty biotech firms with technical expertise," Mr. Sashidhar says. "Companies can build sales and marketing capabilities in-house and ensure effective marketing support for the commercialization of biosimilars."

Effective sales communication to the scientific community, along with continuous promotional activities as well as close and constant interaction with physicians and pharmacists, are expected to promote greater biosimilar uptake.

In December 2011, Amgen and **Watson** Pharmaceuticals Inc., one of the generic industry leaders, agreed to team up and produce biosimilar cancer drugs. The companies will develop and commercialize on a global scale several oncology antibody biosimilar medicines. This collaboration reflects the common belief that the development and commercialization of biosimilar drugs will not follow a pure brand or generic model, and will require significant expertise, infrastructure, and investment to ensure safe, reliably supplied therapies for patients.

"The pairing of Amgen's 30 years of experience in biologics together with Watson's substantial generics and specialty pharmaceutical experience and complementary commercial and distribution capabilities provides great potential for worldwide patient access to high quality oncology biosimilar medicines," says Robert A. Bradway, president and chief operating officer at Amgen. "Biosimilars provide an exciting long-term growth opportunity for Amgen. We have a dedicated team to leverage existing capabilities and capacity and drive the success of the collaboration."

Amgen has primary responsibility for developing, manufacturing, and initially commercializing the oncology antibody products. Parsippany, N.J.-based Watson will contribute up to $400 million in joint-development costs throughout the development process, including the provision of development support, and will share product-development risks. Watson is contributing significant expertise in the commercialization and marketing of products in highly competitive specialty and generic markets, including helping to effectively manage the life cycle of biosimilars. Products resulting from the collaboration are expected to be sold under a joint Amgen/Watson label. Watson will initially receive royalties and sales milestones from biosimilar revenue. The collaboration will not produce biosimilars of Amgen's proprietary products.

"This collaboration places Amgen and Watson in an unparalleled position in the global biosimilars market by capitalizing on best-in-class capabilities in both innovative biologics and specialty pharmaceuticals and generics," says Paul Bisaro, Watson president and CEO. "Forging this collaboration delivers on the Watson promise to be a leader in the field of biosimilars, and does so in a way that helps manage the substantial financial investment, operational capabilities and broad commercial skills required to bring safe, high-quality and cost-effective biosimilar therapies to patients. We believe that biosimilars are the next frontier in the evolution of the healthcare market, and we are prepared to bring all of our resources to bear in this collaboration to ensure this partnership can most effectively compete in the biosimilar space, and thereby generate significant long-term value for our respective shareholders."

The **Merck** Group of Germany and **Dr. Reddy's** Laboratories Ltd. of India during June 2012 announced a partnership to jointly develop a portfolio of biosimilar compounds in oncology. The portfolio is mainly concentrated on monoclonal antibodies (MAbs). The partnership covers joint development, manufacturing and commercialization of the compounds worldwide, with some country exceptions.

"Our expertise in developing, manufacturing and commercializing biopharmaceuticals gives us a clear advantage in the biosimilars field and the partnership with Dr. Reddy's will bring their first-in-market experience in biosimilars, as well as their expertise in generics and Emerging Markets, to the table," says Stefan Oschmann, executive board member of Merck and head of Merck Serono. "Sharing know-how, risks and rewards is the right approach to enter the emergent biosimilars market and will be a win-win for both parties. It further strengthens Merck Serono's promise to live science and transform lives, by increasing access to quality medicines for patients and physicians, while also broadening the value offered to payers."

The partnership marks the first step by the Merck Group to enter the biosimilar arena. The Merck Serono division began exploring the opportunity in 2011 to assess how the company could capitalize on its expertise in biopharmaceuticals and its growing presence in key markets, including certain emerging markets. Earlier in 2012, Merck Serono set up a dedicated biosimilars unit that will be located in the Canton of Vaud in Switzerland, where the main biologics manufacturing facilities of the division are based.

"We strongly believe that biosimilars is an important area of future growth and these products give us the opportunity to provide affordable and innovative medicines to patients across the globe," says Dr. Reddy's Vice Chairman and CEO G.V. Prasad. "With the recent EMA and FDA guidance on biosimilars, it is clear that any significant player in the field will need strong biologics development, manufacturing and commercialization capabilities. Merck's and Dr. Reddy's joint expertise in these fields makes for a powerful global partnership."

Merck and Dr. Reddy's will jointly develop the molecules included in the deal. Dr. Reddy's will lead early product development and complete Phase I studies. Upon completion of Phase I, Merck Serono will take over manufacturing of the compounds and lead Phase III development. The pact is based on full R&D cost sharing.

Merck Serono will undertake worldwide commercialization, outside the United States and with the exception of certain emerging markets that will be co-exclusive or where Dr. Reddy's maintains exclusive rights. Upon commercialization, Dr. Reddy's will receive royalty payments from Merck Serono. The entities will co-commercialize the products in the United States on a profit-sharing basis.

The move into biosimilars by Merck Serono is a part of the Merck Group's transformation program, via a diversified business concentrated on delivering long-term value and growth opportunities. Merck Serono has formed a dedicated biosimilars unit to develop, manufacture and commercialize biosimilar medicines. The unit is a part of the pharma division of Merck Serono. The unit is concentrated on developing molecules via its in-house R&D expertise in biologics, and in partnering with other biosimilar players in key therapeutic fields such as oncology and inflammatory disorders.

DEVELOPMENTS FROM JUNE 2012 BIO CONFERENCE

Deuteria Pharmaceuticals Inc. was recognized by the Biotechnology Industry Organization as the Pipelines of Promise Buzz of BIO winner for the June 2012 BIO International Convention. Founded during 2010, Deuteria is a virtual and private biotech company located in Boston.

"The Buzz of BIO competition is an exciting opportunity for emerging companies to capture the spotlight and level the playing field a bit amongst their more established industry peers," according to Jim Greenwood, president and CEO of BIO. "As a Buzz winner, this company will now enter the convention with a heightened sense of anticipation and buzz, allowing for endless partnering opportunities."

Deuteria is pioneering Deuterium-Enabled Chiral Switching (DECS) to improve the profile of medicines that interconvert between enantiomers both *in vitro* and *in vivo*. Representative drugs include the immunomodulator **Revlimid**, the diabetes product **Actos**, the Alzheimer's disease medication **Aricept**, the antidepressant **Wellbutrin**, and the platelet aggregation inhibitor **Effient**. Introducing deuterium allows for dosing of a single, deuterated enantiomer to create an improved new chemical entity with new composition-of-matter patent protection.

The company is revolutionizing **Sepracor** Inc.'s (now known as **Sunovion** Pharmaceuticals Inc.) successful business model known as 'chiral switching.' After the development of chiral separation methods during the 1990s, several products were 'switched' from a mixture of two mirror-image isomers to a single preferred isomer that had superior properties, resulting in an improved drug profile. Successful and profitable 'chiral switches' include the gastrointestinal drugs **Prilosec** to **Nexium**, the antidepressants **Celexa** to **Lexapro**, and the sleep aids **Zopiclone** to **Lunesta**.

"As an emerging company with a pioneering approach to therapeutics, Deuteria Pharmaceuticals is pleased to be recognized as the Pipeline of Promise company by the premier conference in the biotechnology industry," noted Dr. Sheila DeWitt, president of Deuteria. "This recognition from BIO 2012 provides and strengthens the visibility of Deuteria Pharmaceuticals." ■ MEDADNEWS

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TOP 100 BIOTECHNOLOGY COMPANIES

REVENUE — TOP 100 BIOTECHNOLOGY COMPANIES

Rank in 2011	Company	Revenue in 2011	Revenue in 2010	Net Income/(Loss) in 2011	Net Income/(Loss) in 2010	Earnings/(Loss) Per Share in 2011	Earnings/(Loss) Per Share in 2010
1	Roche	$31,195,159,106 (biotech estimate)	$34,819,961,634 (biotech estimate)	$10,769,577,973 (for entire Roche Group)	$10,032,723,990 (for entire Roche Group)	$12.39 (for entire Roche Group)	$11.41 (for entire Roche Group)
2	Amgen Inc.	15,582,000,000	15,053,000,000	3,683,000,000	4,627,000,000	4.04	4.79
3	Gilead Sciences Inc.	8,385,385,000	7,949,420,000	2,803,637,000	2,901,257,000	3.55	3.32
4	Biogen Idec Inc.	5,048,634,000	4,716,423,000	1,234,428,000	1,005,273,000	5.04	3.94
5	Celgene Corp.	4,842,070,000	3,625,745,000	1,317,456,000	880,192,000	2.85	1.88
6	UCB SA	4,522,002,600	4,482,995,800	327,378,500	143,489,300	1.77	0.78
7	CSL Ltd.	4,446,399,600	4,912,426,445	999,059,700	1,117,864,992	1.85	1.97
8	Grifols SA	2,501,468,470	1,380,185,963	69,972,627	160,578,458	0.26	0.75
9	Actelion Ltd.	2,026,701,647	2,176,674,566	(165,108,328)	440,709,772	(1.39)	3.63
10	Ipsen Group	1,720,339,190	1,630,344,930	197,123,650	197,123,650	2.34	2.28
11	Vertex Pharmaceuticals Inc.	1,410,626,000	143,370,000	29,574,000	(754,626,000)	0.14	(3.77)
12	Elan Corp.	1,246,000,000	1,169,700,000	560,500,000	(324,700,000)	0.94	(0.56)
13	Alexion Pharmaceuticals Inc.	783,431,000	540,957,000	175,315,000	97,030,000	0.91	0.52
14	Cubist Pharmaceuticals Inc.	753,972,000	636,458,000	33,023,000	94,325,000	0.52	1.55
15	United Therapeutics Corp.	743,183,000	592,899,000	217,868,000	105,916,000	3.67	1.78
16	Amylin Pharmaceuticals Inc.	650,678,000	668,813,000	(543,399,000)	(152,313,000)	(3.73)	(1.06)
17	ViroPharma Inc.	544,374,000	439,012,000	140,659,000	125,608,000	1.68	1.47
18	The Medicines Co.	484,732,000	437,645,000	127,877,000	104,635,000	2.35	1.97
19	Onyx Pharmaceuticals Inc.	447,174,000	324,515,000	76,110,000	(84,847,000)	1.19	(1.35)
20	Regeneron Pharmaceuticals Inc.	445,824,000	459,074,000	(221,760,000)	(104,468,000)	(2.45)	(1.26)
21	BioMarin Pharmaceutical Inc.	441,358,000	376,267,000	(53,836,000)	205,819,000	(0.48)	1.73
22	Biocon Ltd.	426,499,350	558,737,975	67,112,095	73,068,790	0.34	0.37
23	Alkermes Inc.	389,977,000	186,640,000	(113,678,000)	(45,540,000)	(0.99)	(0.48)
24	PDL BioPharma Inc.	362,041,000	344,975,000	199,389,000	91,874,000	1.15	0.54
25	Dendreon Corp.	341,613,000	48,057,000	(337,806,000)	(439,480,000)	(2.31)	(3.18)
26	Acorda Therapeutics Inc.	292,237,000	191,005,000	30,605,000	(11,769,445)	0.76	(0.31)
27	Exelixis Inc.	289,636,000	185,045,000	75,697,000	(92,330,000)	0.58	(0.85)
28	Emergent BioSolutions Inc.	273,384,000	286,171,000	23,019,000	51,698,000	0.64	1.59
29	Questcor Pharmaceuticals Inc.	218,169,000	115,131,000	79,591,000	35,071,000	1.21	0.54
30	Spectrum Pharmaceuticals Inc.	192,963,000	74,113,000	48,517,000	(48,844,000)	0.84	(0.99)
31	Cangene Corp.	149,707,000	150,471,000	1,509,000	16,467,000	0.02	0.24
32	Optimer Pharmaceuticals Inc.	144,978,373	1,480,362	7,821,624	(47,339,742)	0.17	(1.25)
33	MorphoSys AG	140,392,657	121,250,281	11,446,263	12,811,366	0.50	0.56
34	SciClone Pharmaceuticals Inc.	133,641,000	85,112,000	28,464,000	21,081,000	0.50	0.43
35	Galapagos NV	133,580,180	170,529,371	(46,107,431)	6,087,847	(1.74)	0.24
36	Human Genome Sciences Inc.	130,975,000	157,351,000	(381,106,000)	(233,231,000)	(1.97)	(1.24)
37	Zeltia SA	112,334,012 (biopharma only)	110,667,864 (biopharma only)	6,604,687	(10,240,678)	0.03	(0.04)
38	Enzo Biochem Inc.	102,029,000	97,082,000	(12,960,000)	(22,233,000)	(0.34)	(0.59)
39	NPS Pharmaceuticals Inc.	101,645,000	89,414,000	(36,267,000)	(31,441,000)	(0.45)	(0.54)
40	Isis Pharmaceuticals Inc.	99,086,000	108,473,000	(84,801,000)	(61,251,000)	(0.85)	(0.62)
41	Bavarian Nordic AS	97,805,361	58,666,667	(50,139,348)	(72,832,913)	(2.41)	(3.51)
42	Targacept Inc.	97,637,000	85,713,000	(8,529,000)	10,899,000	(0.27)	0.36
43	Seattle Genetics Inc.	94,778,000	107,470,000	(152,030,000)	(66,265,000)	(1.34)	(0.66)
44	Progenics Pharmaceuticals Inc.	84,796,000	7,952,000	10,381,000	(69,725,000)	0.31	(2.14)
45	Alnylam Pharmaceuticals Inc.	82,757,000	100,041,000	(57,649,000)	(43,515,000)	(1.36)	(1.04)
46	Neurocrine Biosciences Inc.	77,413,000	33,501,000	37,571,000	(7,968,000)	0.67	(0.15)
47	Array BioPharma Inc.	71,901,000	53,880,000	(56,324,000)	(77,631,000)	(1.02)	(1.55)
48	Nektar Therapeutics	71,480,000	159,039,000	(133,978,000)	(37,938,000)	(1.19)	(0.40)
49	Medivir AB	66,636,148	11,146,922	23,674,127	(20,920,959)	0.59	(0.84)
50	Genmab AS	65,552,629	108,728,309	(111,397,777)	(60,045,951)	(2.48)	(1.34)
51	Anika Therapeutics Inc.	64,778,635	55,556,594	8,466,680	4,315,995	0.62	0.32
52	AMAG Pharmaceuticals Inc.	61,249,000	66,245,000	(77,069,000)	(81,153,000)	(3.64)	(3.90)
53	Xoma Corp.	58,196,000	33,641,000	(32,743,000)	(68,756,000)	(1.04)	(3.69)
54	Sinovac Biotech Ltd.	56,841,892	33,401,426	(844,696,000)	(8,507,344)	(0.02)	(0.16)
55	Halozyme Therapeutics Inc.	56,086,436	13,624,115	(19,769,851)	(53,241,650)	(0.19)	(0.56)
56	Vitrolife AB	54,889,947	45,865,316	4,723,327	4,497,981	0.24	0.23
57	Lee's Pharmaceutical Holdings Ltd.	51,346,334	32,863,144	10,794,311	7,441,066	2.25	1.60
58	Dyax Corp.	48,737,000	51,399,000	(34,599,000)	(24,503,000)	(0.35)	(0.26)
59	Enzon Pharmaceuticals Inc.	48,072,000	97,865,000	(20,763,000)	177,243,000	(0.40)	3.03
60	ArQule Inc.	47,310,000	29,221,000	(10,762,000)	(30,129,000)	(0.20)	(0.68)
61	AVI BioPharma Inc.	46,990,000	29,420,000	(2,318,000)	(32,177,000)	(0.02	(0.29)
62	Intercell AG	45,810,700	47,664,917	(40,769,072)	(355,494,044)	(0.85)	(7.37)
63	Diamyd Medical AB	43,888,073	17,668,907	16,034,078	(51,899)	0.55	(0.00)

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REVENUE — TOP 100 BIOTECHNOLOGY COMPANIES

Rank in 2011	Company	Revenue in 2011	Revenue in 2010	Net Income/(Loss) in 2011	Net Income/(Loss) in 2010	Earnings/(Loss) Per Share in 2011	Earnings/(Loss) Per Share in 2010
64	QLT Inc.	42,228,000	44,697,000	(30,416,000)	(17,539,000)	(0.61)	(0.33)
65	Osiris Therapeutics Inc.	41,140,000	43,021,000	14,892,000	13,125,000	0.45	0.40
66	Bioniche Life Sciences Inc.	36,907,639	46,998,771	(15,703,461)	(1,628,097)	(0.17)	(0.02)
67	Active Biotech AB	36,159,099	1,750,362	(14,573,507)	(34,073,954)	(0.21)	(0.52)
68	AEterna Zentaris Inc.	36,053,000	27,703,000	(29,191,000)	(27,259,000)	(0.29)	(0.38)
69	Cerus Corp.	33,044,000	23,109,000	(16,982,000)	(16,911,000)	(0.35)	(0.42)
70	Flamel Technologies SA	32,600,000	37,094,000	(8,774,000)	(8,975,000)	(0.36)	(0.37)
71	Vanda Pharmaceuticals Inc.	31,270,000	35,709,000	(9,802,000)	7,192,000	(0.35)	0.25
72	Transition Therapeutics Inc.	30,382,091	4,611,808	13,212,148	(19,771,565)	0.57	(0.85)
73	Ligand Pharmaceuticals Inc.	30,037,000	23,538,000	10,176,000	(10,373,000)	0.52	(0.53)
74	Vical Inc.	30,018,000	8,711,000	(7,283,000)	(30,385,000)	(0.10)	(0.51)
75	InterMune Inc.	25,630,000	259,291,000	(154,774,000)	122,374,000	(2.58)	2.13
76	PharmAthene Inc.	24,266,274	20,993,605	(3,797,573)	(34,849,277)	(0.08)	(1.08)
77	Repligen Corp.	23,450,247	21,384,639	(1,612,625)	1,987,178	(0.05)	0.06
78	Dynavax Technologies Corp.	21,614,000	23,950,000	(48,597,000)	(57,308,000)	(0.39)	(0.69)
79	Unigene Laboratories Inc.	20,508,346	11,340,214	(17,925,659)	(27,868,494)	(0.19)	(0.30)
80	Transgene SA	20,124,723	19,659,427	(60,775,381)	(47,670,489)	(1.92)	(1.73)
81	BioCryst Pharmaceuticals Inc.	19,643,000	62,381,336	(56,948,000)	(33,853,183)	(1.26)	(0.76)
82	Bionor Pharma ASA	19,545,714	2,247,510	8,756,560	(8,470,779)	0.05	(0.05)
83	Vernalis Plc.	19,508,288	22,776,247	(12,313,003)	(31,538,934)	(12.35)	(33.85)
84	ImmunoGen Inc.	19,305,000	13,943,000	(58,274,000)	(50,912,000)	(0.85)	(0.87)
85	GenVec Inc.	17,744,000	16,467,000	(7,441,000)	(12,274,000)	(0.58)	(0.10)
86	Tekmira Pharmaceuticals Corp.	16,837,203	21,598,806	(10,050,497)	(12,557,378)	(0.89)	(1.21)
87	SciGen Ltd.	16,675,000	12,369,000	(17,728,000)	(7,702,000)	(0.03)	(0.02)
88	Innate Pharma SA	16,354,994	6,018,192	(9,723,838)	(19,026,960)	(0.26)	(0.50)
89	Biota Holdings Ltd.	15,506,129	71,760,303	(29,823,153)	17,236,700	(16.35)	0.10
90	Nabi Biopharmaceuticals	14,838,000	35,005,000	(4,531,000)	878,000	(0.11)	0.02
91	Curis Inc.	14,762,580	15,999,565	(9,858,895)	(4,435,310)	(0.13)	(0.06)
92	GTx Inc.	14,739,000	60,613,000	(33,294,000)	15,294,000	(0.58)	0.39
93	Immunomedics Inc.	14,709,479	60,930,342	(15,070,421)	36,996,226	(0.20)	0.49
94	Novavax Inc.	14,688,000	343,000	(19,364,000)	(35,708,000)	(0.17)	(0.34)
95	Theratechnologies Inc.	14,566,603	31,096,496	(19,364,000)	8,015,144	(0.28)	0.15
96	Siga Technologies Inc.	12,725,792	19,215,837	13,594,176	(28,195,339)	0.09	(0.62)
97	Arena Pharmaceuticals Inc.	12,719,000	16,613,000	(109,224,000)	(124,534,000)	(0.80)	(1.14)
98	Oxford Biomedica Plc.	12,381,987	17,892,758	(20,263,913)	(16,508,247)	(2.17)	(3.03)
99	TopoTarget AS	12,253,292	20,141,216	(6,166,246)	(10,402,354)	(0.05)	(0.08)
100	Pain Therapeutics Inc.	11,484,000	16,809,000	(2,613,000)	(12,023,000)	(0.06)	(0.28)

Sources: eKnowledgeBase.com and company documents

Notes to pages 14, 16, 18, 19, and 22 charts: Some of these notes pertain to listings in *Med Ad News'* June 2011 top 100 biotechnology company report. The following companies are new to *Med Ad News'* top 100 biotechnology company ranking for the 2011 financial year: Active Biotech AB, Bionor Pharma ASA, Galapagos NV, Grifols SA, GTx Inc., Innate Pharma SA, Ipsen Group, Lee's Pharmaceutical Holdings Ltd., Novavax Inc., Optimer Pharmaceuticals Inc., Progenics Pharmaceuticals Inc., Tekmira Pharmaceuticals Corp., Transition Therapeutics Inc., Vical Inc., Zeltia SA.

Adolor Corp., No. 59 on last year's top 100 biotechnology revenue list, was acquired by Cubist Pharmaceuticals Inc. in December 2011.

Alkermes 2011 figures are for the fiscal year ended March 31, 2012. Alkermes 2010 figures are for the fiscal year ended March 31, 2011.

Antisoma Plc. (antisoma.com), No. 70 on last year's top 100 biotechnology revenue list, did not generate enough revenue in 2011 to make this year's top 100 ranking.

Array BioPharma 2011 figures are for the fiscal year ended June 30, 2011. Array 2010 figures are for the fiscal year ended June 30, 2010.

Biocon 2011 figures are for the fiscal year ended March 31, 2012. Biocon 2010 figures are for the fiscal year ended March 31, 2011.

Bioniche Life Sciences 2011 figures are for the fiscal year ended June 30, 2011. Bioniche 2010 figures are for the fiscal year ended June 30, 2010.

Biota Holdings 2011 figures are for the fiscal year ended June 30, 2011. Biota 2010 figures are for the fiscal year ended June 30, 2010.

Cangene 2011 figures are for the fiscal year ended July 31, 2011. Cangene 2010 figures are for the fiscal year ended July 31, 2010.

Celldex Therapeutics Inc. (celldextherapeutics.com), No. 54 on last year's top 100 biotechnology revenue list, did not generate enough revenue in 2011 to make this year's top 100 ranking.

Cephalon Inc. (cephalon.com), No. 9 on last year's top 100 biotechnology revenue list, was acquired by Teva Pharmaceutical Industries Ltd. in October 2011.

Cleveland BioLabs Inc. (cbiolabs.com), No. 92 on last year's top 100 biotechnology revenue list, did not generate enough revenue in 2011 to make this year's top 100 ranking.

CSL 2011 figures are for the fiscal year ended June 30, 2011. CSL 2010 figures are for the fiscal year ended June 30, 2010.

Cytos Biotechnology AG (cytos.com), No. 82 on last year's top 100 biotech company list, did not generate enough revenue in 2011 to make this year's top 100 ranking.

Diamyd Medical 2011 figures are for the fiscal year ended Aug. 31, 2011.
Diamyd 2010 figures are for the fiscal year ended August 31, 2010.

Enzo Biochem 2011 figures are for the fiscal year ended July 31, 2011. Enzo 2010 figures are for the fiscal year ended July 31, 2010.

Genzyme Corp. (genzyme.com), No. 6 on last year's top 100 biotechnology revenue list, was acquired by Sanofi SA in April 2011.

ImmunoGen 2011 figures are for the fiscal year ended June 30, 2011.
ImmunoGen 2010 figures are for the fiscal year ended June 30, 2010.

Immunomedics 2011 figures are for the fiscal year ended June 30, 2011.
Immunomedics 2010 figures are for the fiscal year ended June 30, 2010.

Maxygen Inc. (maxygen.com), No. 62 on last year's top 100 biotechnology revenue list, did not generate enough revenue in 2011 to make this year's top 100 ranking.

Micromet Inc., No. 73 on last year's top 100 biotech company list, was acquired by Amgen Inc. in March 2012.

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RESEARCH & DEVELOPMENT — TOP 100 BIOTECHNOLOGY COMPANIES

Rank in 2011	Company	R&D expense in 2011	R&D expense in 2010
1	Roche	$9,395,170,390 (for entire Roche Group)	$11,313,473,257 (for entire Roche Group)
2	Amgen Inc.	3,167,000,000	2,894,000,000
3	Celgene Corp.	1,600,264,000	1,128,495,000
4	Gilead Sciences Inc.	1,229,151,000	1,072,930,000
5	Biogen Idec Inc.	1,219,602,000	1,248,604,000
6	UCB SA	1,086,618,000	982,135,500
7	Vertex Pharmaceuticals Inc.	707,706,000	637,416,000
8	Regeneron Pharmaceuticals Inc.	529,506,000	489,252,000
9	Actelion Ltd.	516,464,681	546,466,937
10	Ipsen Group	353,290,160	308,014,410
11	CSL Ltd.	345,052,500	336,263,747
12	Onyx Pharmaceuticals Inc.	268,060,000	185,740,000
13	Elan Corp.	232,500,000	258,700,000
14	BioMarin Pharmaceutical Inc.	214,374,000	147,309,000
15	Human Genome Sciences Inc.	196,182,000	196,370,000
16	Cubist Pharmaceuticals Inc.	184,533,000	157,854,000
17	United Therapeutics Corp.	180,015,000	165,306,000
18	Seattle Genetics Inc.	163,396,000	146,410,000
19	Amylin Pharmaceuticals Inc.	161,215,000	183,083,000
20	Isis Pharmaceuticals Inc.	157,397,000	145,160,000
21	Exelixis Inc.	156,836,000	210,678,000
22	Alkermes Inc.	141,893,000	97,239,000
23	Alexion Pharmaceuticals Inc.	137,421,000	98,394,000
24	Nektar Therapeutics	126,766,000	108,065,000
25	Emergent BioSolutions Inc.	124,832,000	89,295,000
26	Galapagos NV	117,661,226	117,924,522
27	The Medicines Co.	110,180,000	85,241,000
28	Grifols SA	106,850,770	50,987,460
29	Genmab AS	99,468,946	108,809,564
30	Alnylam Pharmaceuticals Inc.	99,295,000	106,384,000
31	Targacept Inc.	95,215,000	64,546,000
32	MorphoSys AG	80,071,405	65,336,004
33	Zeltia SA	78,933,046	77,563,629
34	InterMune Inc.	74,973,000	67,470,000
35	Dendreon Corp.	74,290,000	75,941,000
36	Transgene SA	73,901,169	59,236,005
37	NPS Pharmaceuticals Inc.	73,831,000	60,814,000
38	Xoma Corp.	68,137,000	77,413,000
39	AVI BioPharma Inc.	66,862,000	35,972,000
40	ViroPharma Inc.	66,477,000	39,613,000
41	Array BioPharma Inc.	63,498,000	72,488,000
42	ImmunoGen Inc.	63,453,000	50,280,000
43	Arena Pharmaceuticals Inc.	58,706,000	75,459,000
44	AMAG Pharmaceuticals Inc.	58,140,000	54,462,000
45	Halozyme Therapeutics Inc.	57,563,470	51,773,504
46	BioCryst Pharmaceuticals Inc.	56,898,000	82,473,014
47	Progenics Pharmaceuticals Inc.	53,183,000	50,640,000
48	Dynavax Technologies Corp.	51,322,000	53,680,000
49	Active Biotech AB	49,103,394	33,487,469
50	Bavarian Nordic AS	48,888,391	35,233,212
51	ArQule Inc.	45,011,000	47,034,000
52	QLT Inc.	43,533,000	33,485,000
53	Optimer Pharmaceuticals Inc.	43,085,307	32,797,672
54	Acorda Therapeutics Inc.	42,108,000	30,600,369
55	Intercell AG	41,691,304	104,120,294
56	Enzon Pharmaceuticals Inc.	41,106,000	57,018,000
57	Dyax Corp.	34,676,000	31,522,000
58	GTx Inc.	31,938,000	28,495,000
59	Neurocrine Biosciences Inc.	30,951,000	31,151,000
60	Vanda Pharmaceuticals Inc.	28,996,000	12,338,000
61	Oxford Biomedica Plc.	28,630,338	31,893,484
62	Medivir AB	28,370,788	23,443,694
63	Spectrum Pharmaceuticals Inc.	27,720,000	57,301,000
64	Biocon Ltd.	26,725,704	18,167,919
65	Flamel Technologies SA	25,089,000	28,687,000
66	AEterna Zentaris Inc.	24,517,000	21,257,000
67	Immunomedics Inc.	23,368,586	19,853,880
68	Biota Holdings Ltd.	21,958,079	21,958,079
69	Vernalis Plc.	21,839,336	34,442,717
70	PharmAthene Inc.	21,219,853	20,875,536
71	Innate Pharma SA	20,677,783	19,560,517
72	Tekmira Pharmaceuticals Corp.	20,126,397	22,386,956
73	Osiris Therapeutics Inc.	19,156,000	23,501,000
74	Siga Technologies Inc.	18,367,348	22,658,959
75	Bioniche Life Sciences Inc.	18,255,171	19,421,462
76	Vical Inc.	17,975,000	19,692,000
77	Novavax Inc.	17,885,000	28,032,000
78	Nabi Biopharmaceuticals	17,765,000	26,078,000
79	GenVec Inc.	17,416,000	20,936,000
80	Questcor Pharmaceuticals Inc.	16,778,000	10,934,000
81	Cangene Corp.	15,937,000	13,482,000
82	Diamyd Medical AB	15,003,283	12,637,955
83	Curis Inc.	13,692,659	11,372,850
84	SciClone Pharmaceuticals Inc.	12,346,000	12,415,000
85	Theratechnologies Inc.	10,725,891	13,723,519
86	Ligand Pharmaceuticals Inc.	10,291,000	22,067,000
87	TopoTarget AS	10,151,303	13,375,922
88	Repligen Corp.	9,461,960	8,744,54
89	Unigene Laboratories Inc.	9,015,749	6,428,041
90	Sinovac Biotech Ltd.	9,006,550	8,507,796
91	Pain Therapeutics Inc.	8,300,000	15,746,000
92	Transition Therapeutics Inc.	8,163,223	13,446,112
93	Enzo Biochem Inc.	7,806,000	9,704,000
94	Vitrolife AB	7,271,494	6,650,020
95	Cerus Corp.	7,178,000	5,195,000
96	Anika Therapeutics Inc.	6,168,937	6,874,633
97	Lee's Pharmaceutical Holdings Ltd.	1,520,407	718,131
98	SciGen Ltd.	139,000	236,000
—	PDL BioPharma Inc.	N/A	N/A
—	Bionor Pharma ASA	N/A	N/A

Sources: eKnowledgeBase.com and company documents

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NeuroSearch AS (neurosearch.com), No. 97 on last year's top 100 biotechnology revenue list, did not generate enough revenue in 2011 to make this year's top 100 ranking.

Palatin Technologies Inc. (palatin.com), No. 94 on last year's top 100 biotechnology revenue list, did not generate enough revenue in 2011 to make this year's top 100 ranking.

Repligen 2011 figures are for the nine-month period ended Dec. 31, 2011. Repligen 2010 figures are for the nine-month period ended Dec. 31, 2010. Repligen has changed its fiscal-year ending from March 31 to Dec. 31.

Synta Pharmaceuticals Corp. (syntapharma.com), No. 93 on last year's top 100 biotechnology revenue list, did not generate enough revenue in 2011 to make this year's top 100 ranking.

Talecris Biotherapeutics Inc., No. 11 on last year's top 100 biotechnology revenue list, was acquired by Grifols SA in June 2011. Grifols ranks No. 8 in this year's top 100 ranking.

Theratechnologies 2011 figures are for the fiscal year ended Nov. 30, 2011.
Theratechnologies 2010 figures are for the fiscal year ended Nov. 30, 2010.

Transition Therapeutics 2011 figures are for the fiscal year ended June 30, 2011. Transition Therapeutics 2010 figures are for the fiscal year ended June 30, 2010.

Trimeris Inc., No. 76 on last year's top 100 biotechnology revenue list, was acquired by Synageva BioPharma Corp. in November 2011.

Zalicus Inc. (zalicus.com), No. 55 on last year's top 100 biotechnology revenue list, did not generate enough revenue in 2011 to make this year's top 100 ranking.

Zeltia Inc. 2011 and 2010 revenue is for the company's biopharmaceutical business only and excludes its consumer chemicals segment.

LOCATION, YEAR ESTABLISHED — TOP 100 BIOTECHNOLOGY COMPANIES

UNITED STATES

State / Company, City	Year est.	Website
California		
Amgen Inc., Thousand Oaks	1980	amgen.com
Amylin Pharmaceuticals Inc., San Diego	1987	amylin.com
Arena Pharmaceuticals Inc., San Diego	1997	arenapharm.com
BioMarin Pharmaceutical Inc., Novato	1997	bmrn.com
Cerus Corp., Concord	1991	cerus.com
Dynavax Technologies Corp., Berkeley	1996	dynavax.com
Exelixis Inc., South San Francisco	1994	exelixis.com
Gilead Sciences Inc., Foster City	1987	gilead.com
Halozyme Therapeutics Inc., San Diego	1999	halozyme.com
InterMune Inc., Brisbane	1998	intermune.com
Isis Pharmaceuticals Inc., Carlsbad	1989	isispharm.com
Ligand Pharmaceuticals Inc., La Jolla	1987	ligand.com
Nektar Therapeutics, San Francisco	1990	nektar.com
Neurocrine Biosciences Inc., San Diego	1992	neurocrine.com
Onyx Pharmaceuticals Inc., South San Francisco	1992	onyx-pharm.com
Optimer Pharmaceuticals Inc., San Diego	1998	optimerpharma.com
Questcor Pharmaceuticals Inc., Anaheim Hills	1990	questcor.com
SciClone Pharmaceuticals Inc., Foster City	1989	sciclone.com
Vical Inc., San Diego	1987	vical.com
Xoma Corp., Berkeley	1981	xoma.com
Colorado		
Array BioPharma Inc., Boulder	1998	arraybiopharma.com
Connecticut		
Alexion Pharmaceuticals Inc., Cheshire	1992	alexionpharm.com
Maryland		
Emergent BioSolutions Inc., Rockville	2004	emergentbiosolutions.com
GenVec Inc., Gaithersburg	1992	genvec.com
Human Genome Sciences Inc., Rockville	1992	hgsi.com
Nabi Biopharmaceuticals, Rockville	1969	nabi.com
Novavax Inc., Rockville	1987	novavax.com
Osiris Therapeutics Inc., Columbia	1992	osiris.com
PharmAthene Inc., Annapolis	2001	pharmathene.com
United Therapeutics Corp., Silver Spring	1996	unither.com
Vanda Pharmaceuticals Inc., Rockville	2003	vandapharma.com
Massachusetts		
Alkermes Inc., Waltham	1987	alkermes.com
Alnylam Pharmaceuticals Inc., Cambridge	2002	alnylam.com
AMAG Pharmaceuticals Inc., Lexington	1981	amagpharma.com
Anika Therapeutics Inc., Bedford	1993	anikatherapeutics.com
ArQule Inc., Woburn	1993	arqule.com
Biogen Idec Inc., Weston	2003	biogenidec.com
Cubist Pharmaceuticals Inc., Lexington	1992	cubist.com
Curis Inc., Lexington	2000	curis.com
Dyax Corp., Cambridge	1989	dyax.com
ImmunoGen Inc., Waltham	1981	immunogen.com

UNITED STATES

State / Company, City	Year est.	Website
Repligen Corp., Waltham	1981	repligen.com
Vertex Pharmaceuticals Inc., Cambridge	1989	vrtx.com
Nevada		
PDL BioPharma Inc., Incline Village	1986	pdl.com
Spectrum Pharmaceuticals Inc., Henderson	1987	spectrumpharm.com
New Jersey		
Celgene Corp., Summit	1980	celgene.com
Enzon Pharmaceuticals Inc., Piscataway	1981	enzon.com
Immunomedics Inc., Morris Plains	1982	immunomedics.com
NPS Pharmaceuticals Inc., Bedminster	1986	npsp.com
The Medicines Co., Parsippany	1996	themedicinescompany.com
Unigene Laboratories Inc., Boonton	1980	unigene.com
New York		
Acorda Therapeutics Inc., Hawthorne	1995	acorda.com
Enzo Biochem Inc., New York	1976	enzo.com
Regeneron Pharmaceuticals Inc., Tarrytown	1988	regeneron.com
Siga Technologies Inc., New York	1995	siga.com
Progenics Pharmaceuticals Inc., Tarrytown	1986	progenics.com
North Carolina		
BioCryst Pharmaceuticals Inc., Durham	1986	biocryst.com
Targacept Inc., Winston-Salem	1997	targacept.com
Pennsylvania		
ViroPharma Inc., Exton	1994	viropharma.com
Tennessee		
GTx Inc., Memphis	1997	gtxinc.com
Texas		
Pain Therapeutics Inc., Austin	1998	paintrials.com
Washington		
AVI BioPharma Inc., Bothell	1980	avibio.com
Dendreon Corp., Seattle	1992	dendreon.com
Seattle Genetics Inc., Bothell	1997	seagen.com

OTHER COUNTRIES

Country / Company, City	Year est.	Website
Australia		
Biota Holdings Ltd., Notting Hill	1985	biota.com.au
CSL Ltd., Parkville	1916	csl.com.au
Austria		
Intercell AG, Vienna	1998	intercell.com
Belgium		
Galapagos NV, Mechelen	1999	glpg.com
UCB SA, Brussels	1928	ucb-group.com
Canada		
AEterna Zentaris Inc., Quebec City	1991	aeternazentaris.com
Bioniche Life Sciences Inc., Belleville	1979	bioniche.com
Cangene Corp., Winnipeg	1984	cangene.com
QLT Inc., Vancouver	1981	qltinc.com
Tekmira Pharmaceuticals Corp., Burnaby	1992	tekmirapharm.com
Theratechnologies, Montreal	1993	theratech.com
Transition Therapeutics Inc., Toronto	1998	transitiontherapeutics.com
China		
Sinovac Biotech Ltd., Beijing	1993	sinovac.com
Denmark		
Bavarian Nordic AS, Kvistgaard	1994	bavarian-nordic.com
Genmab AS, Copenhagen K	1999	genmab.com
TopoTarget AS, Copenhagen	2002	topotarget.com
France		
Flamel Technologies SA, Venissieux	1990	flamel.com
Innate Pharma SA, Marseilles	1999	innate-pharma.com
Ipsen Group, Boulogne-Billancourt	1929	ipsen.com
Transgene SA, Illkirch-Graffenstaden Cedex	1979	transgene.fr
Germany		
MorphoSys AG, Martinsried/Planegg	1992	morphosys.com
Hong Kong		
Lee's Pharmaceutical Holdings Ltd., Shatin	1994	leespharm.com
India		
Biocon Ltd., Bangalore	1978	biocon.com
Ireland		
Elan Corp., Dublin	1969	elan.com
Norway		
Bionor Pharma ASA, Oslo	2000	bionorimmuno.com
Singapore		
SciGen Ltd.	1988	scigenltd.com
Spain		
Grifols SA, Barcelona	1940	grifols.com
Zeltia SA, Madrid	1939	zeltia.com
Sweden		
Active Biotech AB, Lund	1983	activebiotech.com
Diamyd Medical AB, Stockholm	1996	diamyd.com
Medivir AB, Stockholm	1988	medivir.se
Vitrolife AB, Västra Frölunda	1993	vitrolife.com
Switzerland		
Actelion Ltd., Allschwil	1997	actelion.com
Roche, Basel	1896	roche.com
United Kingdom		
Oxford Biomedica Plc., Oxford	1995	oxfordbiomedica.co.uk
Vernalis Plc., Winnersh	1986	vernalis.com

POPULAR COUNTRIES AND STATES (three or more companies)

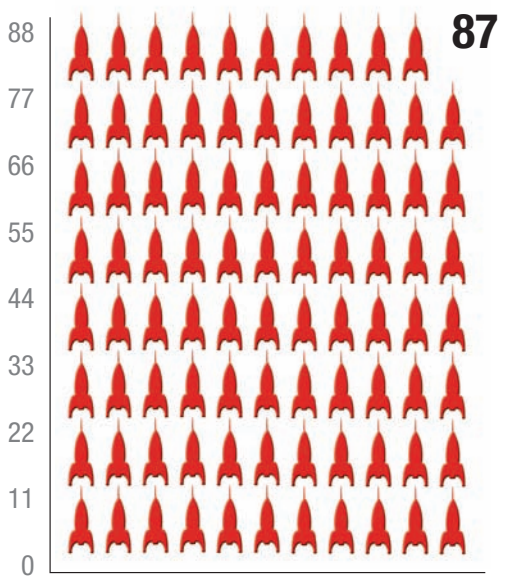
Country	Number of companies
United States	64
California	20
Massachusetts	12
Maryland	9
New Jersey	6
New York	5
Washington	3
Canada	7
France	4
Sweden	4
Denmark	3

POPULAR CITIES (three or more companies)

City	Number of companies
San Diego	6
Rockville, Md.	5
Cambridge, Mass.	3
Lexington, Mass.	3
Waltham, Mass.	3

Sources: eKnowledgeBase.com and company documents

Get the most out of your launch.



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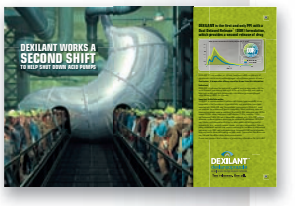
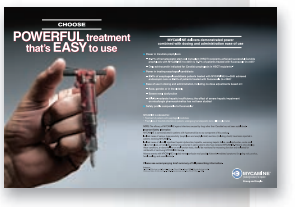




AbelsonTaylor
Extra-strength branding

EMPLOYEES — TOP 100 BIOTECHNOLOGY COMPANIES

Rank in 2011	Company	Employees in 2011	Employees in 2010
1	Roche	80,129 (for entire Roche Group)	80,653 (for entire Roche Group)
2	Amgen Inc.	17,800	17,400
3	Grifols SA	11,259	6,108
4	CSL Ltd.	10,000+	10,000+
5	UCB SA	8,506	8,898
6	Biocon Ltd.	6,200+	5,500
7	Biogen Idec Inc.	5,000	4,850
8	Gilead Sciences Inc.	4,500	4,000
9	Ipsen Group	4,479	4,489
10	Celgene Corp.	4,460	4,182
11	Actelion Ltd.	2,570	2,462
12	Vertex Pharmaceuticals Inc.	2,000	1,691
13	Regeneron Pharmaceuticals Inc.	1,704	1,395
14	Dendreon Corp.	1,475	1,497
15	Amylin Pharmaceuticals Inc.	1,300	1,400
16	Alkermes Inc.	1,200	600
17	Human Genome Sciences Inc.	1,100	1,100
18	Alexion Pharmaceuticals Inc.	1,008	792
19	BioMarin Pharmaceutical Inc.	1,002	871
20	SciClone Pharmaceuticals Inc.	875	261
21	Galapagos NV	835	815
22	Emergent BioSolutions Inc.	811	767
23	Cangene Corp.	700	800
24	Zeltia SA	688	697
25	Cubist Pharmaceuticals Inc.	669	638
26	Sinovac Biotech Ltd.	614	483
27	United Therapeutics Corp.	543	520
28	Enzo Biochem Inc.	535	527
29	Lee's Pharmaceutical Holdings Ltd.	498	440
30	Seattle Genetics Inc.	483	348
31	MorphoSys AG	446	464
32	Nektar Therapeutics	423	408
33	The Medicines Co.	421	420
34	Onyx Pharmaceuticals Inc.	420	299
35	Elan Corp.	400+	1,219
36	Intercell AG	343	408
37	Acorda Therapeutics Inc.	328	305
38	Bavarian Nordic AS	311	412
38	ViroPharma Inc.	311	232
40	Isis Pharmaceuticals Inc.	281	270
41	Optimer Pharmaceuticals Inc.	278	87
42	Flamel Technologies SA	267	N/A
43	Arena Pharmaceuticals Inc.	266	351
44	Array BioPharma Inc.	259	340
45	ImmunoGen Inc.	248	211
46	Transgene SA	235	N/A
47	Bioniche Life Sciences Inc.	231	211
48	Vitrolife AB	220	220
49	Questcor Pharmaceuticals Inc.	206	152
50	InterMune Inc.	201	105
51	Exelixis Inc.	200	383
52	Xoma Corp.	188	230
52	QLT Inc.	188	172
54	Genmab AS	179	189
55	Spectrum Pharmaceuticals Inc.	176	139
56	AMAG Pharmaceuticals Inc.	174	226
57	Medivir AB	170	77
58	Dynavax Technologies Corp.	150	128
59	Targacept Inc.	142	132
60	Repligen Corp.	137	66
61	Halozyme Therapeutics Inc.	135	102
62	Anika Therapeutics Inc.	129	114
63	Enzon Pharmaceuticals Inc.	126	126
64	Immunomedics Inc.	121	122
65	Dyax Corp.	120	137
66	Alnylam Pharmaceuticals Inc.	115	172
67	Vical Inc.	112	114
67	Novavax Inc.	112	88
69	Progenics Pharmaceuticals Inc.	105	159
70	ArQule Inc.	103	115
71	AVI BioPharma Inc.	98	98
71	Oxford Biomedica Plc.	98	75
73	GTx Inc.	90	111
74	AEterna Zentaris Inc.	89	88
75	NPS Pharmaceuticals Inc.	86	63
76	Vernalis Plc.	84	84
77	Cerus Corp.	82	79
78	Active Biotech AB	80	87
78	Innate Pharma SA	80	86
80	GenVec Inc.	78	83
81	BioCryst Pharmaceuticals Inc.	75	76
82	Tekmira Pharmaceuticals Corp.	74	94
83	PharmAthene Inc.	73	85
84	Neurocrine Biosciences Inc.	71	66
85	Siga Technologies Inc.	68	65
86	Unigene Laboratories Inc.	57	68
87	Osiris Therapeutics Inc.	54	56
88	TopoTarget AS	42	50
89	Vanda Pharmaceuticals Inc.	38	28
90	Curis Inc.	35	32
91	Diamyd Medical AB	29	24
92	Ligand Pharmaceuticals Inc.	21	31
93	Transition Therapeutics Inc.	20	28
94	Bionor Pharma ASA	17	20
95	Nabi Biopharmaceuticals	16	35
96	Pain Therapeutics Inc.	10	18
97	PDL BioPharma Inc.	10-	8
—	Biota Holdings Ltd.	N/A	N/A
—	SciGen Ltd.	N/A	N/A
—	Theratechnologies Inc.	N/A	N/A

Sources: eKnowledgeBase.com and company documents

The patient journey, re-envisioned

Companies need to redo their traditional way of constructing patient journeys, and use comprehensive methods to cover unmet needs, spot growth opportunities, and position their products in a more favorable way.

by Maneesh Gupta, Dr. Simone Seiter, and Healther von Allmen, IMS Consulting; and **Howard Jaffe**, TRiG

The "patient journey" is a description of how patients experience a disease or condition from their first awareness of symptoms through all stages of diagnosis and treatment; culminating in a cure, remission, or worsening of the condition and even death. For years, companies have built their patient journeys on data collected via primary research. However, brand strategies devised exclusively from patient journeys created this way will have significant gaps and not serve to maximize a brand's potential. Due to the long list of what, why, where, and how questions that must be answered before a company can devise an effective product strategy, most companies must first seek an understanding of the patient journey when a compound is in Phase II of clinical development. Additionally, because the market is dynamic, the understanding of it cannot be static. The patient journey should be revisited when launch is imminent and at least every two years once the product is on the market.

A more complete view of the patient journey will extend from disease awareness through final treatment, covering the current situation as well as how the treatment paradigm is likely to evolve in the next few years. This view will not only reveal what and how often it happens, but why – from the physician's and patient's perspectives. Obtaining such a comprehensive view requires multiple research sources and methods, such as secondary data, social media listening platforms, and projective research. With these comprehensive methods, companies can uncover unmet needs, spot growth opportunities, and position their products in ways that resonate favorably with providers and patients. Finally, brand teams need to figure out "where to add value" within the patient journey and use these findings to design strategies and tactics to win in the marketplace.

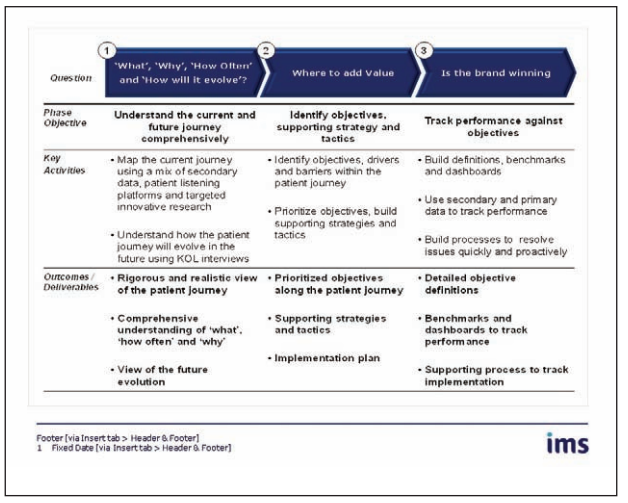
THE IMPORTANCE OF THE PATIENT JOURNEY

At each juncture along the way, the patient journey reflects the decisions made and hurdles faced by patients and providers, the rationale behind those decisions, and the emotions felt. A comprehensive depiction of the patient journey will provide both quantitative data surrounding each milestone on the journey and qualitative data on what patients, caregivers, and providers are thinking and feeling.

Conducting qualitative studies with a few dozen physicians followed by quantitative research with a hundred or so more is simply inadequate for building a successful product strategy. Too much is left unexplored, including the patient and payer perspective. For example, it's impossible to gain insight from physicians about the beginnings of the patient journey – before the patient presents in a consultation, or the aftermath of the physician visit.

The foundation for the brand's go-to-market strategy may therefore be skewed, sending a product in the wrong direction, or incomplete, preventing the product from realizing its full potential. Regardless of the quality of a company's research into the patient journey, many companies face another stumbling block in converting the brand strategy to deployable tactics. Often, opportunities are overlooked when objectives are set and the behavioral components are not tracked – even as the brand team focuses its resources on somewhat disconnected awareness, trial, and usage studies.

For many years, companies built their patient journeys on data collected via primary research with physicians. These studies, typically consisting of interviews with a few dozen physicians followed by a quantitative survey of a few hundred physicians, were at one time the soundest approach available. However, despite the fact that the market environment has evolved considerably, and patients, caregivers, and payers have become important decision makers, the approach to building and using patient journeys has stayed primarily the same. This introduces inherent shortcomings that limit usefulness in forming business-critical brand plans. Relying on decades-old approaches in building patient journeys is no longer acceptable. (See "Building the journey/using the journey" chart for an illustration of what can go wrong using the traditional patient journey method.)



Question	1 'What', 'Why', 'How Often' and 'How will it evolve'?	2 Where to add Value	3 Is the brand winning
Phase Objective	Understand the current and future journey comprehensively	Identify objectives, supporting strategy and tactics	Track performance against objectives
Key Activities	• Map the current journey using a mix of secondary data, patient listening platforms and targeted innovative research • Understand how the patient journey will evolve in the future using KOL interviews	• Identify objectives, drivers and barriers within the patient journey • Prioritize objectives, build supporting strategies and tactics	• Build definitions, benchmarks and dashboards • Use secondary and primary data to track performance • Build processes to resolve issues quickly and proactively
Outcomes / Deliverables	• Rigorous and realistic view of the patient journey • Comprehensive understanding of 'what', 'how often' and 'why' • View of the future evolution	• Prioritized objectives along the patient journey • Supporting strategies and tactics • Implementation plan	• Detailed objective definitions • Benchmarks and dashboards to track performance • Supporting process to track implementation

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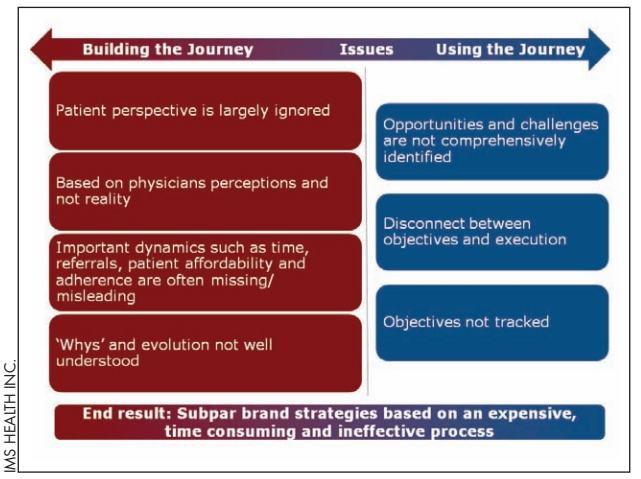

IMS HEALTH INC.

Mistakes made at the beginning of tracking the patient journey will result in a subpar marketing plan.

A NEW JOURNEY OF DISCOVERY

For the past decade, it has been possible to use a wealth of secondary data sources to analyze patients' touch points with providers – creating a map of how patients flow through the system from diagnosis through adherence. The input for these maps comes from diverse and rich databases, including EMR data from physician offices and hospitals, diagnostic data from labs, longitudinal patient-level databases and claims data covering diagnosis, treatment and adherence, and managed care data covering prescription fulfillment.

Drawing from an array of such robust databases that incorporate information on millions of de-identified patients and thousands of physicians and payers, one can quantify the treated patient population and various market dynamics. In addition to providing a standardized framework that is easier to refresh than primary research, it provides the most accurate view of actual patient behaviors. This research answers questions such as: "How many patients reach each step of the journey?", "Are there patients who never get drug treatment?", "How many patients move through multiple treatments and how quickly?", "Do patients fill their scripts and adhere to their treatment regimen?", and, "How does the cost burden influence patient behavior?", along with many others.

The rise of social networking has given patients an electronic avenue for practicing "peer-to-peer healthcare," the tendency of patients to "lend a hand, lend an ear, lend advice," using the speed and scale of the Internet. In fact, patients can become members of online communities through such sites as PatientsLikeMe.com, MedHelp.org, and CureTogether.com, which instantly connect them to fellow sufferers.

At minimum, companies can "listen in" to public conversations conducted via online forums to get a sense of what is on patients' minds. Ensuring, of course, that all laws and FDA guidelines are followed, companies can gain more systematic insight into conversations conducted in social media through data aggregator companies, which scan social media key words and then code and analyze them for trends.

Experiences, opinions, and decision making exist in two domains – the rational and emotional. Often, individuals are unaware of the important emotional drivers of their behaviors, as many act on a subconscious level, and influence the more easily observed rational processes. To understand the underlying emotional themes that drive patient and physician decisions it is generally necessary to use less direct research techniques. Under direct questioning, respondents do not always speak the truth. They can be embarrassed, they can anticipate the answer the interviewer is seeking, or they can be unaware of their inner emotions and only present rational explanations for their behavior.

One solution is to use projective research techniques, such as those employed in psychological diagnosis and assessment. These techniques prompt interviewees to project their feelings onto an ambiguous stimulus – such as an incomplete picture or story. When asked to draw themselves with cancer patients, oncologists drew dramatically different pictures at different stages in the disease progression. Initially, they showed themselves as holding the patient's hand. However, once the cancer had recurred, they added space between their figure's and the patient's. Once the tumor had metastasized, physicians stopped drawing the patient's facial features and portrayed the tumor as the patient's dominant feature. This reflected physicians' need to disengage emotionally as they lost control of their fight against the disease. Ultimately, the cancer came to define the patient in the physicians' eyes.

Even as brand teams conduct awareness, trial, and usage studies throughout the year, there is often not enough attention paid to tracking performance on behavioral objectives. Brand teams can follow five steps to ensure that the brand is winning in the marketplace: identify and define leverage points, e.g. patient adherence; design and implement tactics to influence, e.g. co-programs with hospitals and health systems, patient apps, and SMS reminders; develop methodology and definitions for performance tracking, including defining the targets, e.g. ensuring that 80 percent of patients stay on therapy after three months, as seen in longitudinal patient-level data; develop a dashboard for performance communication, e.g. looking at persistence curves on a monthly basis; and design and implement performance mitigation plan, e.g. e-mail blasts if persistence is below 70 percent after three months, and kick-off market research to understand why patients are not adherent. (See "Recommended approach to building and using the patient journey" chart for more information.)

USING THE PATIENT JOURNEY EFFECTIVELY

Although having a comprehensive patient journey in hand is essential to creating an effective brand strategy, that alone is no guarantee of success. Companies must translate the insights from the brand plan into a strategy and tactics that are implemented and measured. Most pharmaceutical companies do a decent job of identifying behavioral objectives in the patient journey and prioritizing them. However, when it comes to laying out action plans behind these behavioral objectives, IMS has seen several brand teams falter. Many times the patient journey effort is stopped prematurely after the behavioral objectives are identified. In reality, aligning on the behavioral objectives is just the foundation to winning in the marketplace.

The years immediately preceding a pharmaceutical product launch are arguably one of the riskiest periods in business. "Getting it right" has never been more essential – nor more challenging – given increasing development costs, shrinking pipelines, and growing patent losses. Even after launch, the amount of change in the marketplace dictates that brand teams must constantly refresh their understanding of current conditions and alter their strategy accordingly. ■ MEDADNEWS

BEYOND BIRTH CONTROL

Although recent news has focused on the politics of women's access to hormonal contraceptives and birth-control devices, experts say price, not politics, is what controls the women's healthcare market, and companies are reacting to genericization of this market by expanding their portfolios to products that will treat menopausal problems and other ailments of aging women.

by Christiane Truelove chris.truelove@ubm.com

Back in March, Rush Limbaugh illustrated the controversy over the provision of oral contraceptive products to all insured women with his attack on Georgetown University graduate student Sandra Fluke. The question of access to these products remains open. According to the Guttmacher Institute, as of June 1, 20 states allow certain employers and insurance to refuse to comply with the federal mandate that requires new private health plans written on or after August 1, 2012 to cover contraceptive counseling and services and all FDA-approved methods without out-of-pocket costs to patients.

Although the impact of these laws on at least the sales of hormonal contraceptives and emergency contraceptives will be unknown, between 2006 and 2011 sales of branded and unbranded oral contraceptive products grew from $2.96 billion to $3.51 billion, according to IMS Health. And Mary Grube, engagement manager, IMS Consulting Group, says though these state regulations may have a small impact on sales, ultimately it's the cost of these products to the end patient that will drive the contraceptive market.

"At the end of the day, it's not going to change the need for contraception," Ms. Grube says. "Most women understand the fact that whatever you have to do to access contraception, it's still a lot easier than dealing with an unplanned pregnancy."

According to IMS Health, the leading oral contraceptive in 2011 sales was **Loestrin 24 FE**, which is marketed by **Warner Chilcott** (warnerchilcott.com). Sales of this contraceptive were $565.2 million, and comprised 16.1 percent of the total market share. The drug generated $37.5 million in 2006.

The second-leading branded oral contraceptive in 2011 was **Ortho** Pharmaceuticals' **Ortho-Tri-Cyclen Lo**, generating $432.5 million in sales. The product held 12.3 percent of the 2011 market. In 2006, the drug had sales of $389.4 million and a 13 percent share of the market.

No. 3 in 2011 sales was **Teva** Pharmaceuticals' **Gianvi**, generating $281 million. Gianvi, which held 8 percent of the 2011 market, was launched in 2009.

Bayer's **Yaz-28** was the fourth-leading branded contraceptive in 2011, with sales of almost $148 million and a 4.2 percent market share. The product's peak was in 2009, with sales of $781.8 million and a 22.8 percent share of the market.

Ocella, also marketed by Teva (tevapharm.com), was the fifth best-selling branded oral contraceptive in 2011, with sales of $147.1 million and a 4.2 percent share of the market. The product's peak sales were in 2009, at $378 million, and an 11 percent share of the market.

Generic forms of hormonal contraceptives can be picked up for as little as $4 per prescription under Wal-Mart's pharmacy program. But those women without health insurance who can't afford the doctor's office fee to obtain a prescription may have to use OTC methods of contraception. And still others who are insured may decide to turn to the use of intrauterine devices such as **ParaGard** and **Mirena**.

"With OTC contraceptives, patients have easy access and they're relatively inexpensive, so I definitely think there would be an increase with those products," Ms. Grube says. "On the flip side, you may see an increase with ParaGard, with Mirena, because what's happening is you may have to shell out more money up front with the office visit, and to get the device inserted, but then you don't have to worry about it for five years. I think you would see more of an increase in those kinds of devices."

According to Ms. Grube, Bayer HealthCare, the marketer of Mirena, and Teva, the marketer of ParaGard, have done a "decent job of trying to assure women that these are not your mother's IUD kind of campaigns," but their promotion has not been as widespread as the campaigns for oral contraceptives. "I would expect those companies to jump on that boat and try to increase awareness around how today's IUDs are different than the ones used in the '60s and '70s, from an efficacy and safety standpoint, and try to play to potential customers that way," she says.

According to IMS Health, the leading intrauterine device in sales in 2011 was Mirena, which generated $457.6 million. The product held 99.2 percent of the IUD market. Mirena sales were $173.6 million in 2006.

ParaGard generated sales of $3.71 million, compared with sales of $1.7 million in 2006.

GENERICS FORCE A NEW DIRECTION

Ms. Grube points out with the heavy genericization of the oral contraceptive market, the leading women's healthcare companies are rethinking their strategies and are looking at the therapeutic needs of older women.

"Companies are looking at the expense that they are going to have to lay out to get into this different, but related, therapeutic area," she says. "I would definitely expect that companies may not be necessarily reformulating specific birth control products for other uses, but [they are] certainly taking some of those same parent compounds and trying to extend them, whether it be a vaginal cream or a vaginal gel, they're making vaginal rings for menopausal symptoms. You also have some companies that are trying to redevelop drugs that they are selling for depression, and trying to get them approved for hot flashes and other menopausal symptoms. So you're definitely seeing a trend that these companies that are involved in contraception, they're getting involved in the menopause space. Also extrapolating that into overactive bladder disorder, which many women start to suffer from as they age – you see companies that are definitely out in that area as well, Bayer is very active in that area."

Contraception, who cares?

By Peter Pitts

During an episode of "Mad Men," someone asks (apropos of an advertising campaign for pantyhose), "What do women want?" Strolling by, agency principal Roger Sterling quips, "Who cares?"

Who cares, indeed?

There's been a lot of news lately about pharmacists not wanting to be forced to dispense medicines about which they have moral objections, specifically **Plan B**, "the morning after pill." A thorny topic, to say the least. Yet, despite all the hoopla from the usual suspects, there has been total silence from an important voice in the debate – the pharmaceutical industry.

On the one hand, that's not surprising. Why, after all, would anyone want to interject themself into such a no-win, high stakes, high profile battle? But doesn't a manufacturer who makes a product have a responsibility to stand up and be counted when their product is under attack?

(And, let's face it, contraceptives are under attack. No value judgment here – just a fact.)

What? Pharma take a stand? Not only is this not unheard of, it is regular and accepted practice when scientific questions are raised. It is regular and accepted practice when safety and efficacy are debated. It is regular and accepted practice when legislative questions arise.

Here's a relevant example – pseudoephedrine. When many state and federal legislators wanted to ban (or severely restrict) the availability of many OTC products in order to address the scourge of methamphetamine (pseudoephedrine is a common ingredient, or "precursor," in the manufacture of methamphetamine) both manufacturers and their trade association (the Consumer Health Products Association) went on the offensive.

But, then again, there's no pro-meth lobby.

When it comes to pharmacists not wanting to dispense Plan B – there's nothing but silence from the manufacturer. Has Planned Parenthood approached **Teva** (the maker of Plan B) to enlist its support? If so, what explains the company's silence? And, if not – why not? Doesn't Teva have the courage to speak out in favor of its own product? When the initial Rx-to-OTC switch debate was raging, Barr Labs (subsequently purchased by Teva) was quite vocal in its support of Plan B as an avatar for reproductive rights. Today – silence. Qui tacet consentire videtur? Not likely. So why is mums the word?

Could it be that leveraging reproductive rights at FDA was in Barr's financial interest but that debating it "in the streets" isn't? Is Teva afraid (should they side with Planned Parenthood and other such organizations) that there might be a boycott against many of its other products?

Mums the word? Consider this couplet from Piers Plowman:

Thou mightiest beter meten the myst on Malverne hulles
Then geten a mom of heore mouth til moneye weore schewed!

That translates as, "You may as well try to measure the mist on the Malvern Hills as to try and get her to speak without first offering payment," or, in more modern parlance, "Show me the money."

Why the silence from Teva?

It's a shame and a sham that a principled stand on reproductive rights was silenced when it became associated with potential commercial risk – just as Secretary Sebelius' recent reversal of FDA on further Plan B access was done to mitigate potential political repercussions. When politics and profit come before the public health – bad things happen.

As my father used to say, "A principle doesn't count until it hurts."

Ouch.

Peter J. Pitts, a former FDA associate commissioner, is president of the Center for Medicine in the Public Interest.

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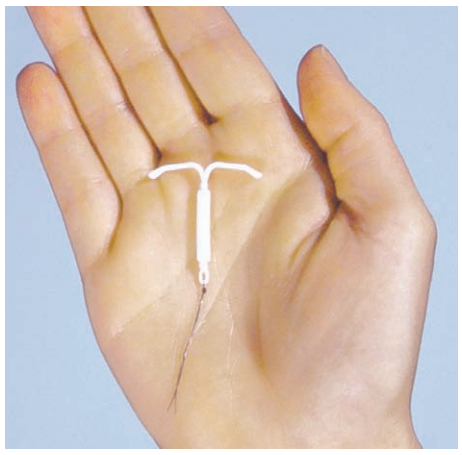
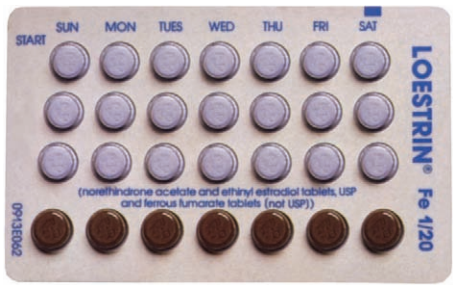


Mirena was the best-selling IUD in 2011, according to IMS Health.



Loestrin Fe was the best-selling contraceptive in 2011, according to IMS Health.

For example, in 2010, **Bayer Schering Pharma** (bayerhealthcare.com) signed an agreement with **EndoCeutics** Inc. (endoceutics.com), a Canadian company, to develop and market **dehydroepiandrosterone** (DHEA), for the treatment of vaginal atrophy and female sexual dysfunction. DHEA is an endogenous hormone secreted by the adrenal gland, and serves as precursor to male and female sex hormones (androgens and estrogens). DHEA levels in the body begin to decrease after age 30. The intravaginal formulation licensed to Bayer is known as **Vaginorm**.

"Vaginorm is an important late stage addition to our Gynecological Therapy R&D pipeline," says Phil Smits, head of Women's Healthcare at Bayer Schering Pharma. "We are pleased to work with EndoCeutics towards bringing a new treatment alternative for vaginal atrophy and female sexual dysfunction to an area of high unmet medical need."

EndoCeutics is developing an oral combination of DHEA and acolbifene called **Femivia**. The drug is being developed for the other problems of menopause such as bone loss, muscle loss, type 2 diabetes, fat accumulation, osteoporosis, hot flushes, skin atrophy, memory loss, cognition loss, and possibly Alzheimer's disease.

Bayer has two other women's health care products in its Phase III pipeline – **LCS 16** and **FC Patch Low** for contraception. In Phase I, Bayer is developing **S-PRAnt** for symptomatic uterine fibroids.

Pfizer Inc. (pfizer.com), after suffering a blow earlier this year when the company was forced to recall almost a million packets of birth control pills due to a manufacturing error, is continuing to develop a treatment for menopausal vasomotor symptoms. **Bazedoxifene-conjugated estrogens** is in Phase III clinical trials.

Companies are also focusing on new products to treat menopausal osteoporosis. **Amgen** Inc. (amgen.com) received approval for **Prolia** in 2010.

Eli **Lilly** and Co. (lilly.com) is developing **blozosumab** for the treatment of osteoporosis. Also known as LY2541546, blozosumab is a biologic entity that binds and neutralizes sclerostin. The drug is in Phase II clinical trials.

"Women who have needed a birth control pill for 30 years, now they're looking for an agent because they have vaginal atrophy and overactive bladder," Ms. Grube says. "As a company, you can develop a full women's health product line, to really start building up the relationship with these women when they are trying to prevent conception in their younger 20s, all the way up through post-menopause."

PLAN B UNDER FIRE

Teva's **Plan B One-Step** may be the women's health product whose sales are most affected by the "conscience" laws passed by states, which allow pharmacists or individual providers to not fill a prescription due to religious objections.

According to the Guttmacher Institute, as of June 1, 13 states allow some healthcare providers to refuse to provide services related to contraception; 10 states allow individual healthcare providers to refuse to provide services related to contraception; and six states explicitly permit pharmacists to refuse to dispense contraceptives (five additional states have broad refusal clauses that do not specifically include pharmacists, but may apply to them). Nine states allow healthcare institutions to refuse to provide services related to contraception, and five states limit the exemption to private entities.

Reports continue to arise of medical personnel refusing to provide emergency contracption. In February, a federal judge ruled that Washington state cannot require pharmacists to dispense emergency contraceptives to customers if doing so goes against their religious beliefs. Judge Ronald B. Leighton said the regulation that required pharmacists to do so was unconstitutional because it blocked pharmacists' right to "conscientious objection."

In 2011, a Sangamon County, Ill., circuit judge struck down a state rule that required pharmacies to dispense emergency contraception. According to the *State Journal-Register*, Judge John Belz ruled in favor of two pharmacy owners – Luke Vander Bleek of Morrison and Glenn Kosirog of Wheaton – who didn't want to dispense or stock Plan B or help patients fill a prescription elsewhere. Both pharmacy owners oppose emergency contraception on religious grounds.

Despite the lack of promotion and access in some areas of the United States, Plan B sales have been growing. According to IMS Health, in 2011, sales were $92.4 million, compared with $30.9 million in 2009. ■ MEDADNEWS

The price of an education

Industry influence on CME may have waned, but has not disappeared.

By Ed Silverman ed.silverman@ubm.com

Two years ago, Stanford University School of Medicine launched what was described as a novel effort to transform continuing medical education. Billed as a fundamental change, the university established what it called an "unbiased" program of postgraduate education on its campus, rather than a program of industry-selected topics that are typically presented to doctors at hotels and resorts.

The move came not long after Stanford also became one of the first medical schools in the country to restrict industry financing of continuing medical education programs by declining to accept funding for specific programs. Instead, drug makers were asked to contribute only to a school-wide pool of money that can be used for any class, even ones that never mention products.

However, the more recent Stanford effort was underwritten by a $3 million, three-year grant from **Pfizer**. The university defended the decision by maintaining the grant came with no conditions and the drug maker is not involved in developing curriculum. "We sought not to prevent partnerships with industry, but rather to redefine it," the medical school's associate dean for CME Robert Jackler said at the time.

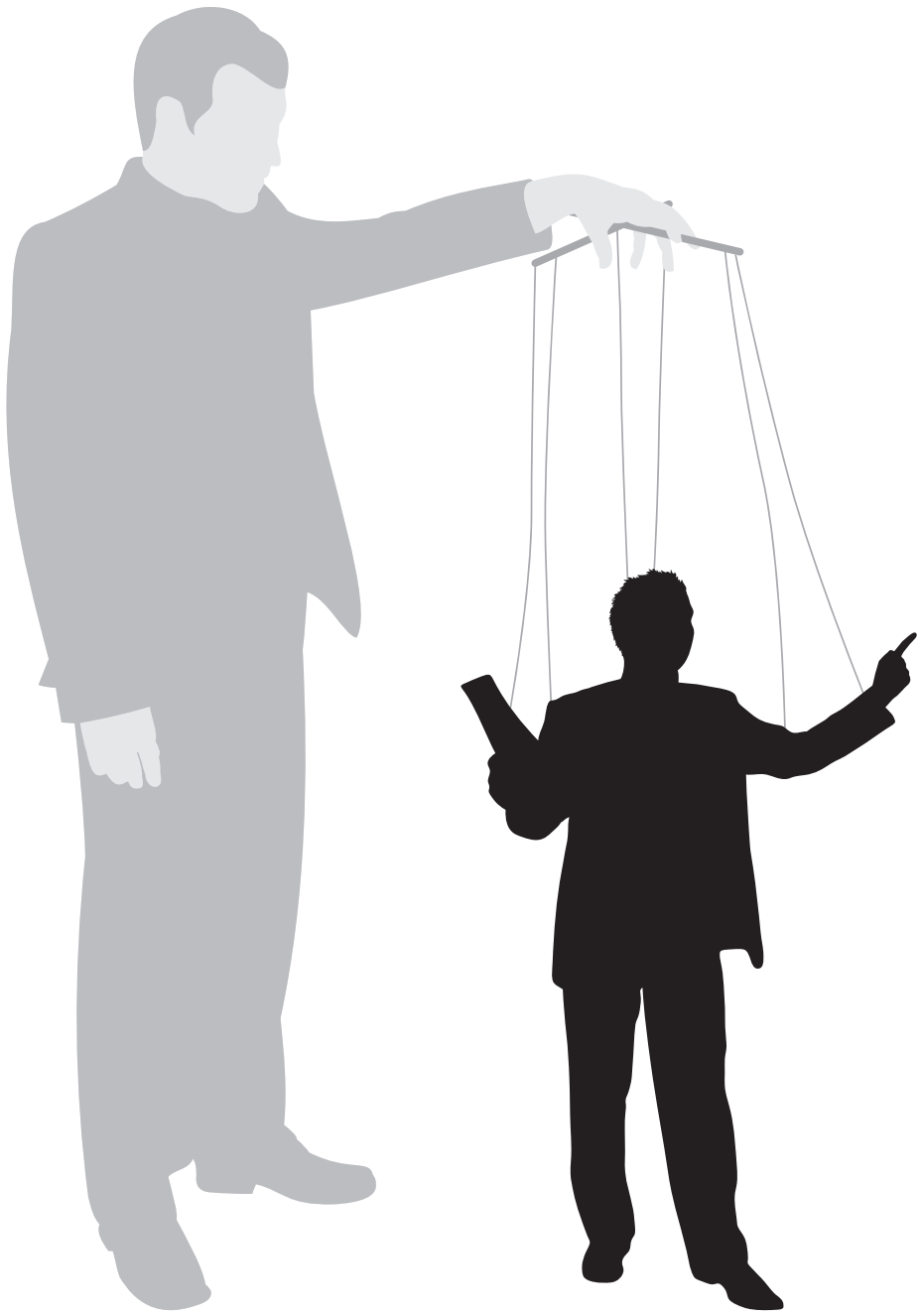
Nonetheless, the move was greeted, in part, with skepticism. Pfizer markets drugs in two of the four areas that a Stanford press release suggested might be pursued: smoking cessation and heart disease. "It still strikes me as satirical," says Adriane Fugh-Berman M.D., a Georgetown University medical professor who runs PharmedOut, a project that promotes "pharma-free" continuing medical education. Those topics were among 36 programs included in the curriculum.

Such withering scrutiny, however, has meant that industry backing of continuing medical education has continued to decline. In 2010, the last year for which figures were available, support from drug and device makers fell 30 percent from 2005 levels, marking a third consecutive annual decline and the lowest level since 2002, according to the Accreditation Council for Continuing Medical Education.

Specifically, industry support fell to $830.8 million, considerably below the $1.2 billion reached in 2007. In general, commercial support generated 37 percent of the $2.2 billion in overall funding for continuing medical education in 2010, down from 47 percent in 2007 (the next annual report from the ACCME, which will showcase data for 2011, will be available in the third quarter).

A few more nuggets: Twenty percent of accredited CME providers and 80 percent of accredited CME activities did not receive any commercial support in 2010. Meanwhile, accredited providers produced more than 81,000 activities in 2010, which amounted to a 14.2 percent decrease from the year before and a whopping 27.8 percent plunge from 2007. There were also more than 660,000 hours of instruction, but this was 4.2 percent less than what was tallied for 2009.

The sustained decline reflects a significant effort to divorce physician education from industry backing. Other factors, however, have likely contributed to the changes, such as the sour economy, stricter rules instituted by the ACCME, and fewer truly new medicines to promote. But the underlying concern remains that industry financial support may unduly influence medical practice.



However, one continuing medical education provider, Tom Sullivan, who is president of Rockpointe Associates and editor of Policymed.com, maintains that the shrinking dollar amounts have meant that survivors are more attuned to these concerns and are more focused on offering programs that meet both physician needs and industry criticism.

"The sky isn't falling, but yes, companies are pinched," Mr. Sullivan says. "All the budgets have gone down. In some respects, though, I would argue that it's helped improve the quality. But we also have to be more focused, because there are fewer resources to do programs. Instead of trying to blanket the countryside with something happening in medicine, you have to figure out how this might improve a physician practice, patient care, and figure out what works better for the audience."

What might turn things around? Mr. Sullivan opines that the increasing number of Risk Evaluation and Mitigation Strategies required by FDA, as well as the advent of biosimilars, will prompt more continuing medical education. "The pharmaceutical industry will receive a boost from this," he says. "There is going to be more education required."

Another boost may come from the Affordable Care Act, which he argues will force primary care physicians to increase their knowledge if accountable care organizations make it more difficult for doctors to successfully refer patients to specialists. The primary care physician, in other words, may have to treat patients if specialists cannot be seen as quickly as in the past. And some state medical boards are revamping certification which, Mr. Sullivan adds, will also generate a need for more education.

"We still have the need for physicians to keep up with the latest science, but no one knows where the money will come from," he says. "It'll have to come from a variety of sources. Doctors will have to pay for some. ACOs and nursing homes will have to participate, and insurers. For the short term, though, you will continue to see a decline [in funding], but this will probably turn around once a lot of these issues start to kick in."

Meanwhile, some say that a tipping point may have been reached. "Although industry support for accredited CME is unlikely to disappear entirely in the near future, a sea change toward greater restriction is beginning to happen as a result of cultural, regulatory, and economic changes," wrote Robert Baron, M.D., a professor of medicine and associate dean for CME at the University of California, San Francisco, and two colleagues in the *New England Journal of Medicine* earlier this year.

In the editorial, Dr. Baron and his colleagues offer no illusions that they believe divorcing pharmaceutical industry influence entirely from continuing medical education should remain a goal, even if this means that fewer independent, for-profit providers may remain. The question for those who advocate such a position, though, is whether this can be accomplished.

"I think there are providers who would be happy to rid themselves of industry influence, because they that don't necessarily like to manage these conflicts of interest, but can't withdraw unilaterally from taking that support because they'll be at a disadvantage," says Michael Steinman, M.D., one of the University of California, San Francisco, professors who co-authored the editorial.

He acknowledges that no easy solutions exist, but suggests that physicians may have to brace themselves for higher fees to compensate for the revenue providers stand to lose if industry financing continues to dwindle. "It's not automatic that doctors will have to pay more fees, but there need to be some regulations and a culture change," Dr. Steinman says.

Meanwhile, academic medical centers are increasingly re-evaluating how they pay for continuing medical education. A growing number are changing their working model. But rather than institute an outright ban on all industry funding, they are instead creating central pools in which industry can contribute, but the money cannot be linked to a particular course, according to Danny Carlat, director of the Pew Prescription Project.

"The purpose of these policies is to create more of a meaningful firewall between industry funding and program content," he says. "If you were to survey major med schools and teaching hospitals, everyone seems to have their own version of how to accomplish this, and some policies are likely to be more or less effective than others."

Indeed, Dr. Fugh-Berman believes the efforts are too spotty to have had a sufficiently meaningful effect – at least, not yet. Although she points to a list of dozens of CME companies, medical societies, and academic centers that somehow restrict industry funding, the overall effort, in her view, is still lacking.

"Putting up firewalls between marketing and education divisions is just window dressing," she says. "There may be a little more complacency in terms of thinking the issue has been dealt with, but it hasn't. Commercial influence on CME is alive and well. The influence may be subtle to ascertain, but it's there and it's effective." ■ MEDADNEWS

JAMIE LEE (PUPPETEER) – KORHAN KARACAN (LECTURER)/ISTOCKPHOTO.COM

"Epilog" professional disease awareness program

By Stephanie Brown, FingerPaint Marketing

Upsher-Smith Laboratories Inc. is a privately held pharmaceutical company whose mission is to improve lives through innovative products. Its portfolio has historically included products in women's health, dermatology and cardiology; more recently, however, the company has begun to pursue product development opportunities in the central nervous system (CNS) therapeutic area for disorders, such as epilepsy and Parkinson's disease.

Our challenge was to create awareness for Upsher-Smith as a credible new entrant in the CNS space, as well as to engage the target clinician audience in meaningful dialog during research and development and prior to the launch of the company's first branded epilepsy product. This would also lay the foundation for possible future product introductions in the CNS arena.

FingerPaint's "Epilog" campaign, developed for Upsher-Smith Laboratories.

BRAND AS INTERACTIVE FORUM.

To satisfy these objectives, FingerPaint created "Epilog," an epilepsy-focused disease awareness brand, website (www.epilog.us) and content marketing plan offering the latest in evidence-based scientific information, current therapy issues and expert insights across a wide range of on-demand formats.

As its name suggests, Epilog (a neologism formed by the mash-up of "epilepsy" and "dialog") was developed to foster critical dialog on epilepsy to improve patient outcomes through education, advocacy and discussion—essentially, serve as a voice for engaged neurologists and epileptologists who were otherwise undersupported.

YOU CAN'T BUY SHARE OF MIND—YOU HAVE TO EARN IT.

Capturing share of mind among the narrow universe of neurologists and epileptologists demanded that we know the audience intimately – from patient information priorities to practice management challenges. This level of understanding, or "empathy," ultimately enabled us to create a content-rich online experience that offered real value to clinicians.

Rather than investing in big-budget banner advertising or NPP programs, we assembled a team of leading epilepsy professionals to serve as advisors and contributors, essentially harnessing their expertise for the benefit of the community and making it available on-site in a variety of physician-preferred formats – videos, podcasts, white papers, article reprints, infographics, and so forth (formats that are easily downloaded and shared).

To maximize our investment in many of these digital assets, in the near future, we will employ a content marketing strategy that involves optimizing them each for search engine visibility and nesting them on sites like YouTube, iTunes, SlideShare and many others to encourage inbound traffic. Similarly, optimized press releases replete with multimedia content are leveraged to promote the program quickly and cost-effectively.

Finally, we incorporated a variety of community building features into the website—from real-time polls and peer surveys, to "Ask the Expert" and "Suggest a Topic" solicitations, to user-generated content opportunities like Agree/Disagree statements. And to further engage these users with the brand, we included key conversion events such as a Subscribe, Feedback and Share mechanisms.

A COMMUNITY APPROACH TO TOPIC DEVELOPMENT.

Remaining true to the mission of Epilog, FingerPaint and Upsher-Smith work closely with our expert advisors to identify and satisfy the changing information needs of our audience.

In developing our editorial calendar, we ask our users to inform content. We request input at trade shows, conferences and on-site. We regularly invite new professionals to join the program. From comorbidities to practice management issues, we attempt to translate the professional community's information priorities into relevant, bimonthly topics on www.epilog.us and beyond.

In an industry where many social media forms present significant barriers, Epilog works to catalyze information exchange, albeit virtually, in the minds of our users.

AUDIENCE ENGAGEMENT—THE MEASURE OF SUCCESS.

For the purposes of the Epilog program, given its emphasis on driving awareness and engagement (not sales), FingerPaint focuses primarily on one key metric – Return on Interaction (the "new ROI") – and results associated with downloads, views, listens, subscribes, feedback, sharing, participation in polls and surveys, and more.

Secondarily, we measure online visibility for both Epilog and Upsher-Smith in terms of organic search engine rankings and the potency of keywords, as well as press release saturation and the number of channel influencers like the Epilepsy Foundation and the American Association of Neurologists, to "mention" Epilog and/or repost content.

Since program launch in January 2012 (with two topics presented: "Women & Epilepsy" and "Epilepsy & Comorbidities"), the Epilog Website has experienced:

- A 55 percent overall engagement rate among visitors
- An increase in visits by topic of 10 to 20 percent month over month
- An increase in email opt-ins of 1 to 3 percent per topic month over month
- Incremental increases in organic rankings by topic month over month
- Press release saturation of about 4,700 posts and reposts per press release

Tell me once, show me twice ... but tapping is oh so nice

By Nicole Johnson, Flashpoint Medica

THE TABLET'S HEAVY TOUCH

The pharmaceutical industry began the transformation of personal and nonpersonal promotion to tablet experiences well before the launch of the iPad. Since then, pharmaceutical companies and the healthcare professionals they serve have transitioned to tablets at an even faster pace. Of 3,015 practicing U.S. physicians recently surveyed, 62 percent use the iPad professionally, with half reporting tablet use at the point of care.

FLASHPOINT AND ADOBE – AT THE EDGE OF INNOVATION

In the two years since the iPad's arrival, Flashpoint Medica has created numerous tablet applications. The tools for engaging customers with tablets are still emerging, and Flashpoint continues to explore innovations in the more immersive, interactive experiences they provide. Our strategic alliance with Adobe is now hastening that process.

Adobe selected Flashpoint as one of the first Omnicom agencies to pilot their Digital Publishing Suite (DPS) with pharmaceutical clients. Flashpoint is delighted to partner with Adobe in integrating rich immersive customer experiences, streamlined production and distribution, and metrics and analytics all in one package for our healthcare clients.

ENRICHING THE CUSTOMER EXPERIENCE

Flashpoint is constantly developing ideas to improve the content and user experience specific to the healthcare realm, and Adobe DPS supports the integration of a wide range of interactive features, including scrollable frames, linking, and audiovisual media. Adobe launched DPS in 2010, which is already transforming tablet experiences in the publishing world. (To see what we mean, just compare the latest iPad edition of *Wired* magazine to its static, inky cousin.)

STREAMLINING PRODUCTION AND DISTRIBUTION

As Flashpoint pilots Adobe DPS, one of the most attractive components to emerge is its ability to create interactive experiences with minimal development effort; in fact designers can create interactive DPS content directly within Adobe InDesign. This can help streamline production, saving time and significantly reducing the cost of programming and quality assurance testing. The demand for tablet content for sales representatives, healthcare professionals and patients is increasingly rapidly, and Flashpoint expects to leverage these offerings to deliver enhanced content for our clients and reduce cost and timing.

INTEGRATING METRICS AND ANALYTICS

For better or worse, digital lives in a metrics-driven world. That's why Flashpoint is analyzing a range of metrics that help inform business decisions that yield a positive return on investments, including:

- Total number of applications distributed and downloaded
- Top reader platforms, including iOS and Android
- Time spent with applications
- Top viewed content
- Top interactivity types
- Average number of times customers engaged with content

The integration of Adobe SiteCatalyst and Adobe DPS also supports accountability with every application developed.

ENGAGED FOR SUCCESS

The world of telling a story with tablets has evolved to showing it, and is yet again being transformed to sharing a story with true customer engagement. With new platforms like Adobe DPS and agencies like Flashpoint with a clear vision, tablets will continue to be at the center of the pharmaceutical industry's efforts to achieve the full potential of their brands.

Successful email marketing methods increase response rates

By Terry Nugent, executive VP sales and marketing, MMS Inc.

Email marketing is the smooth and effective way to deliver messages to healthcare professionals (HCPs). It's an essential aspect of comprehensive marketing campaigns combining email with direct mail and other advertising.

Medical marketers share one common goal: better response rates. By using successful email marketing methods, MMS has been able to substantially increase response rates.

MMS is the industry leader in email marketing to the healthcare industry because we offer unique advantages that separate us from our competition.

MAXIMUM REACH

MMS's permissioned email database reaches more than 1.5 million HCP email addresses, including 900,000 physicians' email addresses, as well as physician assistants and nurse practitioners.

You can reach physicians at their preferred email address, or use MMS's Mult-E-Mail service to reach them at all available email addresses so your message gets delivered to physicians wherever they may be – at home, at work or in between with their mobile devices.

MAXIMUM RESPONSE

MMS achieves 97 percent deliverability by using permissioned email addresses, state-of-the-art delivery technology, close relationships with key internet service providers (ISPs), and 80+ years' experience in HCP direct marketing, including thousands of successful email marketing campaigns.

MMS creative assistance ensures your message optimizes deliverability. MMS assists at every step of the campaign, structuring your email content to generate a powerful call-to-action.

MAXIMUM RELEVANCE

Because Med-E-Mail is AMA-based, you can pinpoint the perfect prospects for your promotions by one of three ways:

1. Provide us with specific ME or NPI numbers from your target file.
2. Target by prescriber profile data.
3. Target by demographic selections from the AMA Masterfile specialty, age, board certifications and more.

In addition, you can use MMS's Enhanced Physician Response Data (ERPD) to target physicians who are proven responders. Because they have responded to similar campaigns, these physicians are more likely to respond to your offer as well.

MAXIMUM ROI AND MAXIMUM EMAIL MEASURABILITY

MMS achieves maximum ROI through a combination of superior delivery and response metrics, plus competitive pricing tailored to meet your budget needs.

SPEED

Standard turnaround time is two to four working days, but we can complete same-day requests if necessary (rush fees may apply).

SUCCESSFUL EMAIL MARKETING METHODS

MMS has developed a white paper on successful email marketing methods.

To find out how to dramatically increase your response rates, contact Terry Nugent, executive VP of sales and marketing at 1-630-477-1553 or t-nugent@mmslists.com.

For more success stories and email marketing tips, follow MMS on Twitter @mmsemail.

The MANNYS 2012

23RD ANNUAL MANNY AWARDS

Agencies honored

The 23rd Annual Manny Awards ceremony, held for the first time at Pier Sixty in New York on the evening of Tuesday April 24, paid tribute to the creative work of agencies serving the healthcare market, their people, and their contributions to the industry. Seventeen awards were presented, including Agency of the Year—Category 1, 2, and 3; Advertising Person of the Year; The Heart Award; Best Professional Campaign and Best Consumer Campaign; and Best Medical Device Campaign. Susan Miller Viray, founding partner of The CementBloc, was honored as Industry Person of the Year.

MANNY AWARD WINNERS AND NOMINEES

Agency of the year—Category I:

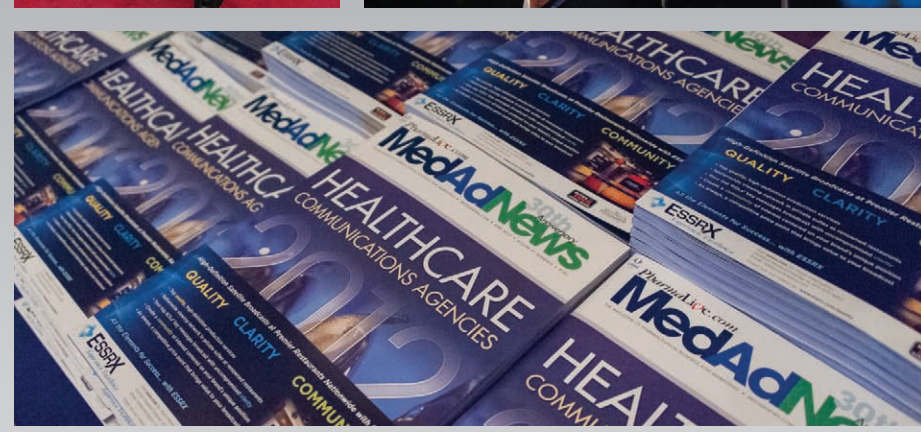
ICC LOWE
AbelsonTaylor, CAHG (nominees)

Agency of the year—Category II:

INTOUCH SOLUTIONS
The CementBloc, Palio (nominees)

Agency of the year—Category III:

ECHO TORRE LAZUR
Area 23, Giant Creative/Strategy (nominees)



By Joshua Slatko joshua.slatko@ubm.com

Closed-door docs slower to adjust to new info

After years of reducing their contact with pharmaceutical sales representatives, physicians now risk an unintended consequence: Doctors who rarely meet with pharmaceutical sales representatives, or who do not meet with them at all, are much slower to drop medicines with the Food and Drug Administration's "black box" warnings and to adopt first-in-class therapies.

According to a study published in *The Journal of Clinical Hypertension*, doctors whose access to pharmaceutical sales representatives is limited can take more than four times longer to change prescriptions based on new information than their peers who have more frequent contact. This longer response time holds true whether the physicians are responding to "positive news" related to an innovative therapy or "negative news" related to a newly discovered medicine risk.

The report, "Can Access Limits of Sales Representatives to Physicians Affect Clinical Prescription Decisions? A Study of Recent Events with Diabetes and Lipid Drugs," studied prescriptions dispensed by primary care physicians and specialists in three areas: a first-in-class new drug launch, a newly imposed black box warning, and the report of perceived negative clinical trial outcome data.

George Chressanthis, professor of healthcare management and marketing and acting director for the Center for Healthcare Research and Management at Temple University's Fox School of Business, led the study in collaboration with ZS Associates, a global sales and marketing consulting company with a significant presence in the health care industry.

"This study analyzed for the first time – and on a large scale – what happens to physicians' prescription decisions when you decrease the access that pharmaceutical sales reps have to doctors," Mr. Chressanthis says. "We saw that increasing access restrictions affect physician decision-making in ways not anticipated by those at health care systems or large group practices who created these policies."

Mr. Chressanthis, his research team, and ZS consultants began to measure the behavior of primary care physicians and specialists in 2008 when Mr. Chressanthis was at AstraZeneca Pharmaceuticals LP. The researchers drew from ZS' annual AccessMonitor report, which since 2006 has tracked how frequently 300,000 physicians and other prescribers meet with pharmaceutical sales reps.

According to AccessMonitor, the number of doctors willing to see reps has declined about 20 percent since 2008. In 2010, about 11 percent of American physicians had "severe" or "no-see" restrictions on rep access, while 34 percent had "some" restrictions.

The study measured doctor prescription activity and behavior from 2006 to 2008 as it related to three major product events: the October 2006 launch of sitagliptin, a first-in-class drug to treat type 2 diabetes; the August 2007 issue of a black box warning (i.e., FDA's most serious medication warning) for rosiglitazone, a drug used to treat type 2 diabetes; and the January 2008 release of a negative outcome associated with a therapy that combined a cholesterol-lowering drug (simvastatin) and another medicine (ezetimbe) to treat dyslipidemia.

In the case of sitagliptin, physicians with a "very low" level of sales rep access took up to 4.6 times longer to introduce the new drug to patients than physicians who employed a "medium" level of access.

For the black box warning, physicians with "very low" access were up to four times slower to reduce their use of this treatment than physicians with "low" access.

In the clinical trial involving the negative outcomes of a lipid therapy prescription, physicians who limited sales rep access showed "significantly less" response in changing their patients' prescriptions than did physicians in less restrictive offices.

According to ZS managing principal Pratap Khedkar, co-author of the study, the research demonstrated that most physicians should seek to balance their information sources.

"Though healthcare professionals work hard to minimize distractions and maximize the time they spend with patients, it's clear that sales rep access restrictions imposed by well-meaning physicians and group practice leaders can result in serious information gaps," Mr. Khedkar says. "Even though pharmaceutical sales representatives are not the only source of information, they do help physicians stay current on therapy developments. These findings should be carefully considered by those who set policy – whether it's at the physician group practice level or on the national stage."

The study also showed that primary care physicians rely more heavily on sales reps for drug information than do specialists.

"When primary care physicians reduce or eliminate contact with these reps, it impairs their ability to stay current and affects their prescription behavior," Mr. Khedkar says. "Because specialists concentrate in a narrow field, they can stay current by other means, including conferences, online forums, podcasts and academic journals. Thus, the updates they receive from reps have less impact on their prescribing abilities."

Unintended consequences

According to new research sponsored by CVS Caremark, FDA drug warnings can have a significantly negative impact on medication adherence when the warnings are not delivered with clear clinical recommendations. The research found that immediately following a high-profile FDA communication questioning the efficacy for a cholesterol-lowering drug, the monthly level of patients who stopped filling their prescription increased by nearly 6 percent. In addition, of those patients who stopped taking the drug after the FDA warning, only 16.5 percent switched to another clinically appropriate therapy.

"These findings suggest that when an FDA communication about a prescription drug is widely reported in the news media and is not related to a safety issue or accompanied by clear guidelines about how to apply this information, the resulting confusion can bluntly reduce overall rates of treatment," says Niteesh Choudhry, M.D., Ph.D., of Brigham and Women's Hospital, a study co-author. "Furthermore, if patients respond to this information by stopping therapy altogether and do not switch to another clinically appropriate medication there could be a negative impact on health outcomes which runs contrary to the intent of the initial communication."

Researchers from Harvard University, Brigham and Women's Hospital, and CVS Caremark, reviewed the impact of an FDA communication made on January 25, 2008 regarding the cholesterol-lowering medication ezetimibe. FDA issued an early communication after results from the ENHANCE trial indicated that adding ezetimibe (known as either **Zetia** or the ezetimibe-simvastatin combination **Vytorin**) to a treatment regimen including simvastatin did not appear to improve patient outcomes. FDA raised questions about the effectiveness of the drug in their communication, but did not advise healthcare professionals to discontinue prescribing these products. The communication received substantial media attention.

"This study provides an interesting perspective on how information made available to both health care practitioners and patients about the effectiveness of a drug can impact patient behavior and result in nonadherence," says Troyen A. Brennan, M.D., executive VP and chief medical officer of CVS Caremark. "The results suggest that a more robust understanding of how and why patients respond to drug information could lead to even more effective public health warnings regarding new data about medications."

The study, "Warnings without guidance: Patient responses to an FDA warning about ezetimibe," was conducted by researchers at Harvard University, Brigham and Women's Hospital and CVS Caremark and was published in the June 2012 issue of the journal *Medical Care*. The researchers reviewed de-identified claims data for more than 860,000 patients identified as new users of ezetimibe between January 2006 and August 2008. The researchers estimated trends in discontinuation rates of ezetimibe during three time periods: before FDA communication (January 2006 – December 2007); during the transition period when the FDA communication was issued (December 2007 – January 2008); and 3) after the communication (January 2008 – July 2008).

In addition to the key findings related to drug discontinuation and low levels of drug switching to a clinically appropriate alternative, the researchers found that several patient characteristics were associated with discontinuation rates after the FDA warning had been issued. Overall, patients who resided in lower-income areas had a 12.9 percent lower rate of discontinuation compared with patients living in the highest income areas; female patients had a 6.9 percent lower rate of discontinuation compared with male patients and younger patients had lower rates of discontinuation with patients ages 18 to 34 having a 32.4 percent lower rate of discontinuation compared with patients over 65 years of age.

Payers to pharma: we don't believe you

Pharmaceutical companies that are first to meet healthcare's new expectations of value could have an advantage in the competition for market share and brand differentiation, according to a report published by the Health Research Institute at PwC US. Physicians, health insurers, and patients now want to know how well a drug will work and affect total medical costs. Yet an HRI survey of health plan executives finds the information currently provided by the biopharmaceutical industry no longer suffices.

As the basis for payment shifts to improved patient outcomes, health organizations are looking for more robust evidence of clinical and economic comparative effectiveness. Drug makers that have faced challenges with formulary acceptance or reimbursement levels should speed their efforts to create and reliably demonstrate better outcomes for patients, PwC's researchers found.

"Pharmaceutical and life sciences companies are now collaborating with payers and providers to achieve better patient outcomes and bend the healthcare cost curve," says Douglas Strang, PwC US pharmaceutical and life sciences advisory co-leader. "Those that can demonstrate value in non-traditional ways have an opportunity to gain market share in a very competitive market for prescription drugs."

A nationwide survey of 100 U.S. health insurers and pharmaceutical benefits managers, conducted by HRI, found that to be considered for drug formulary placement, 82 percent of health plans said a drug manufacturer must demonstrate a clear clinical benefit compared with current branded and generic treatments, and 78 percent demand clear proof of cost savings. Only five percent of health insurers are very confident – and 44 percent aren't at all confident – in the economic data provided by the drug industry when making coverage and formulary decisions. Only seven percent are very confident in the information to evaluate a drug's comparative effectiveness.

Unsurprisingly given this, obtaining more useful information through collaborative data sharing has been hampered by a history of distrust and misalignment between insurers and drug companies. By three to one, insurers characterize their relationship with pharmaceutical companies as "transactional" versus "collaborative." Nearly 60 percent of insurers expect no change in their relationship with pharma. Thus, more than half (52 percent) of insurers rely on independent data to evaluate drug effectiveness. The three most influential factors health plans use when making formulary decisions are the availability of a generic equivalent, physicians' opinions, and regulatory guidance.

"As the U.S. health system undergoes significant change regardless of legislative or legal actions, a new definition of value is emerging, one that places patients and their desired outcomes at the center of the universe," says Karla Anderson, partner, PwC pharmaceutical and life sciences advisory services group. "Leading pharmaceutical companies are increasing their alignment with the rest of the 'four P's' in healthcare – providers, payers and patients. They are creating new expectations across their organizations to re-orient their definition of value for each of these groups."

MOST-RECOGNIZED BRANDS

DERMATOLOGY

The most-recognized dermatology brand in North America is **Retin-A**. The brand was most-recognized by 6.1 percent of physicians in a survey conducted by **Brand Institute** Inc. during the fourth quarter of 2011. Retin-A, comprising tretinoin, is marketed by Ortho Dermatologics (orthodermatologics.com), a subsidiary of **Johnson & Johnson** (jnj.com). The product's three formulations are all indicated for the treatment of acne vulgaris.

Accutane is the second most-recognized dermatology brand in North America. About 3.9 percent of physicians recognize this brand the most. Accutane, composed of isotretinoin, is marketed by **Roche** (roche.com). The product was approved by FDA in May 1982 for the treatment of severe nodular acne.

The third most-recognized dermatology brand in North America is **Differin**. About 2.6 percent of physicians recognize this brand the most. Differin, comprising adapalene, is marketed by **Galderma** Laboratories LP (galdermausa.com). The product was approved by FDA in May 1996 for the topical treatment of acne vulgaris.

The most-recognized dermatology brand in Europe is **Dermovate**. This product was recognized the most by 2.7 percent of physicians. Dermovate, comprising clobetasol, is marketed by **GlaxoSmithKline** (gsk.com). The product is indicated for the treatment of severe inflammatory skin disorders, such as eczema and psoriasis, when milder corticosteroids have not been effective.

Elocom is the second most-recognized dermatology brand in Europe. About 2.3 percent of physicians recognize this brand the most. Elocom is a generic brand name for the corticosteroid mometasone, commonly prescribed to relieve itching, swelling, or other discomfort caused by skin conditions.

The third most-recognized dermatology brand in Europe is **Betnovate**. About 2 percent of physicians recognize this brand the most. Betnovate, composed of betamethasone, is marketed by GlaxoSmithKline. The product is indicated for the treatment of a variety of inflammatory, allergic, or itchy skin disorders when milder corticosteroids have not been effective.

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

ED drugs lead in trust

According to the inaugural Harris Poll Physician Pulse study of American physicians' prescribing behaviors and influences, **Viagra** and **Cialis** are the top-ranked pharmaceutical treatments in terms of trust. In fact, three erectile dysfunction brands, also including **Levitra**, received some of the highest scores across all of the categories surveyed.

The Harris Poll Physician Pulse study asked primary-care physicians and specialists, including psychiatrists, urologists, and endocrinologists, about their prescribing behaviors and ranked key pharmaceutical treatments, based on the Harris Poll multi-dimensional Trust Index. This index measures the five key components of physician trust. The components of the Harris Poll Trust Index relate to the drug itself (Familiarity, Function, and Connection) as well as to the pharmaceutical organization (Company and Representatives).

In this first quarterly study on product-level trust among prescribers, four key, high-volume prescription categories were studied: anti-depressants; anti-psychotics; erectile dysfunction; and non-insulin diabetes treatments. In the anti-depressant category, with a score of 100 being the best, the top three ranked brands were Lexapro (74), Cymbalta (72), and Wellbutrin XL (71). Abilify (74), Seroquel (73), and Geodon (67) led the anti-psychotic category; while Viagra and Cialis tied at 82 to lead the ED category, and Glucophage XR (77), Januvia (73), and Victoza (71) led the non-insulin diabetes treatment list.

As might be expected, some of the biggest names in pharma dominate the trust listings. Among the most trusted brands, **Bristol-Myers Squibb** Co. has two of the highest ranked products, Glucophage XR and Abilify, with Abilify co-promoted through **Otsuka** America Pharmaceuticals Inc. Additionally, **Forest** Laboratories Inc., Eli **Lilly** and Co., and **Pfizer** Inc. each have one top-ranked treatment: Lexapro, Cialis, and Viagra, respectively.

"Physicians have made it clear that trust is important to them," says Joseph Vorrasi, senior VP of healthcare research at Harris Interactive. "The pharmaceutical treatments that rate well across the five key factors of Trust are in a much better position to be written and recommended by physicians. We look forward to expanding and validating this model across more than 20 additional therapeutic categories in the next year."

One of the most compelling findings of the Harris Poll Physician Pulse trust model, its authors believe, is the role of emotional connection in the overall trust of pharmaceutical brands. In fact, the study found that the influence of Connection is on a par with Function and Familiarity in terms of driving brand trust among prescribers. This significant finding about the importance of emotional connection to the prescription medication was consistent across all therapeutic categories and among primary care physicians and specialists alike.

"We tend to think of doctors as completely driven by fact-based approaches, where a formulaic mapping of symptoms, history, and treatment options determines what they prescribe," Mr. Vorrasi says. "While that is generally true, physicians also are influenced by the softer, more emotional elements of the treatments they prescribe. This unconscious effect is actually very similar to the emotional relationship we see among consumers as they make important purchase decisions. The bottom line is that emotional connection with brands matters in the pharmaceutical realm as well."

FACTS & FIGURES

Novartis tops in pharma revenue in 2018; Pfizer only U.S. company in top five

According to projections by EvaluatePharma Ltd, **Novartis** is expected to take the top spot amongst the world's pharmaceuticals manufacturers, in terms of prescription drug sales, starting in 2014 and remain at the top through 2018. Only one U.S.-based drug maker, **Pfizer** Inc., will rank among the top five, with **Sanofi**, **GlaxoSmithKline**, and **Roche** filling out the group. Further down the league table sizeable shifts both up and down the rankings are forecast, as pipeline successes and failures drive the future fortunes of the world's biggest pharma companies.

WORLD'S TOP 15 PHARMA COMPANIES

	Market Rank				Rx Pharma Sales ($bn)				Annual growth
	2011	2014	2016	2018	2011	2014	2016	2018	2011–18
Novartis	2	1	1	1	46.7	47.6	49.0	50.8	1.2%
Sanofi	4	3	3	2	39.3	42.9	45.6	47.8	2.9%
Pfizer	1	2	2	3	53.5	46.9	46.5	47.1	-1.8%
GlaxoSmithKline	6	6	4	4	35.0	38.5	43.1	45.6	3.9%
Roche	5	5	5	5	37.0	40.7	42.7	45.0	2.8%
Merck & Co	3	4	6	6	41.9	40.9	42.6	41.0	-0.3%
Johnson & Johnson	9	8	7	7	22.3	25.8	27.2	27.3	2.9%
Teva	11	10	10	8	17.1	22.1	22.8	23.3	4.5%
AstraZeneca	7	7	8	9	32.4	26.7	25.2	22.1	-5.3%
Abbott Laboratories	8	9	9	10	22.4	23.7	23.9	22.1	-0.2%
Bristol-Myers Squibb	12	15	11	11	16.9	14.9	18.9	21.4	3.4%
Novo Nordisk	17	14	13	12	12.4	15.6	18.0	19.9	7.0%
Takeda	14	12	12	13	15.2	16.8	18.7	19.5	3.6%
Bayer	16	16	16	14	13.6	14.6	15.7	16.5	2.7%
Gilead Sciences	21	20	17	15	8.1	10.8	15.0	15.7	9.9%

Interactive&DigitalMarketing

By Joshua Slatko joshua.slatko@ubm.com

Microsoft Kinect: a rising trend in healthcare engagement

By Spring Moore, Razorfish Health

A trend developing at the intersection of healthcare and technology is using Microsoft Kinect to promote engagement. Kinect, and other gestural interfaces which we'll discuss later in this article, have significant potential to impact the way both healthcare professionals and consumers interact with brands and with each other.

Kinect, for those unfamiliar with the technology, is a motion sensing input device. Kinect can to be used with an Xbox or a Windows PC and collects information through gesture tracking. It is capable of facial and voice recognition, as well as skeletal tracking, making traditional input devices such as keyboards and mice unnecessary when it's used. Since it's designed to work with both Xbox and Windows, it can also take advantage of some traditional "desktop computing" services like video chat and Live Messenger, letting people see, hear, and talk to each other through traditional mediums, even though it's an untraditional interface. Kinect's gesture tracking uses the human body as the input device, which is pretty nifty, and opens up a plethora of ways to impact day to day human life outside of gaming. Let's look at a couple of ways Kinect technology can change our experiences with health and wellness.

One major area Kinect can impact within healthcare is in training HCPs to use medical devices. Typically ongoing medical device training is conducted via video. While watching video of a specific device being used certainly imparts knowledge to the HCP, it is a passive experience. Taking advantage of the gestural properties of the Kinect platform turns the experience into a participatory one.

The movement tracking abilities of the Kinect platform enable an HCP to participate in a variety of scenarios, which can take on a game-style format. The HCP can interact with a device, such as a Gamma Knife, and a patient in an environment that provides feedback on proper use and manipulation of techniques and tools based on a set of clinical data. This game play approach is engaging while also providing instant feedback, something that a video can't do.

Microsoft's Kinect may be able to be used in helping train HCPs to use medical devices, or to provide virtual health coaches to patients with motor impairments.

The Kinect platform also offers opportunities to improve the delivery of healthcare to consumers. Kinect can be used to provide virtual health coaches to patients with severe motor and mobility impairments such as multiple sclerosis by using the platform's video conferencing and audio recognition abilities, requiring no touch or gesture whatsoever. Another option? Use Kinect to connect (pun intended) patients in remote areas with specialists they would never have access to otherwise.

In their most basic forms, both of these ideas could be realized using traditional video conferencing devices or Skype. However, if you dig below the surface you can see how Kinect can push them farther. Let's take the health coach for instance. Face-to-face conversation with a pro-coach or seasoned mentor is really the baseline here. Patient outcomes can be improved further when patients tap into a community support network. Kinect's interoperability with Xbox Live and Windows Live Messenger make it easy for patients to connect with one another to share experiences and provide support throughout the progression of a disease. If you also consider the app nature of the latest version of the Xbox live platform, the health coach idea can be pushed even further by including video content, agility building exercise programs, and therapy adherence tracking features that could even send summaries to a set of user provided email addresses.

Microsoft Kinect leads the gestural interface space, but another player to watch is Leap Motion. On May 21, Leap unveiled its new $75 gestural device that shares many of the same properties that Microsoft Kinect has, but at a lower price point and with greater gesture tracking accuracy. However, the platform doesn't have the benefit of an easy to plug into community component like Kinect does. It will be interesting to see what kind of impact Leap has in the marketplace over the next year or so.

The full spectrum of opportunities for applying gestural technology to healthcare is yet to be realized. We're at the very beginning of the trend; it will be interesting to see how far brands, hospitals, agencies, and other healthcare organizations take it.

Spring Moore is the experience director for Razorfish Health.

FACTS & FIGURES

A study published in the May issue of *Clinical Therapeutics* showed that patients who participate in a text message prescription reminder program have significantly higher adherence to chronic oral medications than those in a control group.

The study of 580 employer-sponsored and Medicare members of a national pharmacy benefit manager found that patients receiving text message reminders had better medication adherence rates than those who did not – **85 percent** versus **77 percent**. The adherence rates for those taking chronic anti-diabetes medication were even higher – **91 percent** versus **82 percent**.

According to the authors, this is the first large-scale study in the United States to examine if a text message program providing medication-specific reminders could increase adherence. Previous research has shown a similar positive impact; however, these studies were smaller in scope, often with fewer than 100 participants, and focused on homogenous patient groups, such as those who are being treated for the same disease.

"This research provides strong evidence that technology can play a vital role in improving medication adherence, even among older patients," says Brian K. Solow, M.D., chief medical officer, OptumRx, the company whose text message program was studied. "This is of great importance to all stakeholders in health care because poor medication adherence can lead to inferior treatment outcomes, higher hospitalization rates and increased health care costs."

The study authors noted that additional research is needed to determine if text messaging improves medication adherence in patients known to be non-adherent, as well as long-term medication adherence rates.

Source: OptumRx (optum.com)

E-LAUNCH ROUNDUP

Pfizer launches first consumer mobile app

Pfizer Inc. and EatingWell Media Group, publisher of EatingWell Magazine, have launched Pfizer's Lipitor For You "Recipes 2 Go" mobile application, marking the first time Pfizer has released a consumer mobile app for a prescription product in the United States.

The "Recipes 2 Go" app offers consumers a variety of resources that can help to manage heart health anytime. The app includes access to healthy recipes for appetizers, entrees, side dishes, snacks and desserts; a shopping list feature; and tips on portion sizes and exercise.

Included in the app are 200 healthy recipes from EatingWell with easy-to-follow instructions and full-color photos; intuitive categories and practical search feature to help find specific recipes; and an easy-to-use shopping list that makes planning healthy meals simple. The app also includes a "Favorites" functionality that allows users to keep their favorite recipes at their fingertips; a built-in timer; and a copy of the Lipitor $4 Co-Pay Card with which Pfizer Lipitor for You participants can save their unique ID number to always have their card on hand when refilling their prescription.

Pfizer began working with EatingWell in 2009, licensing the brand's healthy recipes for the Lipitor My Heart Wise Website.

The Lipitor For You "Recipes 2 Go" app extends the newly launched Lipitor For You and Smart Living Website, lipitorsmartliving.com, which features more than 500 additional healthy recipes from EatingWell, helping to inspire patients to cook delicious meals that are compatible with their treatment goals. Statistics show that one in five adults over the age of 20 in the U.S. has high cholesterol, which is a major risk factor for cardiovascular disease, including heart attack and stroke.

The Lipitor For You "Recipes 2 Go" mobile application is the first consumer mobile app released for a Pfizer prescription product in the United States.

"Taking a cholesterol-lowering medication like Lipitor is just part of the equation for maintaining a healthy lifestyle," says Greg Reeder, senior director, team leader, US Brands, Established Products Business Unit, Pfizer (pfizer.com). "The healthy recipes from our partnership with EatingWell gives Pfizer another innovative way to educate patients on the importance of managing cholesterol."

Online talk show for MS

Acorda Therapeutics Inc., makers of the multiple sclerosis drug **Ampyra**, has launched Ampyra Dialogues, the first-ever online talk show where patients and medical experts talk about how walking problems affect people living with MS. The first edition of Ampyra Dialogues debuted on World MS Day, May 30, at AmpyraJourneys.com.

Patient advocate Kristie Salerno Kent, an entertainer and educator who has worked to help people across the United States to understand the impact of MS, will host the series. In the debut of Ampyra Dialogues, Ms. Kent interviews an MS patient and her family about their experience living with MS and how walking problems have affected each of them. In future editions she will interview medical experts who specialize in treating people living with MS, including Ben Thrower, M.D., and Tracy Walker, both from the MS Institute at the Shepherd Center in Atlanta, one of the nation's leading centers for the treatment of MS.

According to its developers, Ampyra Dialogues is the first-ever online talk show where patients and medical experts talk about how walking problems affect people living with multiple sclerosis.

Ampyra Dialogues is one of many educational initiatives available on AmpyraJourneys.com, a Website that features information and patient perspectives on walking problems associated with MS. The site also features a guide specifically for people living with MS on speaking to their doctor about walking problems. Ampyra is an oral medication developed by Acorda Therapeutics and approved by the FDA in 2010 as a treatment to improve walking in patients with multiple sclerosis. This was demonstrated by an increase in walking speed.

"Walking impairment is one of the most common and debilitating effects of MS, and often is not addressed optimally," says Ron Cohen, M.D., president and CEO of Acorda Therapeutics (acorda.com). "The Ampyra Dialogues program will help people living with MS obtain the information and encouragement they need to address their walking issues as effectively as possible."

BI launches tool for cancer caregivers

Boehringer Ingelheim and CancerCare have announced the launch of My Cancer Circle, a free online tool that enables caregivers of people facing cancer to organize and coordinate a circle of family members and friends to provide practical and emotional support. MyCancerCircle.net will provide caregivers of people facing cancer a simple, effective answer to the question, "What can we do to help?"

Powered by Lotsa Helping Hands, MyCancerCircle.net is an online caring community that brings together friends, family, and volunteers to support families and caregivers of people with cancer. Lotsa Helping Hands offers technical assistance through its Member Support Center, ensuring My Cancer Circle communities get the most out of their experience.

MyCancerCircle.net was officially launched May 31 at the Annual Meeting of the American Society of Clinical Oncology in Chicago.

Community support can come in the form of assistance with daily tasks such as cooking meals, driving to medical appointments or helping with household chores. MyCancerCircle.net will encourage message and photo sharing among community members, while providing access to resources available through CancerCare, including counseling services, support groups and educational workshops.

CancerCare is a national nonprofit organization that provides free, professional support services for people affected by cancer. "At CancerCare, we are committed to helping those affected by cancer manage not only the emotional aspects of a cancer diagnosis, but also the practical ones," said Helen H. Miller, CEO of CancerCare. "We are excited to collaborate with Boehringer Ingelheim on My Cancer Circle to provide support for people facing a cancer diagnosis and their families."

AdAgencyUpdate

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

Havas acquires digital wellness agency in Europe

The Havas network has acquired a majority stake in Creative Lynx, a digital health and wellness communications agency in Europe, with 26 digital innovation awards in the last three years and a series of industry firsts in social media, closed-loop marketing, and mobile.

This move, network leaders say, further strengthens Havas' position in the healthcare communications sector, bringing Creative Lynx's digital innovation and creative expertise into the global Havas Worldwide Health network. Havas is already a major player in the healthcare communications landscape with a presence on all continents through Havas Worldwide Health, Euro RSCG Life, and Health4Brands. The network handles approximately 30 global brands, including Sanofi, Pfizer, and Novartis.

"Both our healthcare and digital businesses have been experiencing very strong growth and this acquisition that sits at the intersection of those two key areas will further strengthen our capabilities," says Havas CEO David Jones. "The fact that Creative Lynx decided to join Havas over many other suitors underlines the unique appeal and exciting momentum of our group."

"Both our healthcare and digital businesses have been experiencing very strong growth and this acquisition that sits at the intersection of those two key areas will further strengthen our capabilities," says Havas CEO David Jones.

Creative Lynx's client roster includes Johnson & Johnson, GlaxoSmithKline, GE, and AstraZeneca. Powered by the Havas Health global network, Creative Lynx will be able to service additional clients and markets and grow with a more complete full-service unified offering, from marketing to med-ed, PR to market access. The Havas Health network will provide substantial expertise within professional and public relations and medical education to complement Creative Lynx's existing capabilities. In addition, with Creative Lynx's expertise in delivering global campaigns, the partnership with the Havas Health network is expected to provide unsurpassed global and local support.

"We are excited to be joining the Havas family," says David Hunt, digital director, Creative Lynx. "Through shared strategy, planning and account resources provided by Havas Health, Creative Lynx will be able to fulfill the needs of a far more significant client base. The global infrastructure, expertise, and experience available to us now will significantly enhance our growth and capabilities while ensuring that we continue to offer world-class service, support, and quality."

Hal Lewis Group is now HLG Health Communications

The Hal Lewis Group has announced that it will officially be known as **HLG Health Communications**. Over the past 30 years, the agency has become best known to its clients and peers by its initials, making this a natural transition. Recognizing that clients' needs are ever-changing, the new branding also includes the tagline "Medical marketing for the modern world," which is descriptive of the services the agency provides today, as well as its mission to stay relevant and cutting-edge well into the future.

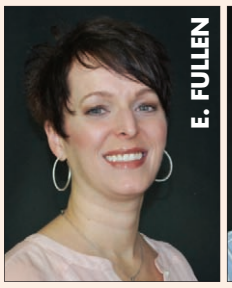
"HLG Health Communications and our new branding are a reflection of the agency's culture and the values we bring to our clients," says David Winigrad, president. "The new HLG offers all the experience we've acquired over the last three decades, with more accessibility and uncomplicated approaches that bring our clients even greater value."

Incorporated in 1982 in Philadelphia, HLG Health Communications is an independently owned full-service advertising and marketing agency specializing in the health sector. Both the agency and its creative team are recipients of the industry's highest awards. Clients who have trusted HLG with their strategic marketing and advertising needs include AstraZeneca, Bristol-Myers Squibb, BD (Becton Dickinson), GE Healthcare, Healthpoint Biotherapeutics, Jazz Pharmaceuticals, Meda Pharmaceuticals, and Merck.

AGENCY PEOPLE ON THE MOVE

AbelsonTaylor

Laura Guarnieri joins AbelsonTaylor (abelsontaylor.com) as an account supervisor, working on a major cardiovascular brand. Ms. Guarnieri was previously a group account supervisor at Chicago-based CAHG (formerly Corbett Accel Healthcare Group), where she helped generate substantial organic growth with two pivotal clients. **Brooke Badzin** is promoted from account coordinator to account executive. Ms. Badzin will provide strategic and tactical counsel on campaigns supporting three products: a sleep aid, varicose vein treatment and wound therapy. She joined AbelsonTaylor in March 2011. **Chad Bernstein** is promoted to senior account executive, from account executive. Since joining AbelsonTaylor in 2008, Mr. Bernstein has worked on a range of professional and consumer accounts, handling projects in print and interactive for products in the cardiovascular and women's health fields. **Katy Kelnhofer** joins the agency as a senior account executive. Ms. Kelnhofer was previous at CAHG, where she worked in multiple disease categories and gained wide-ranging experience in clinical trials as well as the promotional side of the business. **Beth Fullen** and **Paul Pela** are promoted to the position of senior artist in the art production department.



FingerPaint Marketing

FingerPaint Marketing Inc. (fingerpaintmarketing.com) welcomes **Amoreena O'Bryon** to its growing team. In her role at FingerPaint, Ms. O'Bryon will provide creative direction and design for web-based and mobile applications. Prior to joining FingerPaint, Ms. O'Bryon owned a graphic design company, managing and creating national advertising campaigns with a focus on web-based solutions.

HealthEd

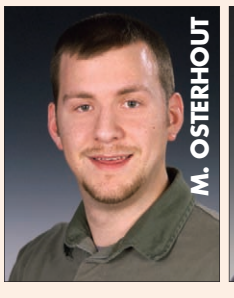
Vicki Kelemen has joined HealthEd (healthed.com) as senior VP and will lead the agency's growing business on the West Coast. Prior to joining HealthEd, Ms. Kelemen held executive positions at Somaxon Pharmaceuticals, Amylin Pharmaceuticals, Maxim Pharmaceuticals, Agouron Pharmaceuticals (Pfizer), Dura Pharmaceuticals, Bayer Healthcare Pharmaceuticals, and The DAVICK Group.

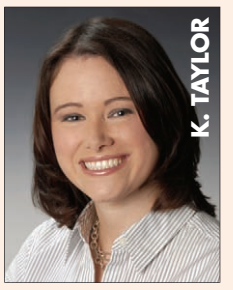
Pacific Communications

Patrick Macke is named group creative director, Pacific Communications (pacificcommunications.com). Mr. Macke will oversee all of the agency's interactive creative output. He brings more than 25 years of experience as a writer and creative manager on both the corporate and agency side to his new role. Before joining Pacific, Mr. Macke was VP, creative director for Ignite Health. **Emily Alford** joins the Botox Therapeutic account team. Ms. Alford was previously an account executive at 3v07 Advertising. **Mary Joan Arreglado** is named senior account executive on the Juvederm account team. Ms. Arreglado was previously a senior account manager at LehmanMillet.

Palio

Ed Decker has been promoted from financial operations manager to VP, director of financial services, Palio (palio.com). Mr. Decker joined Palio in 1999. **Chau Ho** has been promoted from brand designer to senior brand designer. He has been a member of Palio's team since 2007. **Mike Osterhout** has been promoted from senior art director to group art supervisor. Mr. Osterhout celebrates his 10-year anniversary at Palio this year. **Megan Stack** has been promoted from account executive to account supervisor. Ms. Stack joined Palio's team in 2010. **Kori-Ann Taylor** has been promoted from account supervisor to account director. Ms. Taylor joined Palio in 2007. **Uwe Tigör**, M.D., has been promoted from senior VP, chief medical officer, to executive VP, chief medical officer. Mr. Tigör joined Palio's team in 2006.





Publicis Healthcare Communications Group

Ed Cowen has joined Publicis Healthcare Communications Group (publicishealthcare.com) as managing director of Medicus International New York. Mr. Cowen has 15 years of experience launching and growing health and wellness brands, including building The CementBloc, a healthcare communications agency based in New York City, from a three-person boutique to a leading, full-service, multichannel healthcare agency employing more than 175 people.

Toronto office relaunches as Ogilvy Commonhealth

Ogilvy CommonHealth Worldwide, the health behavior experts of Ogilvy & Mather, has announced that the Ogilvy Healthworld office located in Toronto has relaunched the company under the new name, Ogilvy CommonHealth.

Ogilvy CommonHealth Worldwide is a WPP company. The organization houses and maintains individual Ogilvy CommonHealth and Ogilvy Healthworld brand identities within the marketplace.

"We are very pleased to now be officially known as Ogilvy CommonHealth," says Terry Cully, managing director of the newly rebranded group. "With this relaunch, there will be a clear and succinct differentiation between ourselves in Toronto and the Ogilvy Healthworld office located in Montreal. We look forward to continuing to work closely with Ogilvy CommonHealth Worldwide's global network resources and delivering quality, expertise and service to our clients."

Ogilvy CommonHealth Worldwide, with 66 offices across 36 countries, provides marketing services including brand identity and development, clinical trial recruitment, digital/interactive services, direct-to-consumer, direct-to-patient, global integration, managed care marketing, market research and analytics, media planning and buying, medical advertising and promotion, medical education, public affairs and relations, relationship marketing, and strategic consulting. The network also offers scientific communications and publications services through a wholly owned separate legal entity.

McCann Healthcare Worldwide Japan's CMG and MDS combine to form MDS-CMG

McCann Healthcare Worldwide Japan, a division of McCann Healthcare Worldwide, McCann Worldgroup, and Interpublic Group, has announced the creation of MDS-CMG, a new Japanese healthcare communications leader in scientific content across all therapeutic areas. This new business entity has been formed through the acquisition of a 51 percent interest in MDS Co. Kazuko Oneda, who has run MDS, will continue as president of MDS-CMG, reporting to Amar Urhekar, president of McCann Healthcare Worldwide Japan.

"This is an exciting and validating moment," Mr. Urhekar says. "For some time, we have been working to elevate our scientific offering by several orders of magnitude. Combining MDS and CMG Japan gives us the best scientific offering in Japan."

Under Mr. Urhekar, McCann Healthcare Worldwide Japan has been on a mission to redefine healthcare communications in Japan.

In the last year, the organization won Campaign Asia's Specialist Agency of the Year award for the fourth straight year; its second Grand Global Award; a first-ever Digital Gold at the 2011 Spikes Asia Advertising Festival; and a Gold CLIO Healthcare Award, among others.

This merger, agency leaders say, further solidifies McCann Healthcare Worldwide Japan's leadership status across all phases of healthcare communications.

"Scientific understanding amid constant content expansion is our passion," Ms. Oneda says. "By combining our strengths, we have become a powerhouse with an offering that is unparalleled locally."

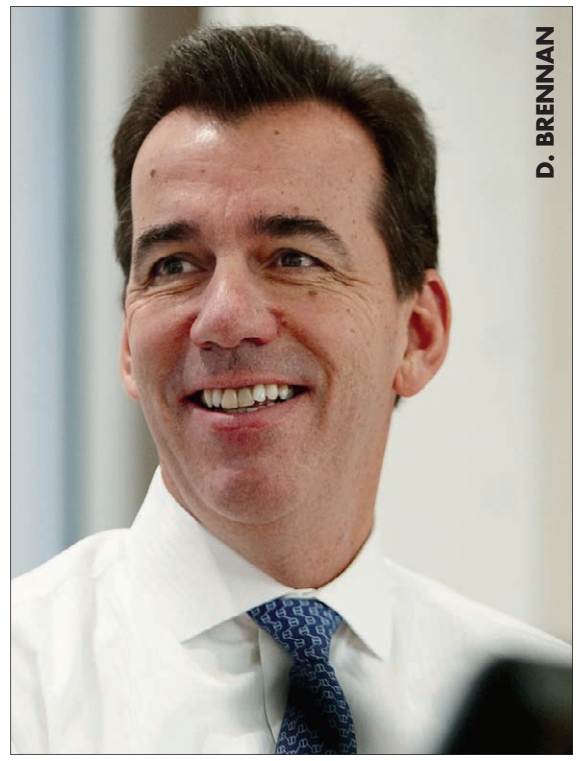
The newly acquired MDS was previously a part of the CMIC Holdings Co., which consists of 17 companies that together offer comprehensive services related to all the processes of a pharmaceuticals company, from research and development to manufacture and sale.

"MDS' staff of 48 scientists has an outstanding track record as a company that fully understands the effective communication of science and medicine," says John Cahill, global CEO of McCann Healthcare Worldwide. "This will greatly strengthen our CMG offering in Japan. We see this major acquisition for McCann Healthcare Worldwide Japan as the beginning of a new era of synergy and cooperation between CMIC and McCann Healthcare Worldwide. Like McCann Healthcare Worldwide, CMIC brings an integrated portfolio of solutions to its clients across their products' lifecycles. The possibilities for future partnerships and collaboration between McCann Healthcare Worldwide and CMIC are endless."

PeopleontheMove

By Joshua Slatko joshua.slatko@ubm.com

Brennan retires from AZ


D. BRENNAN

AstraZeneca's longtime CEO **David Brennan** has decided to retire.

Following Mr. Brennan's decision, the company's board asked Executive Director and Chief Financial Officer **Simon Lowth** to act as interim CEO from June 1, 2012 until a permanent successor is in place. **Julie Brown**, VP group finance, will become interim chief financial officer on the same date. Mr. Brennan retired from AstraZeneca and relinquished his board responsibilities on June 1.

At the same time, AstraZeneca also announced that **Leif Johansson** would succeed **Louis Schweitzer** as non-executive chairman on 1 June 2012 – three months earlier than previously announced – and has become chairman of the nomination and governance committee. This, company leaders say, will enable Mr. Johansson to lead the selection process for Mr. Brennan's successor, including both internal and external candidates. Mr. Johansson's appointment to the AstraZeneca board is subject to approval by shareholders at the company's annual general meeting.


S. LOWTH


L. JOHANSSON


L. SCHWEITZER

"After more than six years as CEO of this great company I have decided that now is the right time to step down and allow a new leader to take the reins," Mr. Brennan says. "The board's decision to appoint Simon Lowth as interim CEO has my full support and I am confident that AstraZeneca will continue to have a positive impact on the lives of patients around the world and by doing so will deliver real value to our shareholders."

"David has led AstraZeneca's business with skill, integrity, and courage during a period of enormous change for the pharmaceutical industry and for the company," Mr. Schweitzer says. "We fully understand and respect David's decision to retire and thank him for his selfless leadership of the company. I know we can count on Simon's leadership, supported by a strong and experienced senior executive team, to maintain focus and momentum as the board seeks a smooth transition to a new chief executive over the coming months."

Mr. Brennan was appointed to his current role in January 2006 and is one of the longest serving chief executives in the pharmaceutical sector. From 2001 until his appointment as CEO, he was president and CEO of AstraZeneca LP, the company's North American subsidiary.

Mr. Brennan began his career in 1975 at Merck, where he started as a sales representative in the U.S. Division and later worked in sales and marketing management in the U.S. and International divisions. He joined AstraMerck in 1992 and helped to build the joint venture into a multi-billion dollar business in the United States, which was then merged to form AstraZeneca in 1999.

Mr. Lowth joined AstraZeneca as an executive director and chief financial officer in November 2007. He joined the company from Scottish Power PLC, where he had served as finance director.

Before working at Scottish Power, Mr. Lowth spent 15 years with the global management consultancy McKinsey & Co., latterly as a senior director responsible for the company's UK industrial practice.

PHARMA

■ **Allen Waxman** is named senior VP and general counsel, Eisai Inc., a U.S. subsidiary of Eisai Co. Mr. Waxman joins Eisai from Kaye Scholer LLP, where he was a partner and chair of the firm's Life Sciences Group. Eisai (eisai.com) is a research-based human healthcare company that discovers, develops, and markets products throughout the world.

BIOPHARMA/BIOTECH

■ **William K. Heiden** is named president and CEO, AMAG Pharmaceuticals Inc. Mr. Heiden has also been appointed to the company's board of directors. He joins AMAG from GTC Biotherapeutics Inc., where he had served as president and CEO since June 2010. AMAG Pharmaceuticals (amagpharma.com) is a biopharmaceutical company that manufactures and markets Feraheme in the United States.

■ **Dr. Sven Jan-Anders Karlsson** is named CEO, Verona Pharma Plc. Dr. Karlsson was formerly the CEO at S*BIO, a Singapore and U.S.-based biotechnology company focused on the discovery and development of novel small molecule anti-cancer drugs. Verona Pharma (veronapharma.com) is a biotechnology company dedicated to discovering new drugs for the treatment of chronic respiratory diseases, such as chronic obstructive pulmonary disease, asthma, allergic rhinitis, and cough.


P. CALAIS

■ **Dr. Philippe Calais** is named CEO of Antisense Pharma. Dr. Calais has more than two decades of international experience in executive positions in biotech and pharmaceutical companies – including Hofmann La-Roche and ICI Pharmaceuticals – and has successfully guided several medicines from their clinical development to their commercialization. Antisense (antisense-pharma.com) is a biopharmaceutical focused on targeted therapies for previously incurable cancer diseases based on antisense technology.

■ **Cynthia Collins** has been appointed as president and CEO, GenVec Inc. In addition, Ms. Collins is expected to be appointed to the board of directors of GenVec. **Paul H. Fischer**, Ph.D. has stepped down as GenVec's president and CEO and as a member of the board. As announced in December, Dr. Fischer is retiring, having served as GenVec's president and CEO since 1996. Ms. Collins previously served as group VP, Cellular Analysis Business of Beckman Coulter from 2007 to until its sale in 2011. GenVec (genvec.com) is a biopharmaceutical company using differentiated, proprietary technologies to create superior therapeutics and vaccines.


C. COLLINS


P. FISCHER

■ **Dr Esteban Pombo-Villar** is named chief operations officer of the OBT group, Oxford BioTherapeutics. Prior to joining OBT, Dr. Pombo-Villar was at Novartis for more than 20 years, the last 12 years of which he focused on all aspects of creating and managing alliances. Oxford BioTherapeutics (oxfordbiotherapeutics.com) is an international biotechnology company focused on delivering innovative and cost-effective first-in-class medicines to fulfill major unmet patient needs in the field of cancer.


E. POMBO-VILLAR

■ **Jennifer Cayer** has joined Rempex Pharmaceuticals Inc. as chief operating officer. Ms. Cayer comes to Rempex from Conatus Pharmaceuticals, where she was co-founder and senior VP of corporate development. Rempex (rempexpharma.com) is a biopharmaceutical company whose mission is to develop important new therapies to combat the growing issue of antibiotic resistance.

■ **Danny Chung** is named chief financial officer, Sinovac Biotech Ltd. Nan Wang, who had served as interim chief financial officer since August 2011, will continue as the company's VP. Mr. Chung joined the company in November 2011 as Sinovac Beijing's finance director. Sinovac (sinovac.com) is a China-based biopharmaceutical company that focuses on the research, development, manufacturing and commercialization of vaccines that protect against human infectious diseases including hepatitis A and B, seasonal influenza, H5N1 pandemic influenza (avian flu) and H1N1 influenza (swine flu), as well as animal rabies vaccine for canines.


A. KNICKERBOCKER

■ **Dan Spiegelman** is appointed executive VP and chief financial officer, BioMarin Pharmaceutical Inc. Mr. Spiegelman most recently served as a consultant to provide strategic financial management support to a portfolio of public and private life science companies. BioMarin (bmrn.com) develops and commercializes innovative biopharmaceuticals for serious diseases and medical conditions.

■ **Aron Knickerbocker** is promoted to senior VP and chief business officer, Five Prime Therapeutics Inc. Mr. Knickerbocker joined Five Prime in September 2009 as its VP, business development, to lead the company's business development and licensing activities. Five Prime (fiveprime.com) is a clinical-stage, privately held biotechnology company discovering and developing innovative antibody and protein therapeutics.

■ **Mireli Fino** joins Protein Sciences Corp. as VP, manufacturing operations. She joins the company from Wyeth (now Pfizer) where she spent the past 20 years in various roles in vaccine development and commercial manufacturing, most recently as director manufacturing sciences and technology – drug substance. Protein Sciences (proteinsciences.com) is a vaccine development and protein production company that is dedicated to saving lives and improving health through the creation of innovative vaccines and biopharmaceuticals.

■ **Bruce Tomlinson** is named VP and chief financial officer, PDL BioPharma Inc. Mr. Tomlinson brings more than 20 years of financial leadership experience to PDL and joins the company from the biopharmaceutical company InterMune Inc. PDL (pdl.com) pioneered the humanization of monoclonal antibodies and, by doing so, enabled the discovery of a new generation of targeted treatments for cancer and immunologic diseases.

■ **Brian Lenz** is named VP and chief financial officer, ADMA Biologics Inc. Mr. Lenz has


B. LENZ

more than 15 years of financial reporting experience, of which 10 years have been in senior management roles of public pharmaceutical and biotechnology companies. ADMA (admabio.com) is a clinical stage biotechnology company which focuses its efforts on the development and commercialization of human plasma and plasma-derived therapeutics.

SPECIALTY

■ **Bob Radie** is appointed president and CEO, Egalet Ltd. Mr. Radie most recently served as president and CEO of Topaz Pharmaceuticals which was acquired by Sanofi Pasteur in the fourth quarter of 2011. Egalet (egalet.com) is a specialty pharmaceutical company using its patented technology to produce novel therapeutics on its own and with partners.

■ **Ron Squarer** is appointed CEO, Array BioPharma Inc. Mr. Squarer most recently served as chief commercial officer at Hospira Inc. Array BioPharma (arraybiopharma.com) is a biopharmaceutical company focused on the discovery, development and commercialization of targeted small-molecule drugs to treat patients afflicted with cancer and inflammatory diseases.

■ **Randy Milby** is named chief operating officer, CorMedix Inc. Mr. Milby worked as the global business director of applied biosciences and in other management positions at Dupont from 1999 through 2010. CorMedix (cormedix.com) is a development-stage pharmaceutical company that seeks to in-license, develop and commercialize therapeutic products for the prevention and treatment of cardiac and renal dysfunction, also known as cardiorenal disease.

■ **Watson Pharmaceuticals Inc.** has created a Global Integration Management Office focusing on planning and implementing the integration of Actavis, following the announcement of Watson's intention to acquire the Zug, Switzerland-based company. Marc Lehnen, Ph.D., has been designated to lead the Global Integration Management Office in the newly created position of senior VP, Global Integration Management. Dr. Lehnen will join Watson effective July 1, 2012. Before his appointment, Dr. Lehnen spent 10 years with McKinsey & Co. Also, Lisa M. DeFrancesco has been promoted to the position of VP, global investor relations. Ms. DeFrancesco joined Watson in 2009 as manager, investor relations, and was promoted to director, investor relations in 2010. Watson Pharmaceuticals (watson.com) is an integrated global specialty pharmaceutical company.

■ **John Tucker** becomes senior VP and chief commercial officer, Incline Therapeutics Inc. Mr. Tucker will serve as a member of Incline's senior leadership team and have broad re-


R. SQUARER

sponsibility for sales, marketing, and other commercial operations. He joins Incline from AMAG Pharmaceuticals where he was VP, commercial operations. Incline Therapeutics (inclinethera.com) is a hospital-focused specialty pharmaceutical company focused on the development of Ionsys, a compact, disposable, needleless patient-controlled system for the short-term management of acute postoperative pain in adult patients requiring opioid analgesia during hospitalization.

■ **Henric Juserius** is named the new head of Medivir AB's commercial activities. Mr. Juserius, who will have overall responsibility for Medivir's pharmaceutical marketing and sales, will join the company in August 2012 and will be part of the management team. He most recently served as commercial director for the Nordic region at Actelion Pharmaceuticals. Medivir (medivir.com) is an emerging research-based specialty pharmaceutical company focused on the development of high-value treatments for infectious diseases.

SERVICE SUPPLIERS

■ **Tim G. Guttman** is named senior VP and chief financial officer, AmerisourceBergen. Mr. Guttman had been serving as the company's acting chief financial officer since Feb. 13, 2012, and was VP and corporate controller since joining AmerisourceBergen in 2002. Before joining AmerisourceBergen, Mr. Guttman was VP of finance at Syncor International Corp. AmerisourceBergen (amerisourcebergen.com) is one of the world's largest pharmaceutical services companies serving the United States, Canada and selected global markets.

■ **Ryan Kocher** is named VP of analytics, CMI. Mr. Kocher will lead CMI's analytical sciences team, where he will oversee all of CMI's analytic service processes and offerings, and guides development of new solutions. He spent the last five years at Ipsos Chicago, serving as director of marketing sciences. CMI (cmiresearch.com) is a full-service marketing research company that combines comprehensive market research expertise with marketing insight to provide clients with a deep understanding of their customers by identifying the choices they make and why.

■ **Darren Kottler** is named associate director at the London headquarters of The Research Partnership. Mr. Kottler brings experience in launching and maintaining syndicated quantitative studies across many therapy areas, including both secondary care market tracker studies and primary care longitudinal database studies. The Research Partnership (researchpartnership.com) conducts high-quality global market research for the pharmaceutical industry.

Watson expands executive team

Watson Pharmaceuticals Inc. has refined and expanded the responsibilities of its senior executive team, in recognition of the company's continued global expansion, particularly following the announcement of Watson's intention to acquire Actavis. **Sigurdur Oli Olafsson**, executive VP, global generics, has been named president of global generics. **G. Frederick Wilkinson**, executive VP of global brands, has been named president, global brands and biosimilars. **Robert A. Stewart**, executive VP, global operations, will assume expanded responsibilities leading the company's Anda Inc. distribution business, and has been named president, global operations. Additionally, **R. Todd Joyce** has been named chief financial officer – global; **Charles M. Mayr** has been named chief communications officer – global; and **Patrick J. Eagan** has been named senior VP, human resources – global.

"In 2007, when I joined Watson, my goals were to establish a global foundation for generic growth; sharpen the focus of our branded business and drive leadership in key therapeutic categories; execute a long-term biosimilars growth strategy; define an accelerated growth strategy for our Anda Distribution business; and ensure that Watson's global supply chain remains the leader in the industry," says **Paul M. Bisaro**, president and CEO, Watson (watson.com). "I recruited the most talented executive team in the industry and they have consistently delivered solid performance that has demonstrated progress against these goals. As we complete the global expansion of our generics business with the proposed acquisition of Actavis, focus on expanding the breadth of our brand product portfolio and commercial position, including in biosimilars, and as we strengthen our global supply chain and distribution business, this team of exceptionally skilled and successful leaders will drive our businesses to continue global growth and success."

With the broader global commercial presence and revenue diversification resulting from the proposed acquisition, Mr. Olafsson has been named president, global generics. Mr. Olafsson joined Watson as executive VP, global generics in September 2010. Prior to joining Watson, Mr. Olafsson served as CEO of Actavis Group, where he was responsible for overseeing Actavis' global pharmaceutical business with operations in more than 40 countries. From 2006 to 2008, Mr. Olafsson served as deputy CEO of Actavis Group, and was CEO, Actavis Inc. US and chief executive corporate development from 2003 to 2006, where he led Actavis US sales and marketing organization, and also led the acquisition and integration of Pharma Avalanche, Biovena, Lotus Laboratories, Amide Pharmaceuticals, and Alpharma Generics.

As a result of the expansion of Watson's brand pharmaceutical business into international markets and into biosimilars, Mr. Wilkinson has been named president, global brands. He was appointed Watson executive VP, global brands in September 2009. Prior to joining Watson, Mr. Wilkinson was president and chief operating officer of Duramed Pharmaceuticals Inc. the proprietary products subsidiary of Barr from 2006 to 2009. Before joining Duramed Pharmaceuticals, Inc., he was president and CEO of Columbia Laboratories Inc. from 2001 to 2006. From 1996 to 2001, Mr. Wilkinson was senior VP and chief operating officer of Watson Pharmaceuticals.

As president, global operations, Mr. Stewart will assume additional responsibility for managing Watson's Anda Inc. distribution business, in addition to global operations. Mr. Stewart has served as executive VP, global operations, since August 2010. He joined Watson in November 2009 as senior VP, global operations. Before joining Watson, Mr. Stewart held various positions with Abbott Laboratories Inc. from 2002 until 2009 where he most recently served as VP, global supply chain. Prior to joining Abbott, he worked for Knoll Pharmaceutical Co. from 1995 to 2001 and Hoffman La-Roche Inc.

As a result of the more challenging and complex global business that will result from the acquisition of Actavis, Mr. Joyce has been promoted to chief financial officer – global. Mr. Joyce has served as executive VP, chief financial officer since March 2011. He had previously served as senior VP, chief financial officer since October 2009. Mr. Joyce joined Watson in 1997 as corporate controller, and was named VP, corporate controller, and Tteasurer in 2001. During October 2006 to November 2007 and from July 2009 until his appointment as chief financial officer, Mr. Joyce served as interim principal financial officer. Before joining Watson, Mr. Joyce served as VP of tax from 1992 to 1996 and as VP of tax and finance from 1996 until 1997 at ICN Pharmaceuticals.

In recognition of expanded global communications, investor relations, and corporate affairs responsibilities following the announcement of the proposed acquisition of Actavis, Mr. Mayr has been promoted to chief communications officer. Mr. Mayr joined Watson as senior VP, corporate affairs in September 2009. Prior to joining Watson, Mr. Mayr operated an advertising and public relations consulting company from 1998 to 2009, serving such clients as Watson, the Generic Pharmaceuticals Association, Barr Pharmaceuticals, and a variety of professional associations and consumer products and service companies. Before starting his consultancy business, he served as director of corporate communications for Barr Pharmaceuticals Inc. from 1994 to 1998.

Mr. Eagan joined Watson in 2011 as senior VP, human resources, initially reporting to David Buchen. In his global role, he will report directly to Mr. Bisaro. He joined Watson from Abbott Laboratories, where he held numerous positions of increasing responsibility in his nearly 20 years with that company. Before taking the Watson post, Mr. Eagan was divisional VP, human resources, global pharmaceuticals operations for Abbott. He was promoted to this position in 2009, having served since 2007 as divisional VP, human resources, pharmaceutical products U.S.

THELASTWORD

Medical innovation: You can't win a race when you're shooting yourself in the feet!

By Sander A. Flaum, managing partner, Flaum Navigators, and Chairman, Fordham Leadership Forum, Fordham University Graduate School of Business

I've read that key segments in the U.S. economy may finally be shaking off the lethargy of the last three years. Wish I could say the same for the biomedical industry. Some days, I feel like we're at the starting line of a race waiting for the gun to go off – while the other runners are already charging down the track. On other days, I think we've got the starting gun and we're blasting off our toes.

It's not as though our industry's stagnation is a secret. The Tufts Center for the Study of Drug Development, which monitors pharma, headlined its January 2011 report: "Drug Developers Are Aggressively Changing the Way They Do R&D." The article rosily predicted that patent expirations and lean R&D pipelines would soon lead to positive changes within the industry and new activism on the part of FDA.

Great news, right?

But then, exactly one year later, in the Tufts 2012 report, we see this headline: "Drug Companies Are Taking Steps to Improve R&D Productivity." And once again, the report trumpets that that patent expirations and lean R&D pipelines will soon etc...

Huh? In the words of Dr. Yogi Berra, this really is déjà vu all over again!

Look, we can't afford to be complacent. According to a 2011 report from the Milken Institute, our industry is responsible for about five million jobs and contributes more than $500 billion a year to the economy. If we don't bounce back, the recovery ain't gonna happen.

Dr. Andrew von Eschenbach, who is chairman of the Manhattan Institute's Project FDA and also a former FDA commissioner, noted recently in the *Wall Street Journal* that although we're still the world leader in biotech, other countries, including Israel, Singapore, and China, are challenging our leadership. According to Dr. von Eschenbach, today's FDA is woefully unequipped to monitor 21st century medicine.

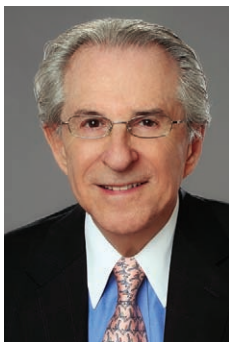
No one disputes the amazing service FDA provided by preventing thalidomide from being used in the United States to treat morning sickness. But that was in the 1950s. Today, FDA's concerns over safety issues that are undetectable without lengthy statistical meta-analysis have added years of study and millions of dollars to the drug development process.

The answer is not to get rid of FDA, but to empower the agency to do its job better. The old Phase 1, 2, 3, et cetera clinical trial paradigm desperately needs updating. Already, diagnostic tests can predict who will —or won't – respond to a particular drug. As increasingly effective drugs are developed for conditions such as cancer, obesity, and Alzheimer's, traditional randomized trials enrolling thousands of patients are impractical. Insisting on them will simply drive drug development out of the United States.

Several years ago, I had the unhappy experience of working on the premarketing development for a drug intended to treat a devastating orphan disease. Despite a favorable safety profile, encouraging efficacy, and a highly positive PDUFA vote, FDA rejected the drug. It's now being used overseas with apparent efficacy and no safety issues that I've heard about. Nevertheless, if you live in the United States, you'll need your passport to get a prescription. I wish I could say this was unusual. Anyone who has worked in global pharma has their own horror stories.

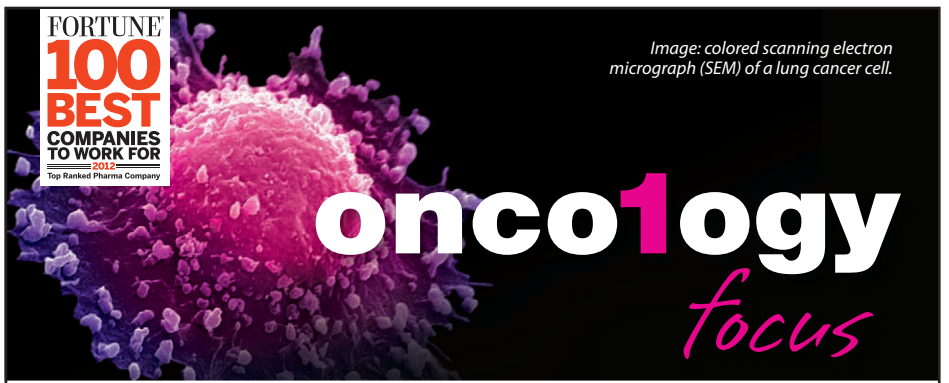
Over the years, my colleagues and I have had quibbles and even quarrels with FDA, but we've always acknowledged that despite its flaws, we still had the world's best system for ensuring the safe and efficient development of new drugs.

Alas, according to the 2012 California Biomedical Industry Report, 80 percent of CEOs of life science companies no longer agree that the FDA approval process is superior, and a similar percentage of CEOs believe we could lose our leadership position within five years.



Don't get me wrong—safety should always be paramount. Some drugs should never be approved. I'm just saying that if we expect the U.S. biomedical industry to stay in front, FDA has to modernize, too. Please, let's not see another "Things Will Soon Get Better in Pharma" headline in 2013. The race for worldwide biomedical leadership is on—and it's still ours to win. ■ MEDADNEWS

Recruitment



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