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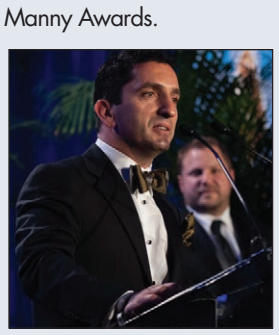

22ND ANNUAL REPORT
TOP 100 BIOTECHNOLOGY COMPANIES

REACHING NEW HEIGHTS

Biotech industry growth is bolstered by increased R&D spending, an upswing of approved first-in-class medicines, elevated Wall Street valuations, and continued forging of pipeline alliances with Big Pharma.

By Andrew Humphreys
andrew.humphreys@ubm.com

The top 100 revenue-generating public biotech companies featured in this annual compilation garnered 2012 revenue of $113.34 billion versus $100.61 billion in the prior year, a 12.7 percent improvement. R&D expenditure for the same 100 companies also rose 12.7 percent, from $26.94 billion during 2011 to $30.38 billion for last year. The employee count for the leading biotechnology players additionally increased year over year, growing 4.1 percent.

The top 10 biotech revenue producers of 2012 each posted sales increases compared to 2011. Those 10 companies combined for $93.01 billion in biotech/biopharma revenue in 2012 versus $82.96 billion during the prior calendar term, accounting for 12.1 percent growth. The leading 10 R&D spenders also each increased their expenditures from 2011 to 2012, growing 14.7 percent from a combined $20.77 billion in 2011 to $23.81 billion for last year. The work-force totals for the 10 largest biotech entities additionally each climbed higher, coming in at a collective 3.9 percent uptick from two years ago to 2012.

BIOTECH STOCKS AND MARKET CAPS CONTINUE TO SOAR

The valuations of listed biotech companies have recovered to reach levels not seen since before the global financial crisis and economic recession. For full-year 2012, the Nasdaq Biotechnology Index improved by 32 percent compared to the previous calendar term. Also in 2012, the AMEX Biotechnology Index rose 42 percent and the Deutsche Borse AG's DAXsubsector Biotechnology Index increased 37 percent versus 2011.

The impressive growth has continued through 2013 for companies of all sizes and market values. As of May 24, the Burrill Select Indice was up 34.5 percent versus the end of 2012, the Burrill Large Cap grew 35.6 percent, the Burrill Mid-Cap advanced 26.9 percent, and the Burrill Small Cap rose 15.8 percent since Dec. 31, 2012. According to a Burrill & Co. report, four leading biotech companies – **Amgen**, **Biogen Idec**, **Gilead** Sciences, and **Celgene** – each ended first-quarter 2013 trading at all-time highs.

Market-cap values for many biotech entities have climbed high during the past year and a half as well. For long-time biotech leader Amgen, the company's market capitalization grew nearly 30 percent from 2011 to 2012,

continued on page 8

MAN CLIMBING: 4X6; DNA: LM/ISTOCKPHOTO.COM

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By Christiane Truelove chris.truelove@ubm.com

I had an urge to restart my garden this year. Spare moments were spent clearing out my two raised beds, hacking up turf, moving many cubic feet of dirt, installing three new raised beds, catching a rampaging groundhog, and attempting to start plants from seed. Even with my little portable greenhouse, however, and lots of attention, I could not get the damn things to sprout. I wound up buying some plants – and that's when the seedlings started popping up. If all goes well, by high summer I'll be drowning in tomatoes and by the fall, Brussels sprouts.

But the growing-my-own-plants-from-seed thing might have gone better if I had actually, oh, I don't know, looked up any information on how to grow plants from seeds and understood the needs of different kinds of seedlings. Still, double shame on me, because lots and lots of free gardening advice is available right there on the Internet and among my friends. And I wound up benefiting from friends' advice when it came to removing the groundhog. After the whistle-pig decimated $100 worth of my neighbor's plants and flowers, I mused on Facebook about how to take it out. One friend not only had a trap to loan, but tips on how to place it and bait it. And sure enough, the advice (and the trap) worked beautifully. Just some cut-up apple and a big enough trap, and he walked right in. Groundhogs ARE dumb.

And the power of networking and soliciting experiences is not only valuable for gardening or groundhog removal. Just about every one of my readers knows that when it comes to designing programs aimed at patients, finding out what patients want or need is key. But even though everyone has been talking about listening to patients for years and years, the message has been getting through very slowly. The patient advocates I spoke with for my story about adherence (see page 18) are just not really feeling the love from pharma. There are a few exceptions (Lilly COI and Sanofi were spoken about very favorably), but overall, the industry has a long way to go, especially on the social media front.

"This is just another example of pharma's continued tone-deafness and lack of essential humanity: they can't stop being brand for long enough to see that, by being brand, they're no longer HUMAN. We are objects to them, occasionally subjects (in clinical trials or focus groups), but never are we people. Pharma is welded to their balance sheets and shareholder value, making them slaves to their own relentless selling machinery."

The biggest resentment seems to be saved for marketers who won't look beyond their own needs – or others who act like that.

One of the advocates I interviewed, Regina Holliday, went full blast on a writer for a trade magazine after the writer cold-contacted her to contribute some thoughts about how pharma marketers can best work with patients to improve their campaigns. The writer had asked, "While this model may work for consumer packaged goods companies, is there any way for pharma could take advantage of this data and do something similar?"

Holliday reacted to this statement as warmly as my seedlings did to 45-degree nights. "A word of advice: Don't ever ask a patient activist how you can take advantage in the realm of patients," she snapped.

Another patient advocate I talked with for my story, Casey Quinlan, replied to Holliday's post with this: "I've been saying the following to pharma audiences for several years now: Stop telling us to 'ask your doctor about ...' You need to start asking US 'are we helping?' They're still not listening to me. I don't know if they'll be smart enough to hear you, either. This is just anther example of pharma's continued tone-deafness and lack of essential humanity: they can't stop being brand for long enough to see that, by being brand, they're no longer HUMAN. We are objects to them, occasionally subjects (in clinical trials or focus groups), but never are we people. Pharma is welded to their balance sheets and shareholder value, making them slaves to their own relentless selling machinery."

Carolyn Thomas, who blogs at Heart Sisters, also had an angry reaction to the inquiry: "Take advantage? TAKE ADVANTAGE? That's the kind of unfortunate out-loud thinking that has helped industry promote what's evolved into marketing-based medicine."

And Gilles Frydman put it this way: "Marketing in a world of networked patients has to be a lot smarter than just using KOLs as shills. In our world, marketers must be providing, to individuals, at least as much value as the value they derive from interacting with these individuals. Few have reached that point."

So yes, these patients are talking and listening to each other – and they don't think much of pharma's ability to do that. If pharma truly wants to have a two-way communication, focus less on the platitudes and more on the actual outcomes of the conversations. Mr. Groundhog was lured into a trap with sweet apple bits. As tempting as it may be to use sweet words to "bait" patients into communicating with you, they're human beings – and they will give as good as they get.

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inside

ON THE COVER

SPECIAL REPORT: BIOTECH • REACHING NEW HEIGHTS
Biotech industry growth is bolstered by increasing R&D spending, an upswing of approved first-in-class medicines, elevated Wall Street valuations, and continued forging of pipeline alliances with Big Pharma.

FEATURES

DEPARTMENTS

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WHAT'S ONLINE

WEBCAST: GAINING STRATEGIC ADVANTAGE THROUGH A 360 CUSTOMER VIEW

Date: June 12, 2013
Time: 12:00 pm - 1:00 pm ET

A key component of the new marketing model is creating a cogent customer experience, as well as effective campaign optimization, across all channels. A full 360 view of the customer is foundational to the process, yet companies generally face two challenges in making it happen. First, getting all the data in one place remains a struggle; e.g., the marketing data is often disconnected from field data, and some sources such as digital may be left out altogether. Second, once you've pulled together a 360 view, what exactly do you do with it in practice? Experts in this webinar will outline the most progressive approaches to pulling this view together, and even more importantly using it on a day-to-day basis to design and optimize their campaigns. Learn how to gain competitive advantage by overcoming the hurdles that continue to trip up so many organizations even today.

Speakers:
Anindita Basu, Principal and COE (Resource Optimization), IMS Management Consulting

Mark Karch, executive VP, Appature

Go to http://bit.ly/18DgAvi to register for this Webcast

WHAT'S IN PRINT

AWKWARD INTERACTIONS
The patients interviewed for *Med Ad News*' story on adherence expressed general dissatisfaction with the industry's social media efforts in its attempts to find out what patients really need.

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SOCIAL STUDIES
Even without guidance from FDA, pharma brand managers are doing their best to work out the conundrum of social media.

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CONTROVERSIAL MAKES FOR BETTER COMMUNICATIONS?
Companies operating in more controversial business sectors, including pharmaceuticals, appear to be among the world's best at digital corporate communications, with three big pharmas appearing in the top ten of Bowen Craggs' index of corporate web effectiveness.

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DRAFT DIVISION PARTNERS WITH QUANTIA
Hudson Global, a division of Draftfcb Healthcare, and QuantiaMD have formed an partnership to deliver a full suite of personalized digital solutions that provide physicians education and service on their terms.

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continued from page 1

and another 20 percent from year-end 2012 through late May 2013. After more than tripling in value during 2012 to $16 billion, **Regeneron** Pharmaceuticals' market-cap value stood at $25.58 billion as of May 20, 2013. Gilead's market cap as of that date came in at $84.34 billion, after almost doubling in value during 2012. Gilead's May 2013 market value was higher than Big Pharma players such as **AstraZeneca**, **Bristol-Myers Squibb**, and **Eli Lilly**.

Additionally, the financing environment for biotech entities has improved compared to previous years, though it remains difficult overall.

BIOTECH M&A TRANSACTIONS HEADLINE 2012'S TOP HEALTHCARE INDUSTRY DEALS

Three of the four healthcare industry's largest merger and acquisition deals of 2012 involved biotech players. The largest biotech company to be purchased during the past year was San Diego-based **Amylin** Pharmaceuticals, a former top 20 revenue generator on *Med Ad News*' leading public biotechnology company lists. Bristol-Myers Squibb of Princeton, N.J., completed the acquisition of Amylin during August 2012 for $31 per share in cash for an aggregate purchase price of $5.3 billion. The total value of the deal, including Amylin's net debt and a contractual payment obligation to Eli Lilly of about $1.7 billion, reached $7 billion. Amylin now operates as a wholly owned subsidiary of Bristol-Myers Squibb.

Amylin's primary concentration has been on the R&D and commercialization of a franchise of GLP-1 agonists for treating type 2 diabetes. That franchise included two type 2 diabetes treatments available in the United States and European Union – **Byetta** (exenatide) injection and **Bydureon** (exenatide extended-release for injectable suspension/exenatide 2 mg powder and solvent for prolonged release suspension for injection) – and a life-cycle management pipeline with delivery devices and formulation improvements.

The addition of Amylin's GLP-1 franchise complements Bristol-Myers Squibb's diabetes franchise and created a comprehensive disease management platform. BMS in recent years has been undergoing a transformation into a next-generation biopharmaceutical company.

The third-largest industry deal of 2012 involved another multi-billion dollar biopharma company acquisition completed in August 2012: **Human Genome Sciences** was purchased by pharmaceutical giant **GlaxoSmithKline**. All outstanding shares of Rockville, Md.-based HGS were acquired for $14.25 per share in cash, amounting to $3.6 billion on an equity basis or $3 billion net of cash and debt. The lead medicine in the HGS portfolio was **Benlysta** (belimumab), which in March 2011 became the first FDA-approved treatment for lupus in more than 50 years. Pipeline assets included the type 2 diabetes drug **albiglutide** (awaiting FDA approval) and the atherosclerosis treatment **darapladib** (U.S. Phase III).

GlaxoSmithKline managers said the HGS acquisition was well-aligned with the London company's long-term strategy of delivering sustainable growth, simplifying GSK's business model, enhancing R&D returns and deploying capital with discipline. Through complete ownership of Benlysta, albiglutide and darapladib, GlaxoSmithKline expected to simplify and optimize R&D, commercial and manufacturing operations to advance these products most effectively and efficiently while securing the full potential long-term value of the assets. GlaxoSmithKline anticipated achieving at least $200 million in cost synergies to be fully realized by 2015.

Valued as the fourth-biggest industry transaction of 2012 was **Dainippon Sumitomo** Pharma's $2.6 billion purchase of **Boston Biomedical**. One of Japan's leading pharma players, Dainippon Sumitomo in April 2012 acquired Boston Biomedical, a Cambridge, Mass.-based biotech company developing a new generation of targeted cancer therapeutics.

Boston Biomedical is regarded as an industry leader in the creation of drugs that are designed to target cancer stem cells. CSCs are a sub-population of cancer cells that are highly malignant and are believed to be fundamentally responsible for cancer growth, recurrence, drug resistance, and metastasis. Cancer stem cells are highly resistant to existing chemotherapies and targeted agents. Targeting CSCs represents significant promise for fundamentally advancing cancer treatment. The drug candidates **BBI608** and **BBI503** may become the first marketed anticancer products in the world targeting cancer stem cells. Dainippon Sumitomo plans to commercialize the two small molecular oral drugs in 2015 or later.

2013 BIOTECHNOLOGY M&A ACTIVITY

"Nothing like Gilead's $11bn swoop on **Pharmasset** at the tail end of 2011 emerged in 2012, so 2013 could well follow as a muted year for multiples," commented EvaluatePharma's publishing arm, EP Vantage, in its 2012 Biotech and Pharma Year in Review report. "But with biotech valuations sky high, it is clear that any acquirer will have to be prepared to pay top dollar to access many of the drug developers that investors have become so excited about."

Top 15 biotech company **Elan** in May 2013 rejected a revised tender offer from the privately held investment firm **Royalty Pharma**. According to Elan execs, Royalty Pharma's revised offer to acquire all of the Dublin, Ireland-based company's shares for $12.50 per share via its shell subsidiary **Echo Pharma Acquisition** substantially undervalues Elan. The first offer to acquire all Elan shares for $11.25 was turned down during April 2013.

May was a very busy month for Elan in addition to rejecting the Royalty Pharma revised tender offer. On May 20, the company announced a variety of transactions to transform and advance Elan for years to come. Elan announced the acquisition of **AOP Orphan** – a private, orphan disease company based in Vienna, Austria – as well as 48 percent of **Newbridge** Pharmaceuticals – a private Africa, Middle East, and Turkey company with headquarters in Dubai, UAE.

Elan also revealed the divestment of **ELND005** into **Speranza** Therapeutics – a private and independent Irish company. ELND005 is undergoing clinical development for bipolar, agitation/aggression in Alzheimer's disease, and Down syndrome. Additionally, Elan announced debt issuance of $800 million to optimize full potential of capital structure and markets, as well as a share repurchase of $200 million – consistent and systematic return of capital to shareholders.

Elan agreed on May 13 to purchase a participation interest in potential future royalty payments related to four respiratory programs partnered with GlaxoSmithKline: **Relvar/Breo** Ellipta, **Anoro** Ellipta, **MABA** (Bifunctional Muscarinic Antagonist-Beta2 Agonist) monotherapy (GSK961081, or MABA '081), and **vilanterol** (VI) monotherapy. Elan was responsible for a one-time cash payment of $1 billion to **Theravance** in exchange for a 21 percent participation interest in the potential future royalty payments from the four programs when, as and if received by Theravance.

During early April 2013, Elan announced the closing of the **Tysabri** (natalizumab) collaboration transaction with Biogen Idec. This deal represented the largest M&A activity for the pharma/biotech arena during first-quarter 2013. Elan gained $3.25 billion in cash and will receive double-digit tiered royalty payments, on all indications, for the life of the complete Tysabri asset. For the first 12 months Elan will receive 12 percent royalties on in-market sales of Tysabri. Then Elan will receive 18 percent royalties on in-market sales up to $2 billion and 25 percent royalties on in-market sales exceeding $2 billion. For 2012, in-market sales of the multiple sclerosis drug amounted to $1.6 billion.

According to Elan, the totality of the strategically driven decisions announced on May 20 along with the Theravance royalty participation deal and dividend pass through as well as the Tysabri transaction, will form a dynamic and unique business foundation for Elan in the years ahead. "Upon approval and closing of this set of transactions (from May 20), the Elan business would be comprised of very high net margin, multi asset and long term revenue streams (within Multiple Sclerosis and Respiratory), an orphan disease platform, and a strong regional commercial presence," says Elan Chief Financial Officer Nigel Clerkin. "All of these are underpinned by a strong balance sheet as well as a highly efficient and strategically advantageous tax structure."

The top M&A transaction of first-quarter 2013 was Gilead's license pact with **MacroGenics**. MacroGenics is a privately held biotech company that develops next-generation antibody therapeutics. On Jan. 7, the two companies agreed on deal for the development and commercialization of Dual-Affinity Re-Targeting (DART) products directed at up to four undisclosed targets. MacroGenics' DART technology is a proprietary, bi-specific antibody platform in which a recombinant molecule can target two different antigens.

The DART technology allows for the generation of highly stable antibody-based therapeutics that can simultaneously target two separate antigens. According to MacroGenics, DART therapeutics can accommodate virtually any variable region sequence in a "plug-and-play" fashion. They are highly potent and have very favorable manufacturing properties. DARTs may be engineered with short or extended serum half-life to support different applications in various disease areas. In one particular configuration, the proteins can redirect the body's cell-destroying, immune effector cells against tumor cells.

MacroGenics has engineered more than 100 different DART proteins developed for internal pipeline programs and external collaborators. The Rockville, Md., venture-backed company intends to file an IND for its first DART product candidate in late 2013.

MacroGenics could receive up to $30 million in license fee payments and an additional $85 million in pre-clinical milestones across the four DART programs. Gilead holds exclusive global rights for three of the programs. For the other, MacroGenics retains development and commercialization rights outside of North America, Europe, Australia and New Zealand, which covers multiple major markets including Japan, China, Korea, Brazil, Russia and others. Gilead will fully fund MacroGenics' research activities for each program. MacroGenics could receive up to $1 billion in clinical, regulatory and commercialization milestone payments if every program

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 2012 or fiscal-year 2012.

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 2012 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 listed 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 changes 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 2012 and 2011, 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 may have been 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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achieves the requisite milestones. MacroGenics may be the recipient of tiered (up to low double-digit) royalties on future net sales.

Gilead completed its acquisition of the drug development company **YM** Biosciences in February 2013. YM has mainly concentrated on advancing its lead product candidate **CYT387**, an orally administered inhibitor of the JAK1 and JAK2 kinases. These kinases have been implicated in a variety of hematological and immune cell disorders such as myeloproliferative neoplasms and inflammatory diseases, as well as particular cancers. Gilead landed YM for $2.95 per share in cash, with a transaction value of $510 million.

Shire was the only biotech company to account for a top 10 industry acquisition during the first three months of 2013. Kicking off the year eight days into it, Shire announced a deal to purchase Cambridge, Mass.-based **Lotus** Tissue Repair. The privately held biotech company has been developing the first protein replacement therapy being investigated for treating dystrophic epidermolysis bullosa. DEB is a devastating orphan disease for which there is no available treatment option other than palliative care.

Lotus Tissue Repair's **ABH001** is an engineered, human fibroblast-derived dermal substitute. ABH001 is generated by culturing human neonatal dermal fibroblasts onto a bioresorbable polyglactin mesh scaffold. The PGLLA mesh serves as the scaffolding onto which fibroblasts are grown; they secrete dermal collagen, other extracellular matrix proteins, growth factors, and cytokines, producing a three-dimensional human tissue containing metabolically active living cells. The final product includes a well-developed dermal matrix and evenly dispersed neonatal dermal fibroblasts.

NEW POTENTIAL BLOCKBUSTER DRUGS

The biotech/biopharma industry has produced a variety of first-in-class medicines in 2012 and 2013 that each could generate more than $1 billion in peak annual sales.

Perjeta (pertuzumab) is approved for marketing in the United States and European Union for treating people with HER2-positive metastatic breast cancer who have not received prior therapy for their metastatic disease. The **Roche** medicine is designed specifically to prevent the HER2 receptor from pairing with other HER receptors (EGFR/HER1, HER3 and HER4) on the surface of cells, a process believed to play a role in tumor growth and survival. Binding of Perjeta to HER2 may additionally signal the body's immune system to destroy the cancer cells. The combination of Perjeta, the established megabrand **Herceptin**, and chemotherapy is thought to provide a more comprehensive blockade of HER signalling pathways. Industry analysts have estimated global sales of nearly $2 billion for Perjeta during 2016.

Another Roche medicine recently cleared by U.S. regulators is **Kadcyla** (trastuzumab emtansine or T-DM1). This is the first FDA-approved antibody-drug conjugate for the treatment of HER2-positive mBC, an aggressive form of the disease. An antibody-drug conjugate is a new type of targeted cancer medicine that can attach to certain forms of cancer cells and deliver chemotherapy directly to them. The drug consists of the antibody trastuzumab and the chemotherapy DM1, which are combined using a stable linker. This is the first antibody-drug conjugate to result from Roche and **Genentech**'s 30 years of HER2 pathway research and the third medicine Roche has developed for the treatment of HER2-positive breast cancer.

Similar to Herceptin, Kadcyla binds to HER2-positive cells and is believed to block out-of-control signals that make cancer grow while calling on the body's immune system to attack cancer cells. Once Kadcyla is taken up by those cells, the drug is designed to destroy them by releasing the DM1 inside the cells. Roche licenses technology for Kadcyla via a deal with **ImmunoGen**. EvaluatePharma analysts have projected 2018 global sales of $1.65 billion for the anti-HER2 (ErbB-2) MAb-DM1 maytansinoid conjugate.

Xeljanz (tofacitinib) is a novel medicine marketed by **Pfizer** for the treatment of rheumatoid arthritis. The drug is available in the United States, Japan, and Russia for treating adults with moderate-to-severe active rheumatoid arthritis with previous treatment history. Xeljanz is the first approved RA treatment in a new class of drugs called Janus kinase (JAK) inhibitors.

Ariad Pharmaceuticals' kinase inhibitor **Iclusig** (ponatinib) was cleared for marketing by FDA in December 2012 via an accelerated approval process. The new medicine is indicated for treating adult patients with chronic phase, accelerated phase, or blast phase chronic myeloid leukemia that is resistant or intolerant to prior tyrosine kinase inhibitor therapy. Iclusig represents the first medicine to reach the marketplace for Ariad, a worldwide oncology company concentrated on the discovery, development, and commercialization of cancer drugs.

Iclusig could reach yearly sales of $800 million for patients for whom previous treatments have failed, and that sales amount could nearly double with approval of additional use against new cases. Iclusig is also being studied in clinical development by Ariad for newly diagnosed chronic myeloid leukemia, lung cancer (FGFR), AML (FLT3), gastrointestinal stromal tumors (C-KIT), and lung cancer (RET).

Biotech entity **Vertex** Pharmaceuticals received the green light from U.S. regulators at the end of January 2012 for **Kalydeco** (ivacaftor). The drug is indicated for treating cystic fibrosis in patients 6 years old or older with G551D mutation in the CFTR gene. This product represents a breakthrough therapy for cystic fibrosis because the already-existing therapies only treat the symptoms of this genetic disease.

Kalydeco sales for 2012 totaled $172 million. During January 2013, Kalydeco gained FDA Breakthrough Therapy Designations as monotherapy for potential additional indications beyond the current approval for CF patients 6 and older with the G551D mutation; and in combination therapy with **lumacaftor** (product code VX-809). Vertex's CFTR corrector lumacaftor is undergoing Phase II trials for the treatment of cystic fibrosis. Industry analysts have projected 2016 worldwide Kalydeco sales of more than $1 billion.

Tecfidera (dimethyl fumarate) was developed and is marketed by a biotech powerhouse. Tecfidera is manufactured by Biogen Idec of Weston, Mass., in capsule form. The drug may decrease a person's white blood cell count (lymphocytes). Lymphocytes aid in protecting the body from infection and low counts can raise the risk of infection, although no significant increase in infections was evident in patients taking Tecfidera in clinical studies.

The immunomodulator gained U.S. regulatory clearance during late March 2013 for the treatment of relapsing-remitting multiple sclerosis and was launched shortly thereafter. The new first-line oral treatment has been clinically proven to significantly reduce important measures of disease activity, including relapses and development of brain lesions. The drug also has been demonstrated to slow disability progression over time, while showing a favorable safety and tolerability profile. Impressive late-stage data revealed that Tecfidera could cut the yearly multiple sclerosis relapse rate by about half. The twice-daily dosage was associated with a decrease in new or expanded lesions by 71 percent to 99 percent, with a 38 percent reduction in progression to disability.

Tecfidera is undergoing regulatory review by health authorities in Australia, Canada and Switzerland. On March 22, 2013, the Committee for Medicinal Products for Human Use issued a positive opinion recommending that the European Commission provide marketing authorization for the drug in the European Union as a first-line oral treatment for adults with RRMS. The European Commission decision is anticipated during second-quarter 2013. Backed by recently granted 15-year U.S. and EU patent protection lasting until 2028, more than $3 billion in sales on an annual basis are projected for Tecfidera.

Another potential blockbuster for Biogen Idec is **Plegridy** (peginterferon beta-1a). The pegylated subcutaneous injectable candidate for relapsing forms of multiple sclerosis (RMS) is awaiting FDA clearance as of May 2013. Plegridy represents a new-generation version of Biogen Idec's long-standing blockbuster MS medicine, the glycoprotein **Avonex** (interferon beta-1a).

The U.S. regulatory filing for Plegridy was based on the results from the first year of the two-year worldwide Phase III ADVANCE study. The data showed that the drug met all primary and secondary endpoints by significantly reducing disease activity such as relapses, disability progression and brain lesions versus placebo. The new molecular entity additionally demonstrated favorable safety and tolerability profiles at one year.

With Plegridy, interferon beta-1a is pegylated to extend its half-life and prolong its exposure in the body, allowing for study of a less frequent dosing schedule. "We believe that based on the efficacy and safety Plegridy has demonstrated, in addition to its less frequent dosing schedule, it has the potential to become a preferred interferon treatment option," stated Douglas E. Williams, Ph.D., Biogen Idec's executive vice president of Research and Development.

As of late May 2013, Biogen Idec intended to file a Marketing Authorization Application (MAA) for Plegridy to the European Medicines Agency within the near term.

Approved by FDA in August 2012, the HIV medicine **Stribild** has been predicted to approach $3 billion in 2018 global sales. Marketed by Gilead, the complete once-daily single tablet regimen is intended for HIV-1 infection for treatment-naïve adults. Stribild unites four drug compounds in one daily tablet: the integrase inhibitor elvitegravir, the pharmacoenhancing agent cobicistat, and the nucleoside analog reverse transcriptase inhibitors emtricitabine and tenofovir disoproxil fumarate.

NEAR-TERM PROSPECTS

FDA approved for marketing about 40 novel biologic or small-molecule agents during 2012. Last year represented the highest amount of FDA approvals for novel drugs since 1997. More than half of the 2012 approvals were marked by FDA priority review or orphan drug designations.

One of the most-anticipated new product launches in 2013 could be **BioMarin** Pharmaceuticals' **BMN-110** for MPS IVA (Morquio A Syndrome). The inherited, autosomal recessive disease results from a deficiency of a particular lysosomal enzyme, N-acetylgalactosamine-6 sulfatase (GALNS). Deficiency of the enzyme leads to excessive lysosomal storage of keratan sulfate in many tissues and organs. This accumulation causes systemic skeletal dysplasia, short stature and joint abnormalities, which restrict mobility and endurance. Thorax malformation impairs respiratory function, and malformation of neck vertebrae and ligament weakness results in cervical spinal instability and potentially cord compression. Other symptoms can consist of hearing loss, corneal clouding, and heart valve disease.

BMN-110 is enzyme replacement of GALNS, which is anticipated to result in clearance of keratan sulfate from the lysosome. As a result, progression of the disease would be halted and may lead to amelioration of some symptoms.

"There are only about 3,000 patients diagnosed with the rare lysosomal storage disorder Mucopolysaccharidosis Type IVA, also called Morquio A syndrome," noted analysis from FierceBiotech. "The condition, the result of an enzyme deficiency, triggers a host of skeletal and bone disorders. But a number of drug developers in the rare disease area have proven time and again that a successful enzyme replacement drug that can control these conditions can earn a significant amount of revenue, with payers of every stripe willing to foot huge bills for these treatments."

As mentioned earlier in this article, albiglutide is a glucagon-like peptide-1 receptor agonist awaiting FDA approval for the treatment of type 2 diabetes. GlaxoSmithKline announced the U.S. regulatory filing for the investigational once-weekly subcutaneous treatment in January 2013 and the EU submission two months later. The biological drug was previously developed by Human Genome Sciences, which was acquired by GlaxoSmithKline.

GLP-1 is a peptide normally secreted from the gastrointestinal tract during a meal, which in turn aids in the release of insulin to control blood sugar elevations after eating. For individuals with type 2 diabetes, GLP-1 secretion in response to a meal is reduced or absent. GLP-1 is quickly degraded while albiglutide has been developed to have a longer duration of action by comprising two copies of modified human GLP-1 fused in series to human albumin.

Though not a first-in-class medicine and it will be joining a crowded diabetes marketplace if approved, albiglutide does represent yearly billion-dollar sales potential.

Pharma power **Sanofi** is seeking global marketing approval of **Lemtrada** (alemtuzumab) for treating multiple sclerosis. The monoclonal antibody selectively targets CD52, which is a protein abundant on T and B cells. Treatment with alemtuzumab leads to the depletion of circulating T and B cells that are believed to be responsible for the damaging inflammatory process in multiple sclerosis. Alemtuzumab has minimal effect on other immune cells. The acute anti-inflammatory effect of the drug is immediately ensued by the onset of a distinctive pattern of T and B cell repopulation that continues over time. This process rebalances the immune system in a way that potentially reduces MS disease activity.

Alemtuzumab came to Sanofi through its acquisition of **Genzyme**, which maintains the global rights to alemtuzumab. Genzyme holds primary responsibility for the drug compound's development and commercialization in multiple sclerosis. **Bayer** HealthCare retains an option to jointly promote alemtuzumab in MS, which the German company plans to carry out. Upon regulatory approval and marketing, Bayer would receive contingent payments based on sales revenue. ■ MEDADNEWS

REVENUE — TOP 100 BIOTECHNOLOGY COMPANIES

Rank in 2012	Company	Revenue in 2012	Revenue in 2011	Net Income/(Loss) in 2012	Net Income/(Loss) in 2011	Earnings/(Loss) Per Share in 2012	Earnings/(Loss) Per Share in 2011
1	Roche	$34,935,779,034 (biotech sales estimate)	$31,296,139,490 (biotech sales estimate)	$10,422,309,907 (for entire Roche Group)	$10,178,095,340 (for entire Roche Group)	$11.90 (for entire Roche Group)	$11.71 (for entire Roche Group)
2	Amgen Inc.	17,265,000,000	15,582,000,000	4,345,000,000	3,683,000,000	5.52	4.04
3	Gilead Sciences Inc.	9,702,517,000	8,385,385,000	2,591,566,000	2,803,637,000	1.64	1.77
4	Biogen Idec Inc.	5,516,461,000	5,048,634,000	1,380,033,000	1,234,428,000	5.76	5.04
5	Celgene Corp.	5,506,713,000	4,842,070,000	1,456,180,000	1,317,456,000	3.30	2.85
6	Shire Plc.	4,681,200,000	4,263,400,000	745,400,000	865,000,000	1.31	1.51
7	CSL Ltd.	4,617,226,820	4,315,549,760	981,224,360	939,283,160	1.89	1.73
8	UCB SA	4,451,785,800	4,174,031,400	324,046,800	306,044,200	1.81	1.70
9	Grifols SA	3,370,271,890	2,308,978,757	328,389,284	64,588,185	0.96	0.21
10	Novo Nordisk A/S	2,958,979,317 (biopharma sales only)	2,748,696,523 (biopharma sales only)	3,700,148,476	1,859,051,828	6.71	5.18
11	Actelion Ltd.	1,843,229,178	1,915,391,916	323,372,081	(156,040,311)	2.74	(1.31)
12	Ipsen Group	1,642,615,090	1,556,157,603	(37,305,245)	1,166,311	(0.45)	0.01
13	Vertex Pharmaceuticals Inc.	1,527,042,000	1,410,626,000	(107,032,000)	29,574,000	(0.50)	0.14
14	Regeneron Pharmaceuticals Inc.	1,378,477,000	445,824,000	750,269,000	(221,760,000)	6.75	(2.45)
15	Elan Corp.	1,202,800,000	1,246,000,000	(137,400,000)	560,500,000	(0.23)	0.94
16	Alexion Pharmaceuticals Inc.	1,134,114,000	783,431,000	254,822,000	175,315,000	1.20	0.91
17	Cubist Pharmaceuticals Inc.	926,359,000	753,972,000	154,075,000	33,023,000	2.10	0.52
18	United Therapeutics Corp.	916,076,000	743,183,000	304,442,000	217,868,000	5.71	3.67
19	LFB Group	598,843,630	556,023,160	4,629,240	(8,872,710)	N/A	N/A
20	Alkermes Inc.	575,548,000	389,977,000	24,983,000	(113,678,000)	0.18	(0.99)
21	The Medicines Co.	558,588,000	484,732,000	51,254,000	127,877,000	0.93	2.35
22	Questcor Pharmaceuticals Inc.	509,292,000	218,169,000	197,675,000	79,591,000	3.14	1.21
23	BioMarin Pharmaceutical Inc.	500,723,000	441,358,000	(114,347,000)	(53,836,000)	(0.95)	(0.48)
24	Biocon Ltd.	466,347,806	394,686,795	93,526,806	62,106,209	0.47	0.31
25	ViroPharma Inc.	427,933,000	544,374,000	5,611,000	140,659,000	0.08	1.68
26	PDL BioPharma Inc.	374,525,000	362,041,000	211,669,000	199,389,000	1.45	1.15
27	Onyx Pharmaceuticals Inc.	362,165,000	447,174,000	(187,787,000)	76,110,000	(2.88)	1.19
28	Dendreon Corp.	325,530,000	341,613,000	(393,610,000)	(337,806,000)	(2.65)	(2.31)
29	Acorda Therapeutics Inc.	305,814,000	292,237,000	154,958,000	30,605,000	3.84	0.76
30	Swedish Orphan Biovitrum AB	283,982,959	282,162,697	(14,896,856)	2,647,185	(0.06)	0.01
31	Emergent BioSolutions Inc.	281,888,000	273,384,000	23,524,000	23,019,000	0.65	0.64
32	Spectrum Pharmaceuticals Inc.	267,707,000	192,963,000	94,545,000	48,517,000	1.46	0.84
33	Seattle Genetics Inc.	210,812,000	94,778,000	(53,782,000)	(152,030,000)	(0.46)	(1.34)
34	Galapagos NV	191,928,290	140,080,802	(7,356,634)	(42,559,432)	(0.28)	(1.61)
35	Medivation Inc.	181,696,000	60,389,000	(41,257,000)	(38,841,000)	(0.56)	(1.11)
36	Bavarian Nordic A/S	175,518,111	90,397,604	(41,435,206)	(46,341,804)	(1.59)	(1.78)
37	SciClone Pharmaceuticals Inc.	156,269,000	132,565,000	9,620,000	28,122,000	0.16	0.49
38	NPS Pharmaceuticals Inc.	130,644,000	101,645,000	(18,735,000)	(36,267,000)	(0.22)	(0.45)
39	Cangene Corp.	111,029,000	149,707,000	(28,287,000)	1,509,000	(0.42)	0.02
40	3SBio Inc.	106,184,204	85,843,754	16,222,719	17,208,407	0.10	0.11
41	Enzo Biochem Inc.	103,083,000	102,029,000	(39,269,000)	(12,960,000)	(1.01)	(0.34)
42	Isis Pharmaceuticals Inc.	102,049,000	99,086,000	(65,478,000)	(84,801,000)	(0.65)	(0.85)
43	Optimer Pharmaceuticals Inc.	101,531,429	144,978,373	(36,986,630)	7,821,624	(0.78)	0.17
44	Zeltia SA	93,087,587 (biopharma sales only)	103,689,832 (biopharma sales only)	8,477,939	6,096,452	0.04	0.03
45	MorphoSys AG	89,507,641	129,589,346	2,497,404	10,565,465	0.10	0.46
46	AMAG Pharmaceuticals Inc.	85,378,000	61,249,000	(16,750,000)	(77,069,000)	(0.78)	(3.64)
47	Array BioPharma Inc.	85,135,000	71,901,000	(23,581,000)	(56,324,000)	(0.33)	(1.02)
48	Genmab A/S	83,670,453	60,587,687	(84,098,961)	(102,960,533)	(1.83)	(2.29)
49	Nektar Therapeutics	81,191,000	71,480,000	(171,855,000)	(133,978,000)	(1.50)	(1.19)
50	Anika Therapeutics Inc.	71,358,505	64,778,635	11,757,460	8,466,680	0.82	0.62
51	Idenix Pharmaceuticals Inc.	69,663,000	6,951,000	(32,400,000)	(51,979,000)	(0.27)	(0.57)
52	Lee's Pharmaceutical Holdings Ltd.	68,884,864	51,526,383	14,576,184	10,832,162	2.89	2.26
53	Alnylam Pharmaceuticals Inc.	66,725,000	82,757,000	(106,014,000)	(57,649,000)	(2.11)	(1.36)
54	Repligen Corp.	62,266,536	23,450,247	14,156,037	(1,612,625)	0.45	(0.05)
55	Vitrolife AB	59,688,575	52,585,609	49,329,602	4,525,037	0.23	0.23
56	Targacept Inc.	57,860,000	97,637,000	(6,998,000)	(8,529,000)	(0.21)	(0.27)
57	Dyax Corp.	54,650,000	48,737,000	(29,265,000)	(34,599,000)	(0.30)	(0.35)
58	Neurocrine Biosciences Inc.	53,140,000	77,413,000	5,025,000	37,571,000	0.08	0.67
59	Cadence Pharmaceuticals Inc.	50,184,000	16,696,000	(80,973,000)	(93,021,000)	(0.95)	(1.41)
60	Sinovac Biotech Ltd.	48,576,700	56,841,892	(15,679,120)	(844,696)	(0.29)	(0.02)
61	Exelixis Inc.	47,450,000	289,636,000	(147,645,000)	75,697,000	(0.92)	0.58
62	Opko Health Inc.	47,044,000	27,979,000	(31,288,000)	(3,662,000)	(0.11)	(0.01)
63	Intercell AG	45,861,624	42,285,536	(32,580,848)	(37,631,864)	(0.63)	(0.78)
64	Enzon Pharmaceuticals Inc.	42,600,000	48,072,000	(2,783,000)	(20,763,000)	(0.06)	(0.40)

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REVENUE — TOP 100 BIOTECHNOLOGY COMPANIES

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65	Halozyme Therapeutics Inc.	42,325,226	56,086,436	(53,552,002)	(19,769,851)	(0.48)	(0.19)
66	Avanir Pharmaceuticals	41,275,073	10,495,895	(59,743,827)	(60,631,563)	(0.45)	(0.51)
67	Sarepta Therapeutics Inc. (formerly known as AVI BioPharma Inc.)	37,329,000	46,990,000	(121,287,000)	(2,318,000)	(5.14)	(0.11)
68	Cerus Corp.	36,695,000	30,602,000	(15,917,000)	(16,982,000)	(0.33)	(0.35)
69	ArQule Inc.	36,414,000	47,310,000	(10,872,000)	(10,762,000)	(0.18)	(0.20)
70	Endocyte Inc.	34,682,111	191,023	(17,291,758)	(40,531,613)	(0.48)	(1.40)
71	Paion AG	34,478,250	4,177,970	20,585,726	(17,595,940)	0.81	(0.69)
72	Ablynx NV	34,368,249	28,121,347	(36,658,437)	(56,444,581)	(0.84)	(1.30)
73	Xoma Corp.	33,782,000	58,196,000	(71,065,000)	(32,743,000)	(1.10)	(1.04)
74	AEterna Zentaris Inc.	33,665,000	36,053,000	(24,621,000)	(29,191,000)	(1.03)	(1.72)
75	Active Biotech AB	33,653,963	34,641,101	(25,843,535)	(13,961,696)	(0.38)	(0.20)
76	Immunomedics Inc.	32,733,827	14,709,479	809,952	(15,070,421)	0.01	(0.20)
77	Vanda Pharmaceuticals Inc.	32,727,000	31,270,000	(27,664,000)	(9,802,000)	(0.98)	(0.35)
78	Bioniche Life Sciences Inc.	32,558,878	35,386,033	(12,807,700)	(15,703,461)	(0.25)	(0.14)
79	Gentium S.p.A.	31,570,131	30,711,150	5,242,614	3,484,789	0.35	0.23
80	Ligand Pharmaceuticals Inc.	31,388,000	30,037,000	(527,000)	9,715,000	(0.03)	0.49
81	Maxygen Inc.	30,011,000	561,000	20,123,000	51,437,000	0.74	1.80
82	Arena Pharmaceuticals Inc.	27,587,000	12,719,000	(85,477,000)	(109,224,000)	(0.45)	(0.80)
83	BioCryst Pharmaceuticals Inc.	26,293,000	19,643,000	(39,081,000)	(56,948,000)	(0.79)	(1.26)
84	InterMune Inc.	26,174,000	5,407,000	(150,081,000)	(154,774,000)	(2.30)	(2.58)
85	Flamel Technologies SA	26,101,000	32,600,000	(3,228,000)	(8,774,000)	(0.13)	(0.36)
86	QLT Inc.	25,475,000	42,228,000	45,698,000	(30,416,000)	0.91	(0.61)
87	PharmAthene Inc.	25,175,887	24,266,274	(4,724,586)	(3,797,573)	(0.10)	(0.08)
88	Biota Pharmaceuticals Inc.	24,346,000	13,329,000	(2,198,000)	(13,289,000)	(0.08)	(0.59)
89	Vernalis Plc.	23,170,745	19,277,248	(8,311,728)	(12,167,178)	(0.02)	(0.12)
90	Novavax Inc.	22,076,000	14,688,000	(28,507,000)	(19,364,000)	(0.22)	(0.17)
91	Sosei Co.	20,671,056	9,100,053	(6,825,536)	(20,622,444)	(0.58)	(1.74)
92	OncoGenex Pharmaceuticals Inc.	20,095,000	5,496,000	(21,098,000)	(14,673,000)	(1.56)	(1.51)
93	Amicus Therapeutics Inc.	18,411,000	21,434,000	(48,785,000)	(44,412,000)	(1.07)	(1.28)
94	SciGen Ltd.	18,367,000	16,675,000	4,143,000	(17,727,000)	0.01	(0.03)
95	Vical Inc.	17,519,000	30,018,000	(22,899,000)	(7,283,000)	(0.27)	(0.10)
96	Curis Inc.	16,971,991	14,762,580	(16,416,907)	(9,858,895)	(0.21)	(0.13)
97	Transgene SA	16,795,140	18,576,111	(55,554,738)	(56,098,673)	(1.75)	(1.77)
98	ImmunoGen Inc.	16,357,000	19,305,000	(73,319,000)	(58,274,000)	(0.95)	(0.85)
99	Agenus Inc.	15,961,000	2,756,000	(11,325,000)	(23,276,000)	(0.51)	(1.21)
100	Peregrine Pharmaceuticals Inc.	15,233,000	13,492,000	(42,119,000)	(34,151,000)	(0.50)	(0.56)

Notes to page 12, 14, and 16 charts:
Some of these notes pertain to listings in *Med Ad News*' June 2012 top 100 biotechnology company report. The following companies are new to *Med Ad News*' top 100 biotechnology company ranking for the 2012 financial year: Agenus Inc., Arena Pharmaceuticals Inc., Avanir Pharmaceuticals, Cadence Pharmaceuticals Inc., Endocyte Inc., Idenix Pharmaceuticals Inc., Maxygen Inc., Novo Nordisk A/S, OncoGenex Pharmaceuticals Inc., Opko Health Inc., Paion AG, Peregrine Pharmaceuticals Inc., Shire Plc., and Sosei Co.

Alkermes 2012 figures are for the fiscal year ended March 31, 2013. Alkermes 2011 figures are for the fiscal year ended March 31, 2012.

Amylin Pharmaceuticals, No. 16 on last year's top 100 biotechnology revenue list, was acquired by Bristol-Myers Squibb in August 2012.

Array BioPharma 2012 figures are for the fiscal year ended June 30, 2012. Array 2011 figures are for the fiscal year ended June 30, 2011.

Biocon 2012 figures are for the fiscal year ended March 31, 2013. Biocon 2011 figures are for the fiscal year ended March 31, 2012.

Bioniche Life Sciences 2012 figures are for the fiscal year ended June 30, 2012. Bioniche 2011 figures are for the fiscal year ended June 30, 2011.

Bionor Pharma (bionorpharma.com), No. 82 on last year's top 100 biotechnology revenue list, did not generate enough revenue in 2012 to make this year's top 100 ranking.

Biota Holdings (which ranked No. 89 on last year's top 100 biotech revenue list) and Nabi Biopharmaceuticals (which ranked No. 90 on last year's top 100 biotechnology revenue list) merged on Nov. 8, 2012. The resulting company was renamed Biota Pharmaceuticals. Biota Pharmaceuticals 2012 figures are for the nine-month period ended March 31, 2013. Biota Pharmaceuticals 2011 figures are for the nine-month period ended March 31, 2012. Biota Holdings previously reported its financials for fiscal years ending June 30.

Cangene 2012 figures are for the fiscal year ended July 31, 2012. Cangene 2011 figures are for the fiscal year ended July 31, 2011.

CSL 2012 figures are for the fiscal year ended June 30, 2012. CSL 2011 figures are for the fiscal year ended June 30, 2011.

Diamyd Medical (diamyd.com), No. 63 on last year's top 100 biotech company list, did not generate enough revenue in 2012 to make this year's top 100 ranking.

Dynavax Technologies (dynavax.com), No. 78 on last year's top 100 biotechnology revenue list, did not generate enough revenue in 2012 to make this year's top 100 ranking.

Enzo Biochem 2012 figures are for the fiscal year ended July 31, 2012. Enzo 2011 figures are for the fiscal year ended July 31, 2011.

GenVec (genvec.com), No. 85 on last year's top 100 biotechnology revenue list, did not generate enough revenue in 2012 to make this year's top 100 ranking.

Human Genome Sciences, No. 36 on last year's top 100 biotechnology revenue list, was acquired by GlaxoSmithKline during August 2012.

ImmunoGen 2012 figures are for the fiscal year ended June 30, 2012.
ImmunoGen 2011 figures are for the fiscal year ended June 30, 2011.

Immunomedics 2012 figures are for the fiscal year ended June 30, 2012.
Immunomedics 2011 figures are for the fiscal year ended June 30, 2011.

Innate Pharma (innate-pharma.com), No. 88 on last year's top 100 biotechnology revenue list, did not generate enough revenue in 2012 to make this year's top 100 ranking.

Medivir (medivir.se), No. 49 on last year's top 100 biotechnology revenue list, did not generate enough revenue in 2012 to make this year's top 100 ranking.

Osiris Therapeutics (osiris.com), No. 65 on last year's top 100 biotechnology revenue list, did not generate enough revenue in 2012 to make this year's top 100 ranking.

Progenics Pharmaceuticals (progenics.com), No. 44 on last year's top 100 biotechnology revenue list, did not

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RESEARCH & DEVELOPMENT — TOP 100 BIOTECHNOLOGY COMPANIES

Rank in 2012	Company	R&D expense in 2012	R&D expense in 2011
1	Roche	$10,186,626,853 *(for entire Roche Group)*	$8,879,172,443 *(for entire Roche Group)*
2	Amgen Inc.	3,380,000,000	3,167,000,000
3	Novo Nordisk A/S	1,881,323,159	1,662,235,420
4	Gilead Sciences Inc.	1,759,945,000	1,229,151,000
5	Celgene Corp.	1,724,156,000	1,600,264,000
6	Biogen Idec Inc.	1,334,919,000	1,219,602,000
7	UCB SA	1,144,451,000	1,000,430,200
8	Shire Plc.	965,500,000	770,700,000
9	Vertex Pharmaceuticals Inc.	806,185,000	707,706,000
10	Regeneron Pharmaceuticals Inc.	625,554,000	529,506,000
11	Actelion Ltd.	491,064,306	488,099,605
12	CSL Ltd.	354,503,000	324,644,860
13	Onyx Pharmaceuticals Inc.	325,256,000	268,060,000
14	Ipsen Group	319,674,740	301,684,999
15	BioMarin Pharmaceutical Inc.	302,218,000	214,374,000
16	Cubist Pharmaceuticals Inc.	277,700,000	184,533,000
17	Alexion Pharmaceuticals Inc.	222,732,000	137,421,000
18	Elan Corp.	188,300,000	232,500,000
19	United Therapeutics Corp.	173,387,000	180,015,000
20	Seattle Genetics Inc.	170,297,000	163,396,000
21	Grifols SA	160,021,254	114,908,024
22	Isis Pharmaceuticals Inc.	158,458,000	157,397,000
23	Nektar Therapeutics	148,675,000	126,766,000
24	Alkermes Inc.	140,013,000	141,893,000
25	Exelixis Inc.	128,878,000	156,836,000
26	The Medicines Co.	126,423,000	110,180,000
27	Emergent BioSolutions Inc.	120,226,000	124,832,000
28	InterMune Inc.	106,571,000	74,973,000
29	Galapagos NV	103,205,048	108,607,114
30	Medivation Inc.	95,628,000	73,432,000
31	NPS Pharmaceuticals Inc.	94,839,000	73,831,000
32	Genmab A/S	92,659,439	91,935,189
33	LFB Group	90,398,770	101,714,690
34	Alnylam Pharmaceuticals Inc.	86,569,000	99,295,000
35	Dendreon Corp.	74,643,000	74,290,000
36	Halozyme Therapeutics Inc.	70,044,073	57,563,470
37	Idenix Pharmaceuticals Inc.	69,663,000	41,341,000
38	ImmunoGen Inc.	69,192,000	63,453,000
39	Xoma Corp.	68,324,000	68,137,000
40	ViroPharma Inc.	67,709,000	66,477,000
41	Transgene SA	62,596,326	68,214,423
42	Bavarian Nordic A/S	61,710,749	45,185,594
43	Ablynx NV	60,267,561	72,405,171
44	Swedish Orphan Biovitrum AB	59,308,782	82,060,070
45	Array BioPharma Inc.	56,719,000	63,498,000
46	Active Biotech AB	55,415,159	47,041,981
47	Arena Pharmaceuticals Inc.	54,112,000	58,706,000
48	Acorda Therapeutics Inc.	53,881,000	42,108,000
49	Sarepta Therapeutics Inc. *(formerly known as AVI BioPharma Inc.)*	52,402,000	66,862,000
50	Zeltia SA	51,949,074	51,775,478
51	BioCryst Pharmaceuticals Inc.	51,464,000	57,249,000
52	Amicus Therapeutics Inc.	50,273,000	50,856,000
53	Targacept Inc.	49,087,000	95,215,000
54	MorphoSys AG	48,444,154	71,854,585
55	Vanda Pharmaceuticals Inc.	45,446,000	28,996,000
56	Optimer Pharmaceuticals Inc.	45,202,722	43,085,307
57	Spectrum Pharmaceuticals Inc.	42,544,000	27,720,000
58	OncoGenex Pharmaceuticals Inc.	39,948,000	21,553,000
59	Neurocrine Biosciences Inc.	37,163,000	30,951,000
60	Peregrine Pharmaceuticals Inc.	35,688,000	29,462,000
61	Endocyte Inc.	35,670,418	28,827,746
62	Questcor Pharmaceuticals Inc.	34,269,000	16,778,000
63	ArQule Inc.	33,966,000	45,011,000
64	AMAG Pharmaceuticals Inc.	33,296,000	58,140,000
65	Biocon Ltd.	30,134,374	25,173,227
66	Dyax Corp.	30,028,000	34,676,000
67	Cangene Corp.	27,109,000	15,937,000
68	Flamel Technologies SA	26,115,000	25,089,000
69	Novavax Inc.	26,061,000	17,885,000
70	Intercell AG	25,422,243	38,483,129
71	Immunomedics Inc.	24,824,024	25,368,586
72	QLT Inc.	24,578,000	43,533,000
73	Avanir Pharmaceuticals	23,066,037	15,253,739
74	Enzon Pharmaceuticals Inc.	21,005,000	41,106,000
75	Bioniche Life Sciences Inc.	20,745,443	19,534,098
76	AEterna Zentaris Inc.	20,604,000	24,517,000
77	Vernalis Plc.	20,569,268	21,580,689
78	Opko Health Inc.	19,520,000	11,352,000
79	PharmAthene Inc.	19,509,629	21,219,853
80	Vical Inc.	17,340,000	17,975,000
81	Sinovac Biotech Ltd.	17,043,565	9,006,550
82	Curis Inc.	15,492,302	13,692,659
83	Biota Pharmaceuticals Inc.	13,583,000	17,769,000
84	3SBio Inc.	11,289,366	6,625,933
85	Ligand Pharmaceuticals Inc.	10,790,000	10,291,000
86	Agenus Inc.	10,564,000	11,023,000
87	Repligen Corp.	10,489,811	9,461,960
88	Gentium S.p.A.	7,849,134	7,114,885
89	Cerus Corp.	7,603,000	7,178,000
90	Cadence Pharmaceuticals Inc.	6,519,000	8,885,000
91	Enzo Biochem Inc.	6,293,000	7,806,000
92	SciClone Pharmaceuticals Inc.	6,143,000	12,346,000
93	Vitrolife AB	6,084,376	6,285,052
94	Anika Therapeutics Inc.	5,388,036	6,168,937
95	Paion AG	4,180,976	15,205,580
96	Sosei Co.	4,069,801	2,399,346
97	Lee's Pharmaceutical Holdings Ltd.	2,101,871	1,525,738
98	Maxygen Inc.	226,000	1,358,000
99	SciGen Ltd.	206,000	139,000
—	PDL BioPharma Inc.	N/A	N/A

continued from page 14

generate enough revenue in 2012 to make this year's top 100 ranking.

QLT 2012 revenue is reported as part of the company's discontinued operations. On Sept. 24, 2012, QLT announced that it completed the sale of the company's Visudyne business to Valeant Pharmaceuticals International. On Dec. 24, 2012, QLT entered into an exclusive option agreement with Mati Therapeutics, a development company led by Robert Butchofsky – QLT's former President and CEO – pursuant to which QLT granted Mati an exclusive 90-day option to acquire assets related to its punctal plug delivery system in exchange for $0.5 million.

Repligen 2012 figures are for the 12-month period ended Dec. 31, 2012. Repligen 2011 figures are for the nine-month period ended Dec. 31, 2011. Repligen changed its fiscal-year ending from March 31 to Dec. 31.

Sarepta Therapeutics changed its name from AVI BioPharma effective July 12, 2012.

Tekmira Pharmaceuticals (tekmirapharm.com), No. 86 on last year's top 100 biotechnology revenue list, did not generate enough revenue in 2012 to make this year's top 100 ranking.

Transition Therapeutics (transitiontherapeutics.com), No. 72 on last year's top 100 biotechnology revenue list, did not generate enough revenue in 2012 to make this year's top 100 ranking.

Unigene Laboratories (unigene.com), No. 79 on last year's top 100 biotechnology revenue list, did not generate enough revenue in 2012 to make this year's top 100 ranking.

Zeltia 2012 and 2011 revenue is for the company's biopharmaceutical business only and excludes its consumer chemicals segment.


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Failure to connect

With billions of dollars of sales lost to nonadherence, the pharma industry has launched its own efforts to help boost adherence; but listen to what these patients say about why pharma is still missing the mark.

by Christiane Truelove chris.truelove@ubm.com

THE FIGURE IS STAGGERING: medication nonadherence costs the pharma industry $564 billion in lost sales each year, according to a study by Cap Gemini and the patient adherence company HealthPrize. Communication with patients, once secondary to communication with physicians, has become the priority with many marketers, as pharma companies realize that better patient adherence would translate to not only a better bottom line, but better health outcomes overall. Yet patients' overall reaction to pharma's efforts to communicate and educate ranges between outright hostility at worst to tepid at best. In talking with five activist patients, *Med Ad News* found many reasons for these attitudes – and as long as patients feel that the industry is not truly listening to them or acknowledging their needs, adherence education efforts will continue to fall flat with them.

AWKWARD INTERACTIONS, ONLINE AND OFFLINE

"E-Patient Dave," Dave de Bronkart, is probably the most famous patient leading the charge towards healthcare empowerment, but he is not the only one. Since starting the Society for Participatory Medicine less than two years ago, de Bronkart has been joined by thousands of patients online, all talking about working with their physicians, other healthcare providers and FDA to improve the healthcare system.

In all of those conversations on e-patients.net, however, there is little about how pharma has reached out to patients, whether on adherence or any other topics. And the patients interviewed for this story expressed general dissatisfaction with the industry's social media efforts in its attempts to find out what patients really need.

Healthcare activist Regina Holliday, whose husband died of cancer and who cares for a son with autism, does not like it when a company reaches out to her with the intent to use her thoughts to get their own brand messages out. And she is especially annoyed with pharma's social media efforts.

"You just get angry, because [companies] act like you want to be my friend, you act like you want to bother to learn about me, but then you don't," Holliday says. "You don't learn anything about me and what our needs are. And that makes people angry. And that's often where social media and pharma have butted heads, because it's a conversation, and there's been a problem with realizing that. You actually have to talk as people, one to the other. It's not marketing, it's not traditional marketing at all. People are really willing to have truthful conversations, but you actually have to have a conversation."

Holliday is very aware that there are no real guidelines from FDA for social media, and companies are restricted from saying many things. But there are other things pharma can talk to patients about.

"I know it's tough, because you can't recommend, you actually can't give medical advice, there are laws that are making it tough for pharmaceutical companies to say a whole bunch of stuff, but they can talk as people though," she says. "They can talk about policy. One of the things they have to do is get their voice out there as people and talk, that's key. It can't be just a campaign, it has to be more than that."

Scott Strange, who has type 1 diabetes, was not impressed by Novo Nordisk's efforts to market its NovoLog Flexpen in its Race With Insulin campaign. Featuring racecar driver Charlie Kimball, who also has type 1 diabetes, the campaign includes a Twitter account through which Kimball talks about his races and living with the disease. The campaign is known for the pharma industry's first branded Tweet, in which Kimball talked about taking Levemir FlexPen before a race.

Strange is sharply critical of the Twitter campaign, calling it "a waste of time and a disaster."

"From my standpoint, I'd see a Tweet from Charlie saying, 'I just took my Levemir and I have a race today!'" Strange says. "And I'm going, 'Hey, that's great, Charlie, I took my insulin today too! Big deal!' So really, all they were doing, they actually weren't interacting with people, they were just talking at people, and that's a very common mistake."

To Strange, Novo Nordisk is treating Twitter as another marketing avenue, and because of that, the campaign rings falsely with him. But like Holliday, he realizes the pharma industry is operating under some real restrictions with social media.

"I know the FDA is very little help in this, it's almost like they're hanging everyone out in the breeze, letting them go until they hit some imaginary line, and then saying, 'whoah, that's too far,'" Strange says.

Kelly Young, known as @rawarrior on Twitter and who blogs at RAWarrior.com, says the reason why efforts to communicate with patients – via social media or specific programs for adherence – often fall flat is that there are a significant number of people at companies afraid to talk with patients.

Attending the American College of Rheumatology meeting as a member of the press and as an exhibitor, Young notices that one role of hers – patient – puts fear into some pharma execs. But she is not attending the meeting as a patient, Young says.

"Whether I'm an exhibitor or have a press badge, neither of them says patient on it," Young says. "And as I move through the exhibitor area and have conversations, some people are very comfortable having conversations but sometimes once a representative of a company recognizes that I'm a patient, they don't want to talk with me anymore. They're afraid to talk to me, they think just because I'm a patient, that there's possibly some violation by having a conversation with me. They're so afraid. I've been told to leave an exhibit when they found out I was a patient."

This overly cautious attitude towards patients has erupted in other incidents, she says. While discussing a consulting contract with one pharma company, Young mentioned that she'd had an adverse reaction to a pneumonia vaccine, something she had even blogged about.

"They stopped cold and changed the conversation to the pneumonia vaccine – 'I need to find out what that vaccine was, whether that was our product. It could be an adverse event and I'm supposed to find out about that,'" Young recalled. "I'm like, 'No!'"

Young says the company she was dealing with does own a pneumonia vaccine, but the vaccine she had a reaction to was not their vaccine. "I didn't mention their product, that shouldn't have entered into the conversation," she says. "It's just an example of what I think is wrong, that it could seem complicated, but it doesn't need to be complicated."

Part of the problem is due to FDA's reluctance to share any social media guidelines, Young believes.

"I don't think the FDA is doing us any favors by not saying anything," she says. "And I don't think there are guidelines that could cover every single circumstances. People are so worried about the FDA that they're oddly hypervigilant about customer discussions. I knew in that circumstance, he didn't necessarily have to respond that way. I have other friends that work for the same company that knew about the pneumonia vaccine reaction on my blog."

This overly cautious attitude makes it very difficult for the industry to effectively communicate with patients, Young says. "Whether it's adherence programs or marketing or research or anything, it's very difficult to build and move forward with patient involvement with pharma," she says.

Holliday says when it comes to social media, pharma has generally become more scared.

"I entered this space four years ago, and a lot of things hadn't been decided four years ago," she says. "And it seemed there were more people Tweeting back then or trying to talk back then, then there are now. Legal smacked down on so many people, but there are still things you can talk about. People became so frightened about screwing up, they stopped talking, period. They deleted accounts, they just disappeared. That's not the way to go, that's the ostrich method."

According to Holliday, executives who refuse to participate in social media, not because their companies actively restrict them from doing so but because of fear, are actually harming their companies in the long run. "They're not playing on the field, they're not being part of the conversation in this new world that is here and becoming more real every day, they're being left behind," she says. "Your job is going to go away! The world has changed, and the traditional forms are going away.

"Now, medicine is a little bit behind the times, they have a lower adoption rate than other fields, but my goodness, the conversations being had in social media are so incredibly important, and oftentimes months ahead of what's going on in traditional media, that you're getting left behind," she says. "You have to jump on board as soon as you can if you're going to stay in any kind of field that is about advocating or promoting a thing or a cause. ... So you're missing where people are actually at, they're on Facebook, they're on Twitter, they're communicating through these mediums, that's where they're spending most of their time. People are leaving television behind, they're leaving traditional print media behind, they're spending all of their time in these real-time media. And if you're not part of that conversation, we forget about you."

ARE YOU LISTENING?

Patient activist and breast cancer survivor Casey Quinlan is not afraid to say exactly what she thinks about pharma's efforts to communicate and to promote adherence.

"I believe that the pharma industry needs to wake up and realize that adherence in a population health model is going to be a dead dinosaur in the next decade," Quinlan says. "This 'Yeah, we have a blockbuster drug that works sort of OK in 60 percent of the population and doesn't do squat for the other 40 percent' – really? Is there a reason why people get prescribed a blood thinner or statin and it's not an SOP drill to give them the CYP genomic testing to figure out if it is even going to work for them, or if it's even the right dosage or the right medication for them? When there is genomic testing available that will tell you if 60 or 70 percent of the drugs that are most commonly prescribed will even work in this human that's standing in front of you, why is that not standard?"

Part of the adherence issue stems from how every party in the healthcare system is not used to listening to patients.

"Everybody's getting in their own way, but it would be a better system if all parts of the transaction had a better understanding of what was possible and what their responsibility was in delivering information," Quinlan says. "Patients need to be honest too. But the power balance has been skewed for so long. Patients have been assigned the meat puppet position, but now that we're waking up and saying, 'Hey, wait a minute,' everyone's getting confused by the fact that we're opening up our mouths and speaking."

Holliday has also noted the general tendency to not listen to patients.

"One of the major problems, why there is so much ambivalence, is that a lot of patients feel we're not getting to the root of the problem, we're just treating symptoms," she says.

Another adherence problem stems from a medication not being a good fit for a person – not just side effects, but lifestyle reasons.

PRIMARY PICTURE/ISTOCKPHOTO.COM

"With my son, he has all sorts of issues with pill-form medication, he can't stand taking a pill," Holliday says. "But there's a tendency to want to prescribe pills for him. He really needs liquids, but liquid medicine isn't accessible, that's part of the problem too. ... you've got to modify the regimen to match the child. But when you smack into the world of medicine, there's very little understanding."

Young says she dislikes what kinds of assumptions are made about why patients are not adherent, when there are good, logical reasons such as side effects.

"When you listen to patients, you can find out why they make decisions," she says. "Patients are just people who had to use medical care, they may not want to use medical care, but they do. Even chronic patients, people with long-term diseases, there are probably some patients – just like some of any group of people – who maybe have a low education or who have anxiety or some kind of psychological problem that would interfere with adherence. But I wouldn't assume just because patients are nonadherent that they're not intelligent or they have emotional problems or they don't have good reasons for making decisions.

"And it seems to me suddenly, when you become a patient, there's some kind of labeling that suddenly you're not bright enough to make decisions or be a part of making these decisions. Or the reasons you make these decisions is something that's subversive and is not a good reason. It's really strange, and you couldn't talk about any race of people or any country, any nationality the way that you read how people talk about patients, there's something about us, we're not logical, we're not engaged."

Carla Berg, who is taking medication for a chronic thyroid condition, says she wants the pharma industry to provide good information so that she can check out what her doctor prescribes for her.

"I find that often frankly, my doctor refers to the first thing on her list, and I decided I don't want to take it, because I don't like the risk profile or something," she says. "And since we're talking about discretionary choices, it's not something like insulin that I absolutely have to have, I have the latitude to satisfy myself about the risk/benefit profile from my point of view. Anything that pharma can do to help me figure that out, the evidence-based links that show me what the outcome studies have been done around this particular med, anything that helps me see what patients have reported about their experiences with this drug. You see that ton of fine print in every magazine ad, every newspaper too, but what you never get in any of that is a sense of proportion. Gee, it might kill me, but how many people does it kill? That proportionality would be nice to get."

Berg also says the industry needs to attend to its image if it wants patients to take seriously the information being offered. "The more things it does to help patients feel that patient welfare matters at least as much as profit to them is reassuring too," she says. "How you do that, I don't know, but I think that when people get skeptical, that's often what it's about."

Quinlan says DTC advertising helps fuel distrust of the industry.

"If they were a little less willing to glitz up and advertise the bleep out of everything, I would feel a little more trusting," she says. "But I feel as though I'm being handed a Madison Avenue game card – check off all the boxes, ask your doctor about all of our stuff.

"Pharma blames the FDA, and it's not like FDA doesn't deserve to get a 5-iron upside the forehead, because they're not really helping the industry or patients see an accelerated path to better health, using pharmacology," Quinlan says. "However, given that the industry itself has shown very little willingness to admit that they're not all about the benjamins, you either want to make a billion dollars and give all the money to your shareholders, and have a shareholders party, or make it much better for people to take your drugs. You have to pick one. ... There's lipservice paid to all the patients we've helped … the scientists are doing great stuff and I love that, but when it really comes down to it, the business decisions made by the industry are made solely on the profit motive and shareholder value. They are not based on human lives."

THE GLIMMERS OF HOPE

Although most companies as a whole and many executives are not seen as good listeners and communicators with patients, some get praise.

Strange and Holliday singled out Lilly Clinical Innovation Team, or Lilly COI, for the team's efforts in reaching out to patients. The Lilly COI team keeps an active presence on Twitter, conversing with patients and letting followers know what is going on at the conferences they attend.

Strange had attended a conference where he had met with Lilly COI team members about improving drug development. "I really like them," Strange says. "That was a very good meeting that left a good impression, because they were very active listeners, you knew that they were paying attention to what you were saying simply because of the way that they were sitting there and looking at you. You could see the thoughts turning in their head as they were getting a different perception."

Holliday also singles out Craig Lipset, head of clinical innovation at Pfizer, for having "an amazing social media presence."

"He talks that way, all the time, he never varies from it, and everyone knows he works for Pfizer," she says. "There are way too many people within hospitals and pharmaceutical companies who are too scared to communicate honestly as the person they are, because they're so scared they're going to put their foot in their mouth, that they're going to say something wrong. So they say nothing at all, and I've got to tell you, saying nothing at all is way, way worse than saying something wrong. Because wrong you can come back from, wrong you can make a huge story and a triumph out of – nothing goes nowhere." MEDADNEWS

SOCIAL STUDIES

Even without guidance from FDA, pharma brand managers are doing their best to work out the conundrum of social media.

By Joshua Slatko joshua.slatko@ubm.com

As has been the case for the last several years, social media remains the junior high gossip topic du jour in pharma marketing – plenty of telling but not much kissing. While brand managers are showing signs of increased awareness of and adeptness with the conversations going on around their brands, the lack of clear regulatory directives from FDA plus the natural conservative inertia against any new medium has sharply limited the list of success stories for pharma brands in social media. But hope still does exist for the future; even pending word from FDA, brand managers are listening more, asking for more, and doing more with social media than ever before.

REGULATORY UNCERTAINTY

In a recent interview with Ed Silverman of Pharmalot, Tom Abrams of FDA's Office of Prescription Drug Promotion claimed that the development of guidance for social media is among the agency's highest priorities. But in the marketing trenches, ad agency leaders have been getting a different impression.

"The development of regulations for social media appears to have stalled out entirely," says Leigh Householder of GSW. "The public hearings created a sense of momentum and possibility. Then, annual planning came and went with no direction. And again. And again. There aren't many marketers who are still looking to the horizon for that holy grail of guidelines. Instead, they're focused on innovating in other mediums."

One of the unfortunate side effects of this unexpectedly long wait, Householder fears, has been its impact on internal guidance. "Most of my clients have detailed internal regulations that guide their use of social media," she says. "Almost all are a virtual prohibition, pending additional regulatory development."

Of course, pharma brands are in social media whether brand teams are actively participating or not; the conversation is happening online irrespective of whether the brands are actively engaged. This creates a challenging situation for legal teams with respect to managing misinformation, reporting of adverse events, and providing customer service. "We cannot learn to participate in, or even control, the conversation when we don't have a clear drawing of boundaries," says Robin Shapiro, executive VP, chief creative officer at CAHG. "How do we safeguard fair and balanced information in situations where character limits prevent the use of full safety disclosures? In an industry notoriously resistant to change, it is hard to imagine that pharma clients will jump in with both feet without having express guidelines."

Another regulatory concern for CAHG's clients is adverse event reporting and the complications that come with a viral media source. "If content from a branded profile is reposted on another profile, then again, and again, and somewhere along the way side effects are mentioned, to what degree is the brand responsible for reporting the event?" Shapiro asks. "In many cases, the brand will have no access to conversations taking place around the post once it leaves the branded profile. Whose responsibility is it to monitor this type of activity? Where is the line drawn?"

Another question for marketers is the scope of the major statement exception to the brief summary requirement.

"Is it permissible in space-limited contexts to rely on a major statement instead of providing fuller risk information?" asks Dale Cooke, VP/group director, regulatory review at Digitas Health. "The regulations call for the major statement in media 'such as radio, television, or telephone.' Is Twitter a medium such as telephone? I participate in Twitter primarily on my cell phone, so that would seem to allow for extension of at least some new media to the definition where the major statement exemption applies. But FDA has said very little about the major statement in general and nothing about its applicability to space-limited contexts."

Brad Einarsen, director of digital insight at Klick Health, notes two key other areas of regulatory uncertainty: the scope of responsibility and automatically generated links.

"If a pharmaceutical company attempts to correct some information on a platform, has it signed up to maintain that information forever?" Einarsen asks. "This goes for traditional social such as forums and blogs as well as Wikipedia, including the 'talk page' associated with a branded drug topic."

Also, when mentioning other users on social media, automatic links are generated and the question remains about how far FDA will go when interpreting ownership of those links. "FDA does not believe that pharmaceutical companies are responsible for the entire Internet, so this should not be an issue, but without clear guidance there are still questions," Einarsen says.

Not everyone, though, is convinced of the importance of FDA guidance. According to Bill Evans, executive VP, chief digital officer, Team Chemistry @ WPP, such guidance is not necessary.

"FDA will most likely issue guidance that is similar in scope and scale to what currently exists for DTC, which is, don't misrepresent claims and make sure to include appropriate balance statements," Evans says. "This seems fairly straightforward, but anything past that would most likely be out of date the minute it was issued. Pharma companies and agencies looking for grand and sweeping guidance are likely going to be disappointed."

Evans believes that much of the uncertainty over social media around the industry is self-imposed. No organization engaging in social, he notes, has ever received a warning letter for following the common sense and clearly understood rules of engagement. "Don't misrepresent claims," Evans says. "Include balance. The regulators that I work with have been getting more and more comfortable with the medium and the programs that will be launching soon will be indicative of that."

ABOVE THE BRAND

While companies in many other industries have integrated social into their corporate communications and identities, pharma has been understandably slow in following this path. But even with all the regulatory uncertainty, some positive steps can be seen.

"Marketers have found more opportunities to engage in social media initiatives when it comes to patient engagement versus professional engagement because patients are already looking online to find recommendations about product and therapy options," says Eugene Lee, executive VP, chief innovation officer, ICC Lowe. "Even in the absence of any pharma-sponsored initiative, patients would naturally create resources where none existed and embrace new resources as they become available."

A good example of this, Lee believes, is the CML Earth project created by **Novartis** Oncology – a rare disease education social portal that helps connect chronic myeloid leukemia patients with one another and with support services worldwide. "Novartis Oncology has made the investment into connecting clusters of patients with other sufferers and treatment centers to educate, support, and communicate with them," he says.

The same company gets another vote of confidence from Einarsen of Klick Health. "One of the companies that is strong on social strategies is Novartis Oncology," Einarsen says. "During social listening engagements (for its competitors) it becomes clear that their social strategies around congresses are unmatched."

Another company that was noted for its social efforts by two different agency leaders was **AstraZeneca** – specifically, the @AZHelps Twitter feed.

"Smart companies see the tools of social media as one means to achieve a greater goal, of listening and talking with all stakeholders as a key aspect of their business strategies," says Johanna Skilling, executive VP, director of planning at Havas Life New York. "AstraZeneca's @AZHelps twitter feed is a great example of using social media to listen and respond to individual patient needs as part of the greater objective of advancing public health."

Cooke of Digitas notes @AZHelps as well, as part of a larger point about how different companies are doing different things well in social, but none are doing everything well just yet.

"I don't think anyone has fully embraced social media in all aspects of their business strategy, but we are seeing very interesting developments from different companies in specific fields," Cooke told *Med Ad News*. "AstraZeneca's @AZHelps is a great example of a company proactively providing useful, timely information to consumers and/or direct those consumers to offline channels to get the help they need. Pfizer is leading the way in its adoption of social media for clinical trials, one of the areas where tectonic shifts in the industry's paradigm are under way."

WHAT'S NEXT

More than a few agency leaders have noted significant changes in the past year in what their clients are asking them to do. One of these is the growth of goal-oriented thinking.

"Clients have moved from a, 'What can I do with Facebook' mindset to, 'How do I use social to accomplish x goal?'" says Evans of WPP. "It's a subtle shift, but an important one, since the business case for social programs needs to be solid. Community engagement isn't, 'Build it and you're done'; it has to live on long past when your client gets promoted. If the business case isn't there, the next brand manager to come along will kill it."

Another new request is social listening, a tool that can offer a vital window into the minds of people in particular patient communities and identify the top influencers with minimal risk.

"More brand managers are asking us to do social listening," says Skilling of Havas. "It's a form of research that didn't have as much credibility as it does today. It's not a substitute for asking questions, there's a greater recognition that these uncensored, unfettered conversations can teach us something different from formal, structured research."

But the usefulness of social listening is giving brand managers a taste for bigger game. " A year from now brand managers will ask how to adapt social listening to influence consumer behavior." says Lee of ICC Lowe. "They will need strategies to modify the results of social listening that will eradicate negative social aspect about their brands. As such, our clients are asking us to build platforms that interconnect their brands by strengthening the conversations between healthcare professionals and their patients in a partnership of treatment and supportive care that will result in successful patient outcomes."

Also, companies that don't have well established processes and guidelines around social media involvement are looking for help to create such guidlines. "That's an area where we're seeing increased requests, as companies move from their prohibitive guidelines telling people what they can't do and toward an organizational culture that embraces social media and encourages employees to engage," Cooke of Digitas says.

JOINING THE COMMUNITY

Perhaps the greatest challenge for brand managers seeking to take advantage of social media is the task of finding ways to participate in the many third-party patient communities that can be found online. These communities are vibrant places, filled with just the sorts of people that pharma brands need to reach but haven't been able to – a study last year by PwC found that organic community social media sites exceeded activity on pharma-sponsored sites by a factor of 24. But joining such communities poses difficulties that will take time and thought to overcome.

According to Shapiro of CAHG, getting brands involved in third-party communities makes too much sense for marketers to let their fears decide the issue. That, of course, doesn't make doing so any easier.

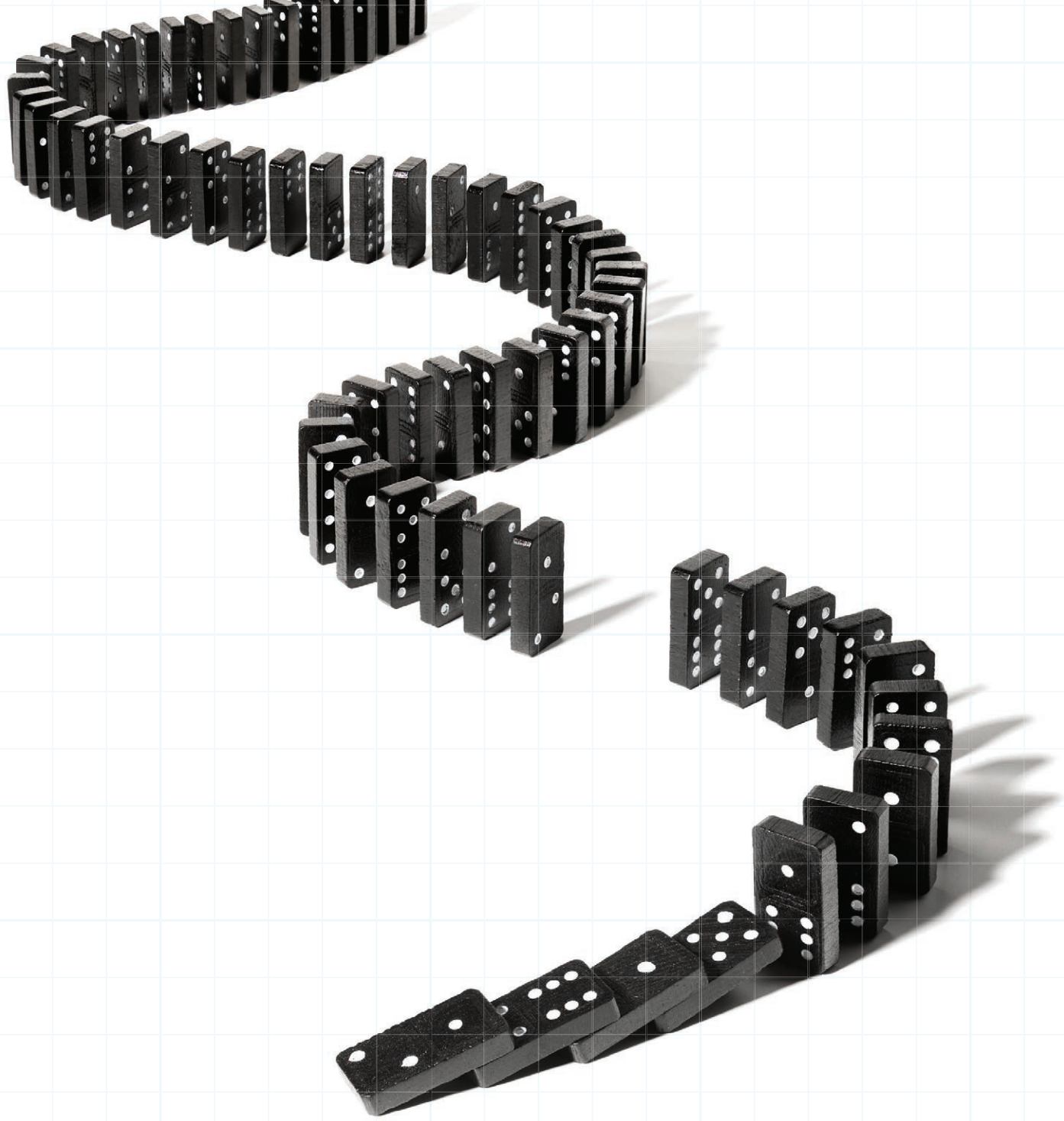
"If you really 'get' social media, you understand that it's about contributing, not controlling the conversation," she says. "It can be more valuable to contribute something meaningful to an unbranded community with an engaged following than creating your own community. But that's easier said than done. Some unbranded communities are against pharma joining the conversation. And when you find an opportunity to join the conversation, how do you control misinformation if you don't control the conversation and without clear guidelines? But there are a number of organizations like WebMD and Mayo Clinic that already have a large patient following and identifying ways to partner with them would give pharma brands the biggest chance for success."

Whatever choices brand managers make regarding social media, they have an underlying challenge that needs to be faced sooner or later: pharma's general lack of skill at communicating complex information to the ordinary patient.

"The core of the challenge that we're dancing around with all this talk about social media is that pharma needs to find more human ways to talk with people," says Householder of GSW. "We have built our own language of legal and medical specificity as a safeguard against a challenging regulatory environment. We put all the required information out there, but we don't do enough to help people understand it."

Householder particularly notes the significance of research done by Professors Steven Woloshin and Lisa Schwartz in developing easier-to-read drug label leaflets.

"That project that was designed to make it as easy to understand the health impact of drug as it is to understand the diet impact of a bag of potato chips," she says. "The faculty's own patients were attracted to the promises of pharma ads, but the 'laundry lists of side effects' and other fine print that followed overwhelmed any deeper comprehension. Worse, the way the fine print of pharma works, even people who read all the details were more likely to be exposed to minor side effects than to the true effectiveness of the drug. So, they redesigned the label to make it work like people read. Those are the shifts that will make actually doing social possible. Until we can get there, we won't truly be able to be a part of any community. We just don't talk and communicate that way." ■ MEDADNEWS



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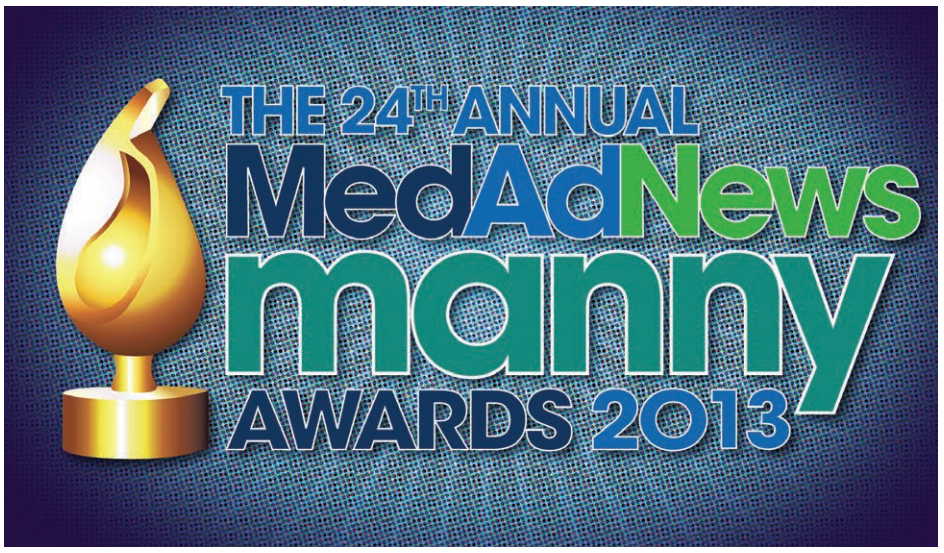
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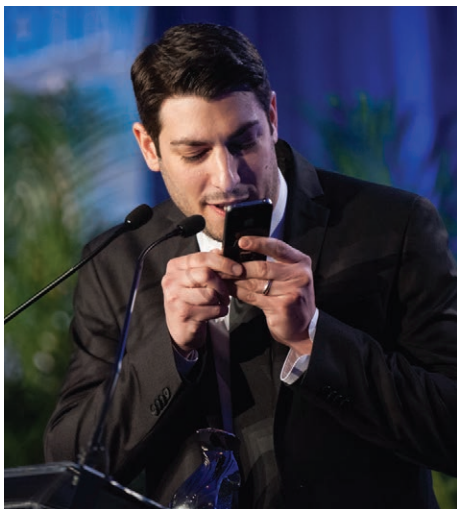

24TH ANNUAL MANNY AWARDS

Agencies honored

The 24th annual Manny Awards ceremony, held at Pier Sixty in New York on the evening of Thursday, April 25, paid tribute to the creative work of ad agencies serving the healthcare market, their people, and their contributions to the industry. Eighteen awards were presented, including Agency of the Year — Category I, II, and III; Industry Person of the Year; the Heart Award; the Vision Award; Best Professional Campaign; Best Consumer Campaign; and Best Medical Device Campaign. Faruk Capan, founder and CEO of Intouch Solutions, was honored as Industry Person of the Year.

MANNY AWARD WINNERS AND NOMINEES

AGENCY OF THE YEAR—CATEGORY I
H4B CHELSEA
GSW, Klick Health (nominees)

AGENCY OF THE YEAR—CATEGORY II
GIANT CREATIVE/STRATEGY
Hobart Group Holdings, McCann Torre Lazur (nominees)

AGENCY OF THE YEAR—CATEGORY III
THE NAVICOR GROUP
Fingerpaint, ICC Lowe Trio (nominees)

By Joshua Slatko joshua.slatko@ubm.com

Drug spend drops; specialty spend to rise two-thirds

Total spending on U.S. medicines fell 3.5 percent on a real per capita basis in 2012 and the use of healthcare services overall declined for the second consecutive year, according to research by the IMS Institute for Healthcare Informatics. Meanwhile, U.S. spending on specialty prescription drugs – those used to treat chronic, complex diseases such as cancer, multiple sclerosis, and rheumatoid arthritis – is projected to increase by two-thirds by the end of 2015, while spending on more traditional prescription drugs will drop by 4 percent, according to a forecast by Express Scripts.

The IMS research report – "Declining Medicine Use and Costs: For Better or Worse?" – finds that total dollars spent on medications in the United States reached $325.8 billion last year, or real per capita spending of $898, down $33 from 2011. Underlying drivers for the overall decline in healthcare service use included fewer patient visits to office-based physicians, fewer non-emergency admissions to hospitals and outpatient facilities, and a less severe flu season in the early part of 2012. Patent expiries in 2012 contributed $28.9 billion to the reduction in medicine spending. This was their largest-ever impact as millions of patients accessed lower-cost generic versions of additional medicines.

Patients with insurance paid higher deductibles, copays and co-insurance for their overall healthcare in 2012, but prescription drug copays for most patients declined. At the same time, new transformative medicines became available to treat a large number of diseases with small or strictly defined patient populations.

"The cost curve for medicines was clearly bent in 2012, for better or for worse," says Murray Aitken, executive director, IMS Institute for Healthcare Informatics. "To some extent, this is a harbinger of more efficient use of our healthcare resources, but it also reflects a decline in utilization that may be the result of under-treatment and an imbalance between prevention and care."

The total cost of medicines declined by 3.5 percent on a real per capita basis to $325.8 billion. In addition to lower utilization of branded drugs, the primary drivers were the increased availability of lower-cost generics, which now account for 84 percent of all prescriptions; the moderating impact of price increases; and lower spending on recently launched medicines. Healthcare costs remain concentrated among relatively few patients suffering from multiple chronic conditions, cancer, or other specialty diseases. In the case of the commercially insured, under age 65 population, 5 percent of the members incurred 51 percent of total healthcare costs by using more than $15,684 of healthcare services per person in 2012.

Patients with insurance are paying higher deductibles and higher copays or co-insurance, with nearly 20 percent of the insured now in a consumer-driven health plan. Average out-of-pocket costs for commercially insured under age 65 patients reached $1,146 in 2012, a 30 percent jump from 2011 and entirely the result of higher deductibles. The average pharmacy benefit copay declined by $2 to $121 in 2012; patients filled 72 percent of all retail prescriptions with a copay of $10 or less.

Patients gained access to 28 new molecular entities in 2012, including seven with orphan drug designations by FDA for rare diseases, a novel oral therapy for rheumatoid arthritis, a treatment for cystic fibrosis that will significantly improve life expectancy for patients with a specific genetic mutation, and an inhalable anti-psychotic. Nine new cancer treatments were introduced last year, the most in more than a decade, including a breakthrough for treating basal-cell carcinoma

According to the Express Scripts analysis, U.S. spending on specialty prescription drugs is projected to increase 67 percent by the end of 2015.

"As we see what's on the horizon, it's time for employers and health plans to act so they can continue to offer an affordable pharmacy benefit for their members," says Glen Stettin, M.D., senior VP, clinical, research, and new solutions at Express Scripts. "New specialty treatments are making a difference in the lives of patients, but the high cost of these drugs creates difficult decisions for plan sponsors on which medicines to cover."

Prescription drug spending on eight of the top 10 specialty therapy classes is expected to continue to increase over the next three years. This, Express Scripts analysts say, is due to both the robust pipeline of new biologics and physicians delaying treatment of patients until the new drugs are on the market. By the end of 2015, Express Scripts expects that cancer, multiple sclerosis, and inflammatory conditions such as rheumatoid arthritis – all specialty conditions – each will command higher drug spending than any other therapy class except diabetes.

Hepatitis C drug spending is projected to quadruple over the next three years, the largest percentage increase by far among therapy classes. By the end of 2015, Express Scripts analysts believe that spending on medications for hepatitis C will exceed that of much more common conditions, including high blood pressure. This increase will be caused by new interferon-free medications expected to gain FDA approval in 2014, as well as an increase in diagnoses related to new screening guidelines.

Potentially mitigating the rising cost of specialty medications would be an improved pathway for biosimilars. Express Scripts recently projected that the country would save $250 billion between 2014 and 2024 if the 11 most likely biosimilar candidates were launched in the United States.

According to the Express Scripts forecast, overall spending on traditional prescription drugs – mostly pills used to treat common conditions such as high cholesterol and depression – will decline 4 percent by the end of 2015, largely because of the availability of generic medications. Only two of the top 10 traditional therapy classes, diabetes and attention disorders, are likely to have spending increases over the next three years, but those increases will be significant.

Diabetes became the costliest prescription drug therapy class in 2011, and according to the new projections, it will continue to hold that distinction at least through 2015. Over the next three years, Express Scripts expects spending on diabetes medications to rise an additional 24 percent because of high prevalence and a robust pipeline of new therapies.

Despite the availability of generic equivalents for many attention disorder therapies, the data projects spending in the category to increase by about 25 percent over the next three years, driven by increased utilization among middle-aged adults and wide geographic variation in diagnosis. Express Scripts research shows that prevalence, medication use, and associated medical and pharmacy costs for attention disorders is highest in the South. However, the Northeast region of the United States experienced rapid growth in attention disorder diagnosis, and that region's associated costs grew nearly 60 percent from 2008 to 2010.

Non-whites, women less adherent: study

A study conducted by researchers at CVS Caremark and Brigham and Women's Hospital and published in the May issue of *The American Heart Journal*, has found that non-white patients had 50 percent greater odds of statin medication non-adherence compared to white patients, while women had 10 percent greater odds of statin non-adherence compared to men.

"These findings help us better understand the impact of certain demographic factors on medication adherence," says Niteesh Choudhry, M.D., Ph.D, associate physician, Division of Pharmacoepidemiology and Pharmacoeconomics, Brigham and Women's Hospital and associate professor, Harvard Medical School. "Since a large number of patients depend on medication therapy for primary and secondary prevention of cardiovascular disease, we believe that efforts to reduce non-adherence for statins can have a significant effect on addressing health care disparities, improving health outcomes and ultimately reducing costs."

The study consisted of a literature review of more than 50 publications focused on gender and racial disparities associated with medication adherence and included more than 1.7 million patients. Of note, the finding that non-adherence was higher based on the patient's gender or race held true even in those studies that adjusted for income, insurance status, co-payment amounts, and other clinically important factors.

"While it has long been known that sociodemographic characteristics are associated with non-adherence, this study is the first of its kind to look at the scale and scope of this association," says Troy Brennan, M.D., executive VP and chief medical officer of CVS Caremark. "This research helps those of us in the health care field better understand how to improve our outreach to patients who may be at a higher risk of non-adherence and develop programs to help these patients improve their medication adherence."

The researchers note that a number of potential reasons exist for non-adherence among women and non-white patients. For example, active prevention of cardiovascular disease may not be a priority for women and their health care providers because of the common misconception that women are less at risk than men. In addition, women also frequently serve as informal caregivers for family members and may be further affected by the fact that caregivers frequently have lower rates of medication adherence.

The reasons that non-white patients may be non-adherent are more complex. As an example, the researchers note that non-white patients are less likely to have a consistent relationship with a primary care provider than white patients which can impact chronic care and adherence. Additionally, both women and various racial and ethnic minorities may be more likely to experience side effects from statins, a commonly cited reason for early discontinuation or poor adherence.

FACTS & FIGURES

Physicians still view reps as the leading influence on their relationships with biopharma companies, according to the recently released J.D. Power and Associates 2013 Physician Manufacturer Experience Study—Oncology. The study looks at oncologist and hematologist satisfaction based on sales representative interactions; contributions to advancing medical care; medical marketing practices; patient education programs and materials; and service process.

According to the study results, Genentech Inc. ranks highest in physician satisfaction with biopharmaceutical companies in the therapeutic category of oncology with an index score of **773** on a 1,000-point scale. Genentech performed particularly well in the contributions to advancing medical care and medical marketing practices factors. Genentech is followed in the rankings by Novartis (**769**) and Bristol-Myers Squibb (**764**).

Sales representative interactions, the study found, are the most influential factor driving overall physician satisfaction with drug companies, slightly more impactful than contributions to advancing medical care. Overall physician satisfaction with biopharmaceutical companies for oncology averages **761** on a 1,000-point scale.

According to the study, physicians indicate that **71 percent**, on average, of their interaction with sales representatives focuses on treatments and products, as opposed to conversations about family, sports, or other non-business-related topics. "It is hard to know if with the 2008 PhRMA code whether that same pattern was in existence," says Rick Millard, senior director of the healthcare practice at J.D. Power. "It may be that it was, but the venue for these interactions was different because there were not prohibitions on sponsored events the same way that there are now and the kinds of material that could be exchanged. However, it seems logical to assume that when these encounters are occurring within an office environment that it is more explicitly professional in that a greater proportion of the time is devoted to business related topics as opposed to personal conversation."

A key point of differentiation among the highest-ranked manufacturers is their perceived commitment to addressing patient needs and working well within the medical community. Together, these factors account for roughly **one-third** of the overall physician experience, nearly as much as the importance weight of the perceptions of the sales reps.

Although there were consistently high satisfaction scores in the sales representative interactions factor across companies, satisfaction with how companies contribute to medical care varied. Some companies are distinguished by their products and innovation, while others differentiate themselves through the service component. Advancing medical care involves more than scientific evaluations of efficacy or effectiveness: it considers the relevance of products and whether they meet an important need. One way that manufacturers advance medical care is by working effectively within the professional community of physicians.

"The results were somewhat surprising to us because we didn't anticipate the impact of the sales representative was going to continue to be as important," Millard says. "There are so many other types of ways of interacting with physicians have been layered in recent years. It does seem fundamentally that the relationships still matter a lot."

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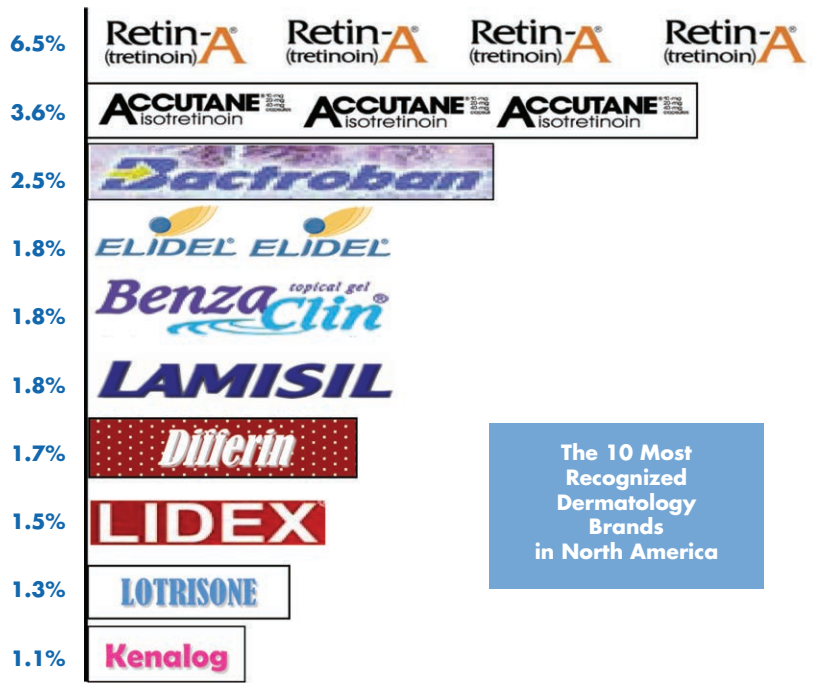
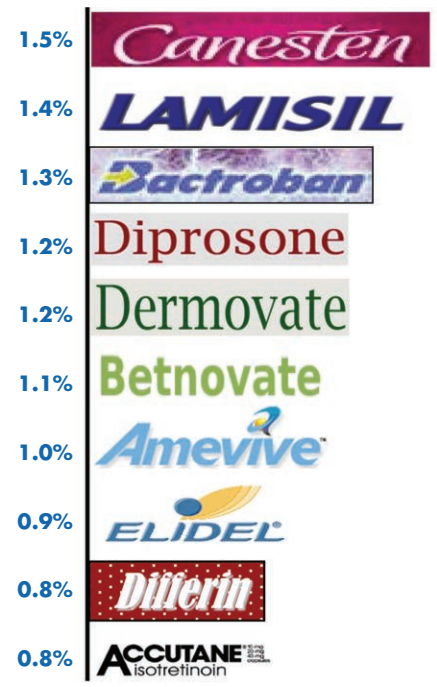


The 10 Most Recognized Dermatology Brands in North America



The 10 Most Recognized Dermatology Brands in Europe

The most-recognized dermatology brand in North America is **Retin-A**. The brand was most-recognized by 6.5 percent of physicians in a survey conducted by **Brand Institute** Inc. during the fourth quarter of 2012. 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 3.6 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 **Bactroban**. About 2.5 percent of physicians recognize this brand the most. Bactroban, comprising mupirocin, is marketed by **GlaxoSmithKline** (gsk.com). The product is indicated for the topical treatment of impetigo due to *S. aureus* and *S. pyogenes*.

The most-recognized dermatology brand in Europe is **Canesten**. This product was recognized the most by 1.5 percent of physicians. Canesten, comprising clotrimazole, is marketed by **Bayer** (bayer.com). The product is indicated for the treatment of a number of fungal infections, including vaginal yeast infection, athlete's foot, and fungal skin infections.

Lamisil is the second most-recognized dermatology brand in Europe. About 1.4 percent of physicians recognize this brand the most. Lamisil, comprising terbinafine, is marketed by **Novartis** (novartis.com). The product is indicated for treatment of infections caused by fungus that affect the fingernails or toenails.

The third most-recognized dermatology brand in Europe is Bactroban. About 1.3 percent of physicians recognize this brand the most.

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.

Investment in commercial ops equals more sales: study

A new study from Temple University's Fox School of Business shows that investment in pharmaceutical commercial operations, along with an innovative orientation, employee engagement, organization alignment, and first-line manager span of control, ultimately results in improved sales revenue. The study, "What Aspects of Commercial Operations Impact Pharmaceutical Company Business Performance?" was commissioned by TGaS Advisors, a benchmarking and advisory services company for pharmaceutical commercial operations.

This is the first such independent research study on the effects of qualitative versus quantitative measures of commercial operations on business performance, according to George Chressanthis, Ph.D., professor of healthcare management and marketing director, Center for Healthcare Research and Management, Fox School of Business. The absence of hard and comprehensive measurement of the impact of commercial operations functions stems from the fact that such information just isn't easy to come by.

"I think that a very straightforward answer is simply that finding enough data of what goes on internally within companies is very, very difficult to come by," Dr. Chressanthis told *Med Ad News*. "In order to do a research study that we did, you need quite a few observations."

According to the study, commercial innovativeness and responsiveness are critical components in achieving business performance. Both attributes work together as well as with spending support for reps to improve performance.

"What is interesting about our study, one of the things is that when a company is simply just innovative, being innovative by itself is not enough," Dr. Chressanthis says. "If a company is very responsive, if it's able to adapt to change very quickly and so forth, that within itself is not enough. But what is important is when the two work together and our empirical results show that. The white paper shows that in fact being very good at strategy and being very good at execution is what matters. You can be a company and come up with the world's greatest strategies. If you can't execute it, then that doesn't do you very much good. You can be a company that is very good at execution, and be responsive but if you don't have good strategies you wind up executing poor strategies, which is also a recipe for disaster. It's when the two happen together does this performance improve."

The study provided empirical evidence to answer the research questions. One question raised in the study was how company size/scale and commercial spending to support sales force activities affect business performance. These factors, the authors say, had substantial impact on business performance. Company size, they found, has an increasing effect at a decreasing rate. However, larger size and higher spending alone are not sufficient. The organizational culture must be conducive to translating resource spending into sustained business performance.

"The results that we found from this study are very encouraging," says Anna McClafferty, senior VP, management advisor, TGaS Advisors. "They are intuitive. They make sense and the work has resulted in us thinking for the future and how we can continue to build our information so we can continue to measure the impact of commercial operations."

Patients respond to clearer medication info

More than 90 percent of patients recalled receiving a newly crafted, clearer patient information document with their prescription and considered the written information useful, according to the results of a quality improvement initiative by Catalina Health. The initiative, launched in August of 2012, was designed to disseminate newly-designed patient medication information to patients filling prescriptions at participating pharmacies. The new PMI was distributed in a leading pharmacy chain in California and Michigan for three medications.

The goal of the Catalina initiative was to provide patients with clearer medication information when they pick up prescriptions at the pharmacy. Through voluntary telephone and online responses, the company surveyed patients to confirm that they received the new PMI, assessed whether they found the information useful, and determined how they would like to receive this newly-formatted patient medication information in the future.

The results of the survey showed that females and males had an equally high recall rate (more than 90 percent) of receipt of the single-page PMI document. All age groups from 18 to 65-plus years old had an equally high recall rate of receipt of the single-page document (more than 90 percent). More than 65 percent of females and males read the information. New patients were more likely to not only read, but also keep, the PMI. More than 90 percent of all patients found the PMI useful. Patients ages 18 to 40 would prefer to have the PMI delivered electronically in addition to receiving the single-page PMI in the pharmacy. And patients of all age groups prefer to have a pharmacist explain the PMI along with receiving a written document.

"This eight-week project demonstrates that patients want, read, and keep a single page of information about their prescriptions that is written in an easy to understand format, rather than multiple pages of complex medical text," says Renee Selman, Catalina Health's president. "Catalina Health is committed to providing patients clearer information, and we are proud to have led this pharmacy pilot with our health care partners."

The QI initiative stems from an ongoing multi-stakeholder workgroup convened by the Engelberg Center for Health Care Reform at the Brookings Institution under a cooperative agreement with FDA. The workgroup includes Catalina Health, the Medical Cognition Laboratory at Duke University, Emory University School of Medicine, the Feinberg School of Medicine at Northwestern University, GlaxoSmithKline, Janssen, Pfizer Inc., and Purdue University College of Pharmacy and the Regenstrief Center for Healthcare Effectiveness Research. FDA has served as an observer. The workgroup was convened in March 2011 after workshops held by the Engelberg Center revealed that more evidence was needed to reform and develop a standardized Patient Medication Information document delivered to patients when they pick up their prescriptions at the pharmacy. Members of the workgroup addressed needed reforms by developing a pilot PMI similar to one of the single-page prototypes that was developed by FDA.

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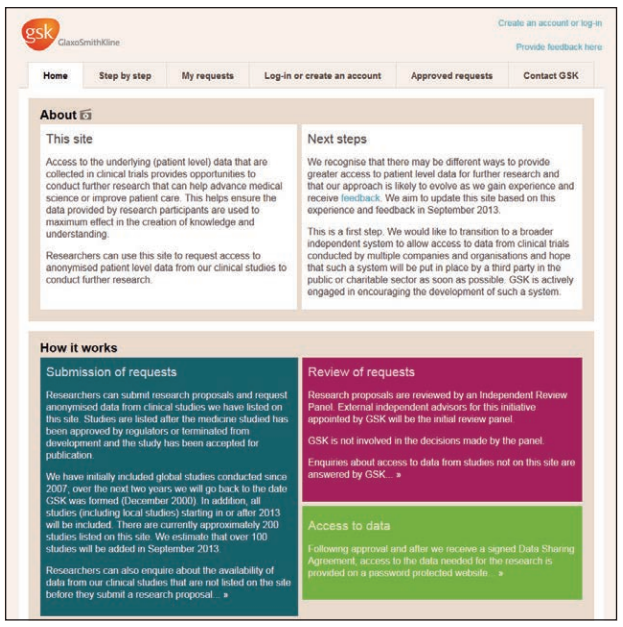
Like no other.

By Joshua Slatko joshua.slatko@ubm.com

"Controversial" companies best at digital communications

Companies operating in more "controversial" business sectors – including pharmaceuticals – appear to be among the world's best at digital corporate communications, according to a new study. Eight of the top 10 best performers in the 2013 *Financial Times* Bowen Craggs Index of corporate web effectiveness fell into the "controversial" category – companies that have suffered reputational damage – and three of these were big pharmas.

"All of the pharmaceutical companies obviously have controversy," says David Bowen, senior consultant at Bowen Craggs. "There has been quite a bit of publicity about Roche not really putting out its side of case when it comes to publishing clinical trial data on Tamiflu." This year's Bowen Craggs report, the organization's seventh, includes 84 of the largest *Financial Times* Global 500 companies ranked by market capitalization, and assesses all digital channels against a range of criteria.



GlaxoSmithKline recently launched an online system for researchers to request access to patient level data from the company's clinical trials.

GlaxoSmithKline was No. 10 among the top 10 performers who are "getting it right." The company has a new website which, according to Bowen Craggs, was well conceived and implemented. The new GSK, analysts say, is notable for its careful integration with social media channels. **Roche** came in at seventh place on the Bowen Craggs list, but still needs to take on its critics. **Novartis** was ninth on the top 10 with a well-managed site, according to the report.

Bowen told *Med Ad News* that if one were to compare the Novartis corporate site to Roche's, Novartis provides the impression of being willing to discuss controversial topics. "You will find that there is a big section in the media area of novartis.com," he says. "It is in the newsroom area and it is called the product related information center. And what you will find there is a list of areas of controversies. What they do is they put their own statements they put their point of view. Roche just doesn't have anything like that. It doesn't even have a space for putting anything that could be regarded as a controversy."

Regarding the willingness to discuss clinical trials, GSK, "particularly is trying to come across as super open on that," Bowen says. "It's got a brand new website and if you look at its homepage it has got an item about it on open data. It is one of the main things that you see on the homepage. Roche is coming across as just being more cautious shall we say than the other big pharmaceuticals on this one."

Novartis is covering all bases with its corporate site, Bowen told *Med Ad News*. "One of the things that we looked at quite a lot was how easy to use a site is which might sound important," he said. "But if you find it easy to move around a site it gives off the right sort of messages. It makes people certainly feel good about you as a company. It is a very subtle brand builder, if you like. It isn't as sleek if you compare it with the Roche site or the GSK site. They look more modern and sophisticated."

Novartis' corporate Website includes a product related information center that offers the company's point of view on controversial product issues.

Social media has become more integrated more rationally with the web, according to Bowen Craggs analysts. Bowen credits GSK in the company's approach to its social media channels. "GSK is interesting because pharmaceutical companies have been very cautious using social media for obvious regulatory reasons," he told *Med Ad News*. "They have to be very careful what they say and they are very nervous. There is a lot of nervousness about it particularly I would say in Europe as well. Obviously the marketing rules in the states are rather more open talking about name brand for prescription products. But in Europe they have always been very, very nervous. I think that it's quite interesting with GSK because the website is basically controlled from London. It is now putting a Twitter and Facebook tab on their homepage which is really quite a big jump for a big pharmaceutical company. I don't think that any of the others do that in the states or in Europe."

Glaxo transparency effort moves forward

By Ed Silverman

Seven months after promising to release clinical trial data, **GlaxoSmithKline** has created an online system for researchers to request access to patient-level data and released the names of a group of experts who will review requests from outsider researchers seeking to examine trial data. The drugmaker maintains the effort will make it possible for outside scientists to study Glaxo data and develop their own findings about safety and effectiveness.

However, one member of the panel – which is described as independent and will be tasked with reviewing data requests – has previously worked as a consultant to the drugmaker. Brian Strom, a professor of public health and preventive medicine, and also a professor of biostatistics and epidemiology of the University of Pennsylvania, received $5,500 last year, according to the ProPublica database.

"That's the challenge when individual companies set up their own review panels," says a Glaxo spokewoman. "We won't have influence over the panel decisions. We've said it won't be perfect first time out, but the important thing is to be transparent about it... We're trying to make this attempt to put this effort forward. Maybe this can accelerate the discussion about what is the right system." She added that Glaxo wants to retain an independent third party to eventually oversee this system and, at that point, the panel may be superceded or even dissolved.

"My role on the committee is completely independent," Strom says. "GSK does not have any say in our decisions... The story here is someone in industry is looking to do it right. I'm an academic. I gave them advice about what this should include. This is a major scientific advance. There are big things that can come out of here, especially if other companies join... The fact that I did consulting in the past is not news... Our choices are going to be independent... I'm independent. My funding comes from an academic center... You can't say go to industry and say get the best people in the industry and then criticize them when they do."

As noted previously, the move comes after years of controversy over the extent to which drugmakers disclose clinical trial data. The pharmaceutical industry has long been criticized for failing to fully make underlying patient-level data available to others who seek to verify results. Drugmakers have insisted the data is proprietary, but critics have said the reluctance to disclose such information can be a red herring for hiding unflattering results that may limit sales.

The debate has factored into numerous scandals in which drugmakers have been accused of withholding important information about side effects. Glaxo, in particular, was cited for such behavior with its **Avandia** drug, which figured prominently in a $3 billion settlement the drugmaker reached last year with the U.S. Department of Justice for a number of infractions.

In agreeing to disclose data, Glaxo also has been at odds with two industry trade groups. Three months ago, the drugmaker publicly supported the AllTrials campaign in its quest to have patient-level data released, a move that PhRMA and the Association of the British Pharmaceutical Industry have opposed.

Only one other drugmaker has taken any similar steps. Last month, **Roche** said it would make available data from all 74 clinical trials for its Tamiflu treatment to a team of Cochrane Collaboration researchers. That came after the drugmaker agreed to widen access more generally for clinical trial information for its medicines in response to increased pressure from academics and a widely publicized online petition.

As for Glaxo, the drugmaker plans to list trials on a new Website once a medicine has been approved by regulators or terminated from development and the study has been accepted for publication. Studies that do not progress to publication will also be included. The site already includes global studies conducted since 2007.

Over the next two years, global studies going back to the formation of GSK in December 2000 will be added. In addition, all studies starting in or after 2013 will be included, the drugmaker says. The system would be run by an independent third party that would be responsible for appointing and overseeing a review panel to assess research proposals. "We are the first organization to develop a system for sharing detailed clinical data in this way," says Patrick Vallance, GSK pharma R&D president. "Now we want to see this initiative transition to a broader independent model that brings together data from multiple organizations."

Vallance did not offer a specific timeline for retaining a third party to run the initiative. For now, the members of the independent review panel - in addition to Strom - include Marc Buyse, an associate professor of biostatistics, Hasselt University Belgium and founder of the International Drug Development Institute; Bartha Maria Knoppers, who heads the Center of Genomics and Policy at McGill University; and John Hughes, the patient and public involvement member of the UK Clinical Research.

Brian Strom, a professor at the University of Pennsylvania and a member of the panel which will review requests to access GlaxoSmithKline's clinical trials data, has previously worked as a consultant to the company.

AdAgencyUpdate

By Joshua Slatko joshua.slatko@ubm.com

McCann promotes leaders

In a series of moves aimed at bolstering the capabilities of its North American operations, **McCann Health** has promoted a number of its leaders to higher positions in the organization.

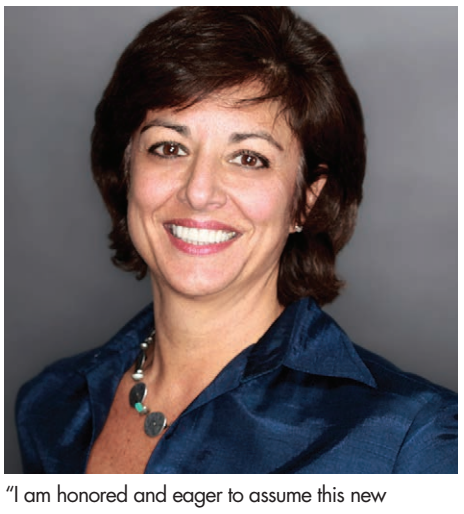
Marci Piasecki, formerly CEO of **McCann Torre Lazur Group**, has been named regional director of McCann Health North America, a newly created position. Piasecki's new regional management responsibilities include overseeing **McCann Torre Lazur**, **McCann Echo Torre Lazur**, **McCann Regan Campbell Ward**, **McCann RCW Healthcare**, and **McCann Managed Markets**.

"Marci is an extraordinary leader and pillar of McCann Health," says John Cahill, global CEO of McCann Health. "Year after year, whatever the business environment, Marci has proven herself again and again by growing her business through her exemplary capabilities and by attracting and retaining remarkably talented staff and roster of clients."

Additionally, Bill McEllen has been promoted to president of McCann Torre Lazur Group, overseeing McCann Torre Lazur and McCann Echo Torre Lazur. McEllen had been president of echo Torre Lazur. Succeeding him as president of McCann Echo Torre Lazur is Sonja Foster-Storch, formerly managing director of **CDM Princeton**. Maureen Regan will retain her leadership role at McCann Regan Campbell Ward Group (consisting of McCann Regan Campbell Ward and McCann RCW Healthcare) as president, while Brendan Ward is transitioning into a complex science role for the agency and Richard Campbell retains his role as head of Planning. And Kim Wishnow-Per has been named president of McCann Managed Markets, previously known as McCann Torre Lazur Managed Markets; Wishnow-Per and the managed markets agency now partner across all McCann Health U.S. agencies under the same governance

According to agency leaders, the new regional structure will put McCann Health's North American agencies in line with its McCann Health Global structure and branding, whereby each region (EU, APAC, and North America) now operates under single governance.

"This new structure not only ensures North American agencies will not compete against one another, but ensures that they will share best practices, innovative solutions, and efficiencies aimed at better client service," Piasecki told *Med Ad News*. "It also provides tremendous opportunity for our talent across and among agencies from New York to New Jersey to California, which helps reinforce our commitment to them and our clients; it has been a great move toward improving talent development and retention. While we intend to have each agency retain its unique culture and brand, this new structure also helps unite us under one unified brand that is McCann."



"I am honored and eager to assume this new level of leadership within McCann Health. Equally importantly, I am excited for my colleagues who have worked alongside me to provide our network with their expanded responsibilities," says Marci Piasecki, newly-named regional director of McCann Health North America.

Marci Piasecki has been in healthcare for 25 years. During her time at McCann Torre Lazur, the agency won *Med Ad News*' Agency of the Year award six times, and Piasecki was recognized by *PharmaVoice* as one of the industry's "Most Inspiring People." Before taking over as CEO of McCann Torre Lazur, she was president of echo-TL, one of three agencies within the group previously known as Torre Lazur Healthcare Group. Preceding her executive positions within McCann, Piasecki spent more than two years at Omnicom. As the executive VP, director of client service at Hyphen, she partnered with the president/CEO, chief information officer, and chief technology officer to create a hybrid agency that combined traditional advertising and clinical trial expertise with cutting edge technology to bring clients a true life-cycle approach to marketing their brands.

Bill McEllen has spent 19 years in the healthcare industry, the last nine with McCann Torre Lazur Healthcare Group. After 10 years in client-side pharmaceutical sales and marketing, mostly at BASF Corp./Knoll Pharmaceutical Co., McEllen worked in account services for McCann Torre Lazur for three years and was executive VP, managing director at the agency for another three years before moving to McCann Echo Torre Lazur, where he has served as president for the past four years. He has significant launch experience in many drug categories, including cardiovascular, CNS, dermatology, infectious disease, and respiratory. McEllen was named one of the 100 Most Inspiring People in life sciences by *PharmaVoice* in 2010.

Bill McEllen has been promoted from president of McCann Echo Torre Lazur to president of McCann Torre Lazur Group.

Sonja Foster-Storch brings 24 years of expertise and innovations in healthcare communications, advertising, and sales to her new position at McCann. Most recently CDM Princeton's managing partner, director of client services, she has spent a significant part of her professional career at Cline Davis & Mann, starting as an account executive and moving up the management ranks. Along the way, Foster-Storch also worked for Pfizer in sales for two years and co-founded and managed a medical education agency, Clinical Connexion, for nearly ten years. Also, she was managing director at the **HealthEd Group** from September 2010 to February 2012 after serving as a partner at **The CementBloc** from December 2008 to August 2010. She was named one of HBA's Rising Stars in 2011.

Maureen Regan will retain her leadership role at McCann Regan Campbell Ward Group as president.

Maureen Regan was one of the founders of Regan Campbell Ward in 1997, the same year she was named Woman of the Year by HBA. Since then, Regan and her partners have launched more than 40 brands in the pharmaceutical marketplace. Under Regan's leadership, Regan Campbell Ward was named Agency of the Year by *Med Ad News* in 2006, and she was named to the *PharmaVoice* 100 the following year. Prior to the founding of Regan Campbell Ward, Regan spent nearly 14 years at Lally, McFarland & Pantello, the last four as president of the agency.

Sonja Foster-Storch joins McCann Health from CDM Princeton, where she served as managing partner, director of client services.

Kim Wishnow-Per has a strong background in the managed care setting with experience creating branded initiatives and unbranded disease management programs that help improve patient care. Prior to taking over as executive VP and managing director at McCann TL Managed Markets in 2009, Wishnow-Per was executive VP of strategic and scientific services at Clinical Connexion. She also spent three years as director of managed markets at Bristol-Myers Squibb. Wishnow-Per was named a Rising Star by HBA in 2006.

"I am honored and eager to assume this new level of leadership within McCann Health," Piasecki says. "Equally importantly, I am excited for my colleagues who have worked along-side me to provide our network with their expanded responsibilities."

Kim Wishnow-Per has been promoted from executive VP, managing director at McCann TL Managed Markets to president of McCann Managed Markets.

Sudler teams with online genetic testing site

Healthcare communication agency **Sudler & Hennessey** has announced an agreement between its eHealth Group and NextGxDx, an online genetic testing marketplace for healthcare providers and hospitals. According to agency leaders, the integration of genetic tests into clinical practice is a growing challenge for healthcare providers as personalized medicine continues to expand and new genetic tests are introduced daily.

The NextGxDx solution consolidates and curates data on genetic tests to help users compare and order tests in a simple way that reduces paperwork and streamlines the ordering process, which leads to more time with patients. GeneTests.org, one of the most commonly used gene test databases, was scheduled by NIH to be discontinued on June 4, making Sudler's move all the more critical.

"The number of genetic testing products available to healthcare professionals is growing exponentially," says Mark Harris, Ph.D., CEO of NextGxDx. "The complexity associated with those tests, the managed care reimbursement confusion regarding the new molecular CPT codes, and the pressure on healthcare professionals to see more patients, has increased the importance of having a resource that brings transparency to the genetic test ordering industry."

Currently, clinicians use a variety of Websites to gather information about which test to order and to what lab to send it, a process that can take between 30 minutes and two hours, depending on their familiarity with the disorder and available tests, Dr. Harris told *Med Ad News*. "The ordering and results process is even more time consuming when you factor in the need to complete requisitions by hand, determine whether a lab accepts a patient's insurance, and in many cases manually enter results into EHR systems, risking errors and wasting time," he says. "Our goal is to become the trusted resource for researching and ordering genetic tests, saving clinicians' significant time and providing clarity and accountability to the ordering and reporting process."

> "Our goal is to become the trusted resource for researching and ordering genetic tests, saving clinicians' significant time and providing clarity and accountability to the ordering and reporting process."

Regarding the discontinuation of GeneTests.org, "Confusion has infiltrated the industry, and clinicians are looking for another option," Harris says. "The NIH's new project, Genetic Testing Registry, has shown promise, but genetic counselors, physicians, and laboratories have shared concerns that GTR has attempted to capture too much information, making it difficult for labs to upload and clinicians to utilize. With our focus being on providing only the information that's most valuable to healthcare professionals in their management of their patients' health, we believe that our platform can not only take the place of GeneTests.org for researching and comparing tests across laboratories, but with the ordering, electronic results reporting features, and integration to EHR platforms, we will provide additional functionality not before seen in the industry."

Last October, the NextGxDx platform was made available at no cost to clinicians, according to Dr. Harris. "The product has been well received as our user base has grown significantly in the past six months," he told *Med Ad News*. "The focus has been on educating healthcare professionals on the platform's value, and how it addresses many of the workflow issues they are currently experiencing when researching and ordering genetic tests. Primarily this has been done through platform demonstrations at industry conferences, online webinars, and face-to-face visits. After June 4, healthcare professionals will be searching for another option, and we will ensure that they know we are available as a dedicated resource focused on providing them with the tools they need to best manage their patient's health. The engagement of the experienced team from Sudler eHealth Group will be essential as we broaden our reach."

"This is an excellent opportunity for Sudler to leverage proven healthcare communications efforts on behalf of our new technology client," says R. Shane Kennedy, executive VP, managing director, Digital & eHealth at Sudler eHealth Group. "We'll be reaching HCPs using a mix of integrated media with a focus on digital as well as approaches new to technology companies such as building relationships with genetic counselors, establishing KOLs in each specialty, and implementing relationship marketing programs that will allow us to drive ongoing conversations."

AGENCY PEOPLE ON THE MOVE

■ AbelsonTaylor

Rachel Keller is promoted to senior media planner, AbelsonTaylor (abelsontaylor.com). Ms. Keller was a media planner. **Erik Spitzer** is promoted to enterprise engineer. Mr. Spitzer was an associate interactive developer.

■ Digitas Health

Graham Mills is named managing director of the New York office for Digitas Health (digitashealth.com). Mr. Mills joined the agency in 2007 as senior VP, group creative director, after spending two years working on consumer brands at Digitas.

■ Fingerpaint

Shaun Webster joins Fingerpaint's (fingerpaintmarketing.com) interactive team. Mr. Webster was owner of Web Valve. **Falon Ferraro** joins the agency's account service team. Ms. Ferraro previously worked at Ward Hill Marketing and Mansfield Sales Partners.

■ Natrel Communications

Heather Cunningham becomes VP, account group supervisor, Natrel Communications (natrelusa.com). Ms. Cunningham has a background in professional and consumer marketing and pharmaceutical sales, with an emphasis on new product launches. **Olivia Ganguzza** is named account group supervisor. Ms. Ganguzza returns to Natrel after a tenure at Valeant Pharmaceuticals as a brand manager. **Trudy Chiavelli** becomes senior account executive. Ms. Chiavelli has 20 years of pharmaceutical advertising experience at companies including Ogilvy CommonHealth and Einson Freeman. **Gianna Esposito** is named account executive. Ms. Esposito was an associate copywriter and traffic coordinator at Noesis Healthcare Interactions. **Diana Rogers** becomes group copy supervisor. Ms. Rogers joins the agency from Pivot Healthcare Communications.

■ Ogilvy CommonHealth Worldwide

Amy Graham is named executive VP, director of client services at Ogilvy CommonHealth Worldwide (ogilvychww.com). Ms. Graham has served in many senior level positions in healthcare marketing, including group manager of global marketing and sales at the American Red Cross' Biomedical Services/Plasma Operations division, director of marketing at Novavax Inc., and executive VP, director of client services at Interlink Healthcare Communications.

Draft partners with Quantia

Hudson Global, a division of **Draftfcb Healthcare**, and QuantiaMD have formed a partnership to deliver a full suite of personalized digital solutions that provide physicians education and service on their terms. The partnership, agency leaders say, represents a profound change in how major healthcare participants, such as payers, hospitals, and life sciences companies can engage physicians at a time when these industries are grappling to find the best means to serve the needs of healthcare providers through transparent and effective interactions.

QuantiaMD is the largest social learning and collaboration platform for physicians, with more than 170,000 validated clinician members nationwide. The company's digital platform enables members to gain practical knowledge and stay current on medicine and the challenges of health reform through short, interactive, case-based learning, discussions, and specialty consults with experts and peers. QuantiaMD's independent faculty includes more than 600 experts from top institutions, such as the Mayo Clinic and Johns Hopkins, and government agencies such as the Centers for Disease Control and the Centers for Medicare and Medicaid Services.

"Physicians are the core of healthcare," says Eric Schultz, executive chairman, QuantiaMD. "Their schedules are already overflowing, and the flood of new requirements on their time is rising fast. Physicians no longer have the time for traditional in-person meetings, learning, or discussions with colleagues. By combining the strengths of our two companies, we are bringing a personalized approach to digital communication that provides physicians access and services on their terms, when and where they want it."

This new partnership is intended to evolve beyond digital media to provide the first comprehensive personalized digital access solution. Hudson's interactive digital content, live interactive broadcast events, and interactive web sharing between physicians and experts, will now be integrated with QuantiaMD's ServiceLink products and with QuantiaMD's physician network online and on mobile. Clients such as payers, hospitals, and life sciences companies can take advantage of these capabilities through a personalized digital channel to access and serve physicians effectively and transparently.

> *"By combining the strengths of our two companies, we are bringing a personalized approach to digital communication that provides physicians access and services on their terms, when and where they want it."*

"Our partnership with QuantiaMD is a perfect synergy," says Robert Blink, president, Hudson Global. "Hudson has the capabilities and resources to produce high-quality content and deliver live meetings and exchanges, and QuantiaMD has the unique platform and receptive audience with a history of deep engagement. By applying the latest social technologies to medicine, we are modernizing how physicians work together and interact with the major participants in healthcare, including hospitals, ACOs, and life sciences companies, to meet a variety of objectives that reduce costs and improve the quality of care."

QuantiaMD has an active and growing membership of validated clinicians who interact using their real names and credentials. In 2012, physician members engaged in more than one million hours of interactive learning on QuantiaMD, with the average member spending 45 minutes a week on the site. One-third of QuantiaMD's members access it via mobile devices.

PeopleontheMove

By Joshua Slatko joshua.slatko@ubm.com

Forest CEO to retire

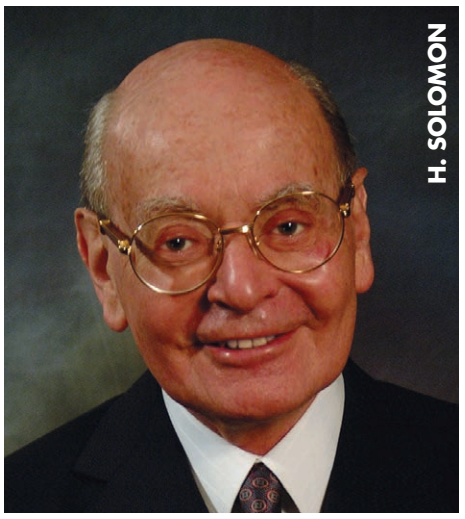
Forest Laboratories, Inc. has announced that Howard Solomon will retire as the company's CEO and president, effective December 31, 2013. Mr. Solomon is expected to remain as Forest's board chairman through the 2014 annual general meeting, at which time another chairman will be elected. Mr. Solomon will retain the title of chairman emeritus after the 2014 AGM and has agreed to serve as senior advisor to the company following his retirement as CEO and president. Mr. Solomon has served as CEO since 1977, chairman since 1998, and president since 2010.

An independent committee of Forest's board has been engaged in a succession planning process, including evaluating internal and external candidates. With Mr. Solomon's retirement announcement, the board has determined to bring the process to a close and expects to name a successor before the end of the year. The committee is being assisted by Spencer Stuart, a leading executive search company.

"On behalf of the board and the entire company, we would like to express our appreciation for Howard's dedication, strategic vision, and immeasurable contributions to Forest and its shareholders for nearly 50 years, 36 of those years as CEO," says Kenneth E. Goodman, the board's presiding independent director. "Under Howard's leadership, Forest has evolved from a small-scale producer of vitamin pills into an innovative and fully integrated pharmaceutical company with a market capitalization of over $10 billion and a proud history of innovation, strong execution and delivering value for shareholders. Today, with the launches of a new generation of products, all advanced under Howard's stewardship, Forest is positioned to build on this success. We are delighted that Howard is available to continue to serve Forest as chairman through to the 2014 annual meeting and as a director and senior advisor to the company following his retirement as CEO and president."

Mr. Solomon began his career as an attorney at leading law firms in New York and joined Forest in 1964 as a director and secretary of the board, while serving as outside counsel for the company. He became CEO of Forest in 1977 and chairman in 1998. Mr. Solomon is a trustee of the New York Presbyterian Hospital and previously served on the board of Cold Spring Harbor Laboratories. He is currently a member of the executive committee of the board of directors of the Metropolitan Opera and chairman of its finance committee, a director and former chairman of the New York City Ballet, and a director emeritus of Lincoln Center. Mr. Solomon graduated from the City College of New York and holds a J.D. from Yale University.

"We have been actively engaged in the succession planning process for some time and agree with Howard that now is the right time to begin the transition to new leadership," says



Gerald M. Lieberman, a member of the independent committee overseeing succession planning "There is no question that Howard has been an extraordinary chief executive. Our mission and focus now is to find the right CEO to take our products forward and build on the platform that Howard helped put in place. We appreciate his clear commitment to ensuring the smoothest possible transition."

The Pharmalot perspective
By Ed Silverman

Carl Icahn has been waiting a long time for this. After years of controversy over his stewardship, Howard Solomon will retire as CEO of Forest Laboratories by the end of the year, and he will relinquish his role as chairman by the time the drugmaker holds its annual meeting in 2014. Meanwhile, a committee has been appointed to choose a successor. He will, however, remain a director.

The move comes after Solomon, who is 85 and has been CEO since 1977, has had a decidedly mixed tenure. On one hand, he helped build the drugmaker into a large purveyor of medicines, but more recently, he presided over setbacks that prompted corporate raider Carl Icahn to attack his leadership and successfully place a representative on the Forest board after accumulating 9 percent of the stock.

A key question now is whether this change will prompt Icahn to move for a sale of the drugmaker. "We think he is likely to do so as the current interest rate environment may not persist until the next window of opportunity, two to three years after the next ceo takes office," writes Sanford Bernstein analyst Ronny Gal in a research note. "There is an open question whether Icahn will actually succeed in pushing this agenda, likely depending on whether Solomon supports the idea, which is a possibility given that he owns a lot of shares. At any rate, we expect the question will likely be raised."

The backdrop for Icahn's actions began three years ago, when Forest pleaded guilty to obstruction of justice, distributing an unapproved drug and illegally promoting two other medicines. The drugmaker paid $313 million as part of a settlement that included $164 million in criminal penalties. The illegal marketing involved two of its best-known medicines – the Celexa and Lexapro antidepressants. The infractions prompted the U.S. Department of Health & Human Services to seek to exclude Solomon from participating in contracts with federal healthcare programs, a move that would have, effectively, precluded Forest from doing business with Medicaid and Medicare. The feds later backed down, though, thanks, in part, to lobbying from U.S. Senator Chuck Schumer, according to sources.

The episode spurred Icahn to begin accumulating Forest shares and seeking to oust Solomon, who he accused of being a sleepy and out of touch CEO who is protected by a cadre of "loyal buddies" and has been angling to have his son succeed him in the c-suite. He also took a shot at David Solomon by saying his only experience involved promoting movies.

Sources familiar with the company have long indicated that the younger Solomon is a prime choice to succeed his father. Whether that occurs in light of recent developments remains to be seen. Not surprisingly, there was no mention of his son in the retirement announcement this morning. Forest was careful to note that the Spencer Stuart executive search firm was retained to help find candidates.

"I recognize that the time has come for me to retire from the full time responsibility of running Forest Laboratories," the older Solomon said in a statement. "I will be 86 this August and I think the company is entitled to the rigorous assurances of continuity that a younger chief executive can provide. I have agreed to serve Forest as an advisor and, if elected, as a director for the next several years.

As Gal writes: "Forest is now in for a 'tough slog' as it works its way out of the Lexapro and upcoming Namenda patent cliff and the debate has gotten contentious. Certainly at age 86, Solomon may have limited appetite for taking on this transition."

PHARMA

■ **Sumant Ramachandra**, M.D., Ph.D., is reappointed senior VP and chief scientific officer, Hospira Inc. Dr. Ramachandra returns to Hospira after departing earlier this year. Hospira (hospira.com) is the world's leading provider of injectable drugs and infusion technologies.

■ **Spyros Artavanis-Tsakonas**, Ph.D., is named chief scientific officer, Biogen Idec. Dr. Artavanis-Tsakonas had served as interim CSO while on sabbatical from Harvard Medical School. He will remain a professor of cell biology at Harvard Medical School, where he was the founding director of the Developmental and Regenerative Biology graduate program. Biogen Idec (biogenidec.com) discovers, develops, and delivers to patients innovative therapies for the treatment of neurodegenerative diseases, hemophilia, and autoimmune disorders.

■ **Deborah M. Autor** is appointed senior VP, strategic global quality and regulatory policy, Mylan Inc. Ms. Autor was deputy commissioner for global regulatory operations and policy at FDA. Mylan (mylan.com) is a global pharmaceutical company committed to setting new standards in healthcare.

■ **Hervé Lilliu** is promoted to general manager, Canada for UCB. Mr. Lilliu was VP of global market access and pricing. UCB (ucb.com) is a biopharmaceutical company dedicated to the research, development and commercialization of innovative medicines with a focus on the fields of central nervous system and immunology disorders.

BIOPHARMA

■ **Annette Clancy** is named chairman of the board, Genable Technologies Ltd. Ms. Clancy was head of transactions and alliance management at GlaxoSmithKline. Genable (genable.ie) is developing new gene therapies to treat "dominant" genetic diseases based on the work of Prof. Jane Farrar, Dr. Paul Kenna, and Prof. Peter Humphries of Trinity College Dublin.

■ **David A. Ramsay** is promoted to chief financial officer, Halozyme Therapeutics Inc. Mr. Ramsay was VP, corporate development. Halozyme (halozyme.com) is a biopharmaceutical company dedicated to developing and commercializing innovative products that advance patient care.

SPECIALTY

■ **Barry D. Quart** is named CEO, A.P. Pharma. Mr. Quart was president and CEO of Ardea Biosciences Inc. **Robert Rosen** is promoted to president. Mr. Rosen was senior VP and chief commercial officer. **Steve Davis** becomes executive VP and chief operating officer. Mr. Davis was executive VP and chief operating officer of Ardea Biosciences. A.P. Pharma (appharma.com) is a specialty pharmaceutical company developing products using its proprietary Biochronomer polymer-based drug delivery platform, which is designed to improve the therapeutic profile of injectable pharmaceuticals by converting them from products that must be injected once or twice per day to products that need to be injected once every one or two weeks.

■ **Eddie Gray** is named CEO, Dynavax Technologies Corp. Mr. Gray was president of Pharmaceuticals Europe at GlaxoSmithKline. Dynavax (dynavax.com) is a clinical-stage biopharmaceutical company that discovers and develops novel products to prevent and treat infectious and inflammatory diseases.

■ **Jim Bennethum** is named CEO, AltheRx Pharmaceuticals. Mr. Bennethum was executive VP at Becker Ventures LLC. AltheRx (altherx.com) is a privately held development company whose business model is to advance projects through clinical development and create partnerships with biopharmaceutical companies for commercialization.

■ **David Apelian**, M.D., Ph.D., is appointed executive VP and chief medical officer, Achillion Pharmaceuticals Inc. Dr. Apelian was clinical director in the infectious diseases group at Bristol-Myers Squibb. **Kevin Kucharski** becomes senior VP of clinical operations. Mr. Kucharski was VP of clinical operations at Pharmasset. Achillion (achillion.com) is an innovative pharmaceutical company dedicated to bringing important new treatments to patients with infectious disease.

■ **Eric Sirota** is appointed chief operating officer, Optimer Pharmaceuticals. Mr. Sirota previously operated a consultant practice in the healthcare industry. Optimer (optimerpharma.com) is a global biopharmaceutical company currently focused on commercializing its antibiotic product Dificid tablets in the United States and Canada, and developing other fidaxomicin products in the United States and worldwide, both by itself and with partners and licensees.

■ **Frederick W. Driscoll** is named chief financial officer, Flexion Therapeutics. Mr. Driscoll previously served as chief financial officer at Novavax. Flexion (flexiontherapeutics.com) is a clinical-stage specialty pharmaceutical company developing innovative therapeutics for musculoskeletal disorders.

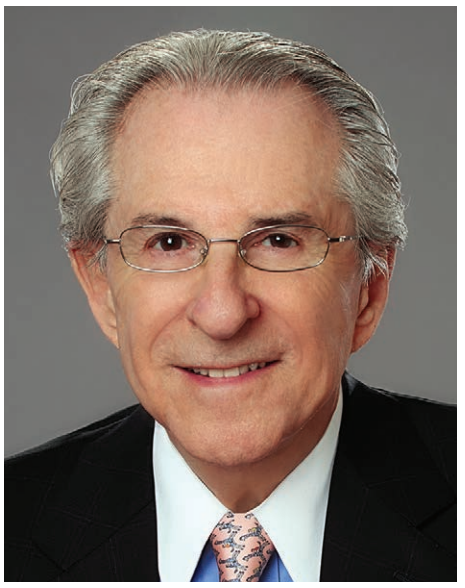
■ **Mats-Olof Wallin** becomes senior VP and chief financial officer, Sobi. Mr. Wallin was CFO at Biotage AB. Sobi (sobi.com) is an international specialty healthcare company dedicated to rare diseases.

SERVICE SUPPLIERS

■ **Kyrie Andersen** is hired to join the quantitative research practice at Insight Research Group, marketed as IQ. Ms. Andersen spent five years at Kantar Health as associate director, managing European and global healthcare market research projects. Insight (insightrg.com) is a UK-based consultancy established in 1983 that specialises in providing market research to the healthcare sector.

Who's your nanny? Ask Mayor Mike!

By Sander A. Flaum, principal, Flaum Navigators; chairman, Fordham Leadership Forum, Fordham University Graduate School of Business



MAYBE SOMEDAY, when I'm out in the Hamptons … alone on the beach … sitting on the sand and feeling the pleasure that comes from feeling a cool offshore breeze, I can enjoy again what was once a small but key pleasure in my life, smoking a Macanudo cigar, and going through a day's worth of email on my iPad.

I certainly can't light up in Central Park anymore. For weeks I hated Mike Bloomberg and his nanny-state policies. Infuriating! Mike was protecting my health by forbidding me to submit to the evils of tobacco? Who asked him? Whose lungs are they anyway? What became of my constitutionally guaranteed right to pursuit of happiness in Central Park?

Of course, beneath my ranting, I did and do understand. Banning cigarettes in restaurants and public buildings hasn't turned out so badly – I hate cigarettes. And Mike's war on illegal handguns is admirable and I fully support his generous $12 million anti-handgun P.R. campaign. I don't much feel the need to pack a Glock, but if I did, I'm pretty sure I could handle the red tape required to get a permit. Mike's ban on 32-ounce sugar-loaded sodas makes sense to me, too.

Eventually, I had to admit that Mike's edicts are not designed to take away my liberties or safeguard my health. The goal is to protect the rights of everyone and to enhance the health of the community at large. Tobacco smoke – direct or second-hand – is simply bad. I can choose to smoke or not, but that doesn't mean I have the right to foul other peoples' air.

And on a larger scale, as a former CEO, I can understand the economics Mike has to consider. Healthcare costs are soaring, and New York's ban on smoking in restaurants and bars paid off immediately, especially for the wait staff. Reducing childhood obesity by banning 32 ounce soda cups would also have huge benefits for our public healthcare costs. Taking guns off the streets makes the city safer. These "nanny" policies are not only the right thing to do ethically, they're also sound management.

As leaders, whenever we make policies for our organization, we have to face the dichotomy between what's fair for the individual and right for the company. But the more you try to influence behavior, the more you stray into "nanny" territory and invite on yourself the dreaded "dictator" label.

How scary are those terms, anyway? One of the most common gripes about Bloomberg – and it nearly cost him the last election – is that he wanted to set aside term limits so he could run for a third time. If you're a New Yorker, you'll recall that he did everything but hand out wads of cash to get the city council to vote his way. And for all I know, maybe he did make a few campaign contributions in exchange for votes. Big deal.

There's no doubt that Bloomberg behaves like a dictator, but not like Stalin – who was a monster. Let's grant that Mike is a *benevolent* dictator. These days, our representative democracy is nothing to brag about. The U.S. Congress currently has a 13 percent approval rating, and a good part of the New York legislature is headed for prison. I say we could use a few more benevolent dictators.

If you were put in charge of your company today, how would you address issues like tobacco use? Would you refuse to hire smokers? Would you offer incentives for smokers to quit? Or reward your nonsmokers with insurance premium discounts? Or would you do nothing? These are not easy decisions, but you have to deal with them, just as Bloomberg had to deal with the healthcare issues facing New York.

I'm hopeful that in years to come we'll see a statue of Mike Bloomberg in Central Park. I also hope we'll be able to take a deep breath of tobacco-free air. But I'm not too confident. Because after Mike has left City Hall, will his successors have the guts to uphold his policies? Will we be governed by "nannies" with the courage to do the right thing? Or by wusses? We'll see soon enough. ■ MEDADNEWS

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