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IN THIS ISSUE:

Ad-ventures in marketing VI

For the sixth year, *Med Ad News* has chosen three Pharmaceutical Marketing Ventures to Watch that could change the way pharmaceutical products are marketed and sold.

By Joshua Slatko joshua.slatko@ubm.com

For the sixth time this past September, *Med Ad News* began anew its search for the future of pharmaceutical marketing. We sought out young companies, spin-offs, offerings, and ventures to profile that are providing the most innovative and interesting products, services, or marketing opportunities to pharmaceutical companies and the healthcare community. As ever, this year's three profilees came to their places in healthcare from a variety of different angles – one of them started somewhere completely different – but all three are highly technology-based, and all three attempt to solve problems of communication – between the different parts of pharmaceutical companies and their sales and marketing organizations, between companies and their external constituencies, and among patients themselves. Here are *Med Ad News*' three Pharmaceutical Marketing Ventures to Watch for 2012.

Appature Nexus

Appature Nexus is a cloud-based relationship marketing tool designed to meet the specific needs of marketing professionals in the healthcare industry. Nexus, its developers believe, is unique for software-as-a-service applications in that it is designed with the stringent security and data storage requirements of the healthcare industry in mind. Although Nexus is not an EMR system, it is designed with the same stringent considerations that systems designed to house medical records are. The tool is built on a core platform that has been tested and deployed for both consumer and healthcare professional related marketing and is capable of scaling to millions of contact records along with the hundreds of millions of associated transactional records.

"Pharmaceutical companies need to communicate with the doctors who prescribe their products and the patients who use them," says Kabir Shahani, Appature's CEO. "They communicate in many different ways, using email, text, Websites, mail, and even phone calls. [Appature Nexus] helps companies keep track of all the information about their customers – such as their contact information, what topics they are interested in, how they like to be communicated to – so they can have helpful conversations with them outside of the doctor's office. Managing all these communications with so many different people can get very complex, so the software works as the 'air traffic control' to get each communication to the right place. It also keeps track of how each customer responds to each communication so that the company knows how to make the conversation even better in the future. This makes it possible for these companies to play a new role in helping to make people well, and to keeping them that way."

The company behind the Nexus tool, Appature, was founded by two lifelong software junkies, Kabir Shahani and Chris Hahn, in 2007. Mr. Shahani, now the company's CEO, came to the venture from the social bookmarking site Blue Dot, where he helped raise a significant amount of angel funding, developed strategic partnerships, and managed public relations. Before Blue Dot, he served as project manager for Avanade, a global consulting company and joint venture of Microsoft and Accenture, where he led teams and executed software projects for Fortune 500 companies. Mr. Hahn, Appature's chief technology officer, has been designing and building both consumer and enterprise software for more than 13 years, working on everything from 3D graphics hardware at ATI Research to Tablet PC solutions and operating systems at Microsoft. After leaving Microsoft, he spent a number of years working with startup companies to build a variety of media and social networking web applications.

"Appature started with a purpose to build fun transformative experiences that inspire and enable," Mr. Shahani says. "We organized around core values, and then set off in search of problems that real people had and were willing to pay for. We spent a lot of time looking at enterprise problems and, back in 2007, saw that nobody had really become the Salesforce.com for marketing (i.e. SaaS-based offering, serving the full set of needs of the marketing department, massively cheaper to deploy than existing solutions). We started in healthcare because we found a quorum of customers that all had similar challenges and were willing to buy the product if we were to build it."

And so began the path to Nexus. Launched by the end of 2007,

continued on page 8

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This month on PharmaLive.com

WEBCAST: The End to End Marketing Ecosystem - December 12, 2012

When you're entering new territory it's a good idea to first lay out a map – and the map for the new marketing model is much bigger than most of us realize. It consists not just of the many channels and touchpoints that are visible to our naked eye, but an entire ecosystem of elements, interdependent across the enterprise, that can either nurture or paralyze a marketing effort. This Webcast examines the end-to-end marketing ecosystem – the seemingly never ending proliferation of channels, but also the many data sources, processes, and organizational capabilities that characterize a healthy environment in the new world of marketing enablement. Learn how to identify which elements of your own ecosystem are well established and thriving, which elements are unhealthy, and which may be absent altogether. Gain insights that will help you navigate this wild untamed territory and plot your course to the strategic commercial ops endstate you seek. You *can* get there from here.

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tothepoint

By Christiane Truelove chris.truelove@ubm.com

Beth always maintained her well-grounded nature and humorous spirit, even at challenging times, and she always had a wonderful way of helping others see new possibilities and stay focused on the outlook and positive opportunities ahead. In Beth's hands, every endeavor or project would attain a new and higher level of performance, thanks to her critical thinking, clear vision, and commitment to constant improvement.

Readers may notice that it's not my picture in the editorial this month. That's because it's a tribute to someone I had only just met recently, but I wish I could have gotten to know better: Beth Everett, Ph.D., secretary for the HBA's Metro chapter. She was a victim of Hurricane Sandy.

Beth and her husband Richard were killed the evening of the 29th. A falling tree hit their truck as they went to check on their horses at their farm. They left behind four children.

According to HBA, "Beth was an inspirational leader and a dedicated mother with passion for many things in life. She was amazingly resourceful, bringing insights to an unlimited range of topics and action to countless worthwhile initiatives. Beth always maintained her well-grounded nature and humorous spirit, even at challenging times, and she always had a wonderful way of helping others see new possibilities and stay focused on the outlook and positive opportunities ahead. In Beth's hands, every endeavor or project would attain a new and higher level of performance, thanks to her critical thinking, clear vision, and commitment to constant improvement."

Some other things to know about her: She earned a Ph.D. in chemistry from the University of California at Santa Barbara. She was a senior management consultant at Carter McKenzie Select at the time of her passing. Her career included positions at SmithKline Beecham, Novartis, Organon USA, Impact Rx, and SAIC. A strong believer in giving to the community, Beth was actively involved in 4-H and served on Hope Church's benevolence team, helping the disadvantaged in Morris County, N.J. She also was a very strong supporter of Habitat for Humanity, volunteering for them since she was in high school. During the past eight years she supported Morris Habitat as two-term board member and founding member of Habitat's Re-Store committee.

I had only met Beth in October when I drove up to PSKW's offices in Bedminster, N.J., for an all-day meeting of the new HBA Metro Chapter Advisory Board. She was the petite blonde woman with the twinkling blue eyes behind steel-rimmed glasses, perched on an office chair along the wall in the crowded conference room. When we were talking about the need for diversification among HBA membership – to attract those on the clinical and science side as well as those on the marketing and advertising side of the pharma industry – Beth talked about the first time she ever showed up at an HBA event. She'd felt out of place, she explained, because here she was, an admitted "nerd," among all these marketing executives. But after she started volunteering, she developed a deep and satisfactory network of friends in all walks of the industry.

An HBA member since 2003, Beth was a board member in the Metro chapter and served as chapter secretary in 2012. She was very active in the HBA, contributing her talents on committees including TOP (Technology Overhaul Project) leading to a new HBA Website, DART (Data Analysis and Review Team), IT, social media, and the Leadership Conference. Beth served as the director at large for technology management on the HBA board in 2009 and 2010.

I warmed to Beth after she talked about her nerd-dom, because I too am a nerd. I am more comfortable among the scientists and the geeks than the marketers (one reason why I enjoy social media so much) and as a journalist, I am the habitual observing outsider. I noticed that Beth did a lot of close observing during that meeting, and she had a pile of notes by the end of it. I wish I could have gotten to know her better; I suspect that we may have had similar senses of humor.

Mother Nature is a cruel mistress, and fate is fickle. We never know what we'll face each day. If there's something to learn from this, it's to take opportunities when they come up – because you'll never know what will happen. Goodbye Beth. You will be missed.

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inside

ON THE COVER

FEATURES

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WHAT'S ONLINE

DotPharma

BUSINESS LEADERS WHO DON'T EMBRACE BIG DATA COULD FIND THEMSELVES REPLACED BY THOSE WHO DO

So-called "Big Data" will drive mainstream management strategy and executives slow to embrace it will lose competitive advantage to those that do, according to findings from a survey of IT, financial services, insurance, life sciences, and other industry executives by the industry information consultancy Knowledgent.

SURVEY FINDS MORE U.S. ADULTS TRUST THE INTERNET MOST THAN THEIR PHARMACISTS

According to a survey by RxAlly, just 18 percent of U.S. adults trust a pharmacist most to help guide and inform healthcare decisions for themselves and their families, compared with 72 percent who trust their doctor the most, 36 percent for friends and family or spouses/ significant others, and 22 percent for the Internet.

HEALTH ACTIVISTS PUSH COMPANIES TO PARTICIPATE IN SOCIAL MEDIA, CORRECT MISINFORMATION

A survey of users of multiple online health communities has found that such users are growing impatient with non-participating companies, and that companies who do not respond to misinformation about their products posted on social media sites are causing harm to the public health.

Go to pharmalive.com/dotpharma to read these stories

WHAT'S IN PRINT

NEW VENTURES TO WATCH: APPATURE NEXUS

Appature Nexus is a cloud-based relationship marketing tool designed to meet the specific needs of marketing professionals in the healthcare industry.

Go to cover page

NEW VENTURES TO WATCH: INSPIRE

Inspire builds online health and wellness communities for patients and caregivers, in partnership with national patient advocacy organizations, and helps life science organizations connect with highly engaged populations.

Go to page 8

NEW VENTURES TO WATCH: PROLIFIQ

Prolifiq's platform, accessible from virtually any device and highly customizable, enables sales reps to use a single point of access to find, share, discuss, and measure managed, compliant content during customer interactions and to immediately establish real-time communications with customers and colleagues.

Go to page 9

MOBILE MARKETING: TAKING MOBILE GLOBAL

To successfully deploy content in mobile ways in emerging markets, pharma needs to keep in mind the type of technologies available and assess the true needs of physicians and patients.

Go to page 10

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continued from page 1

Appature's primary offering has been growing its functionality and client base ever since. Throughout, the company's developers have kept their focus on simplicity; Nexus aims to integrate each client's internal and external data so users get a combined view of behavioral, attitudinal, and demographic data from healthcare data providers, sales force calls, and marketing activity, breaking down and integrating data silos across a client's operations. And the software aims to automate the chore of customer segmentation with a drag-and-drop customer segmentation engine and continuous updates to each customer record behind the scenes with every inbound and outbound interaction.

"Pharma companies want to develop more effective relationships with their customers by better managing data and organizing communications across many channels for the best customer experience," Mr. Shahani says. "They also want to get better insight into performance of their programs in order to optimize ROI. Generally they already have very strong technology capabilities in place to support the sales force, but do not have the necessary capabilities in place for marketing. That's where Appature comes in."

The Nexus offering itself is divided into three segments, each designed to solve particular marketing challenges that life sciences companies face. Nexus 360, the marketing database segment, aims to bring together customer data that was previously siloed – web activity, email metrics, mobile programs, sales force automation data, prescription data, tactics sent by third party vendors, et cetera – allowing for access to every commercially relevant data point and quick customer segmentation. Nexus Touch, the campaign management segment, allows users to use all this data to help design and coordinate the customer experience, customize messages, schedule and automate campaigns, and directly deploy both email and mobile messages. And Nexus Insight, the analytics segment, provides business intelligence reports and data visualization tools that help users understand overall campaign performance, feeding right back into the data in Nexus 360.

Big pharma is clearly paying attention and getting results. Appature's Website includes white papers of its work with Abbott and Johnson & Johnson, and Medtronic is another client. According to a company case study, one Fortune 500 medical device company saw a 22 percent increase in new revenue following one marketing activity to a group of segmented and targeted surgeons by measuring the campaign targets that did not contribute to revenue and later attended the targeted training session. Another healthcare company enjoyed 36 percent open rates and 23 percent click-through rates from a webinar and tradeshow attendance campaign using the Nexus relationship marketing platform.

How does all this happen? "We work closely with marketing teams to ensure they have the best platform in place to managing their customer relationships, and also commercial operations and IT teams to ensure the platform has the right processes in place and connections into other systems," Mr. Shahani says. "Sometimes we are brought in by brand executives who have a need to make their marketing more effective – getting their data in one place, coordinating the delivery of communications across many vendors and channels, and better measuring results. Other times we work with central commercial operations and IT groups that are looking to put in place an effective and easy to use marketing platform that can be used across brands."

Appature Nexus is a conglomeration of three elements: a database to house and quickly access customer information, a campaign management system to help coordinate the customer experience, and a set of analytics tools to see how customers are responding.

With the analysts at Gartner predicting that CMOs will spend more on technology than CIOs by 2017, Mr. Shahani sees his company taking advantage of a growing shift in investment in technology capabilities towards marketing. "We see growing Appature to become the de facto standard of enabling technology for life sciences marketers, the universal "power grid" that sits underneath all marketing campaigns to both consumers and HCPs within the industry," he says. "Appature will also play a much larger role in helping marketers deal with the explosion of Big Data to bring simplicity in the midst of growing complexity."

Inspire

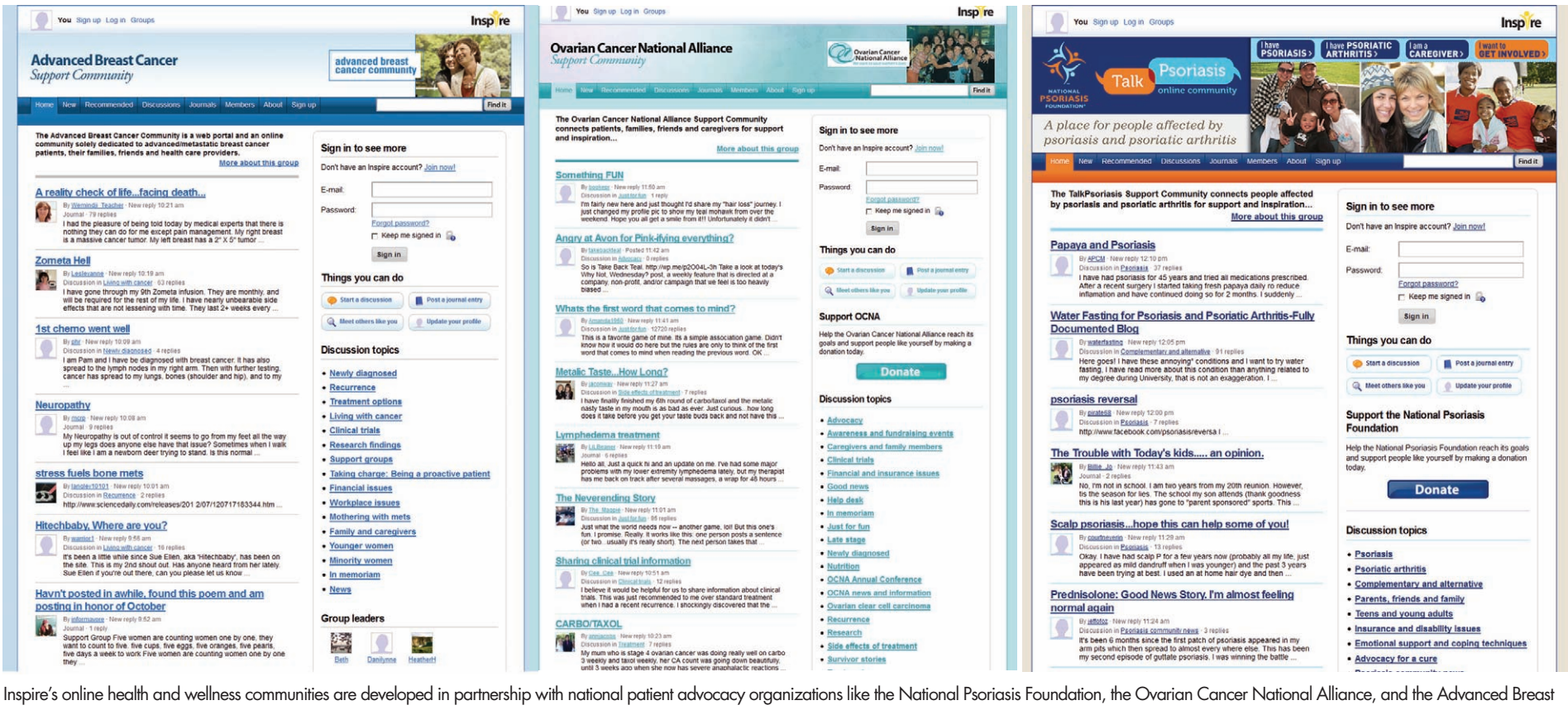
Inspire builds online health and wellness communities for patients and caregivers, in partnership with national patient advocacy organizations, and helps life science organizations connect with highly engaged populations. The company, based in Princeton, N.J., partners with organizations, including the Ovarian Cancer National Alliance, National Osteoporosis Foundation, Arthritis Foundation, and National Organization for Rare Diseases, among others, to provide online patient communities in a safe, privacy-protected environment. Founded in 2005, Inspire now has more than 80 exclusive national patient organization partnerships and more than 250,000 registered members. Inspire communities are free for qualified 501(c)(3) organizations; the company earns revenue by providing research for life science companies.

"Inspire is the leading online patient community," says the company's CEO and co-founder, Brian Loew. "People like you and I join Inspire, choosing disease-specific groups in a trusting, moderated environment. Each of these groups is made up of other like-minded people, and in the group there is a tremendous amount of encouragement as well as practical, emotional, and educational support. When a pharmaceutical company wants to engage with patients to better understand patient experiences, to educate those patients about their brand, or to conduct research, we invite those patients to connect with that pharma company. The important part to us is that it's entirely the patient's decision whether or not to engage."

Maintaining credibility with participants and active communities while actually making money from pharma requires a delicate balancing act by Inspire's decisionmakers, and the company achieves this by drawing a bright line between its patient communities and client research. To do this, Inspire provides pharma companies permission-based access to specific patient populations but does not permit pharma companies to engage with patients within the communities themselves. Rather, patients are invited to participate in research separate from the community in an environment that is appropriate from a legal and regulatory perspective.

"Our typical relationships with companies with pharma are long-term recurring engagements," Mr. Loew says. "Their goals are usually one or more of three things: to better understand patient experiences with diseases and specific therapeutics; to help them recruit patients to participate in clinical trials; and to help raise awareness of and provide education about their brands."

Most of Inspire's disease-specific groups are created in partnership with national patient advocacy organizations, granting them immediate credibility. "For example, our ovarian cancer community was created in exclusive partnership with the Ovarian Cancer National Alliance," Mr. Loew says. "For patients and caregivers who join our community, there's an immediate sense of authority, credibility, and trust that results from the



Inspire's online health and wellness communities are developed in partnership with national patient advocacy organizations like the National Psoriasis Foundation, the Ovarian Cancer National Alliance, and the Advanced Breast Cancer Community.

OCNA's involvement. Also, while you're in the community, high-quality resources from the OCNA are easily available to you. Because Inspire owns and operates the communities, when we work with pharma companies we can involve the patient advocacy organizations on a case-by-case basis as appropriate."

Another differentiating factor about Inspire's communities is that the company employs live moderators to support each of them. With such active moderators and engaged participants, in time the communities become self-seeding.

"Because a large quantity of new information is created every day in the communities, they are highly visible in organic search," Mr. Loew says. "And that, of course, helps new patients discover Inspire and become engaged."

With all this experience at patient community building, Inspire's team has learned a great deal about the specific things that are important to patients, how they engage with each other, and how they engage with the medical community and with industry. The most critical element they've found, not surprisingly, is authenticity.

"One of the most important things to patients, particularly those affected by life-threatening or life-altering diseases, is knowing that the information they're receiving is authentic and transparent," Mr. Loew says. "Authenticity and transparency continue to inform everything we do – how we treat our members and how we invite them to engage with pharma."

Inspire's long-term goal, its leaders say, has always been to advance medical progress by supporting patients and connecting them with information, researchers and resources. To this end, the company plans to continue building its thriving community, with an eye on broadening across more conditions. "In doing so, we will ensure Inspire is the essential place for patients, and for pharma to connect with those patients in trusting, appropriate ways," Mr. Loew says. "Today, Inspire is very strong in oncology, women's health, rare diseases, and chronic conditions, and we have 80 national patient advocacy partners. We will continue to extend our breadth to cover all conditions, and to deepen the value we provide to patients and to industry."

Prolifiq

Prolifiq Software Inc. is a provider of hybrid cloud communications applications for life sciences, technology, and visual media companies. The company's platform, accessible from virtually any device and highly customizable, enables sales reps to use a single point of access to find, share, discuss, and measure managed, compliant content during customer interactions and to immediately establish real-time communications with customers and colleagues. Prolifiq's tools primarily serve field-based sales personnel; however, the company's offering aims to bridge the gaps between sales, medical affairs, marketing, sales operations, corporate communications, training, and compliance.

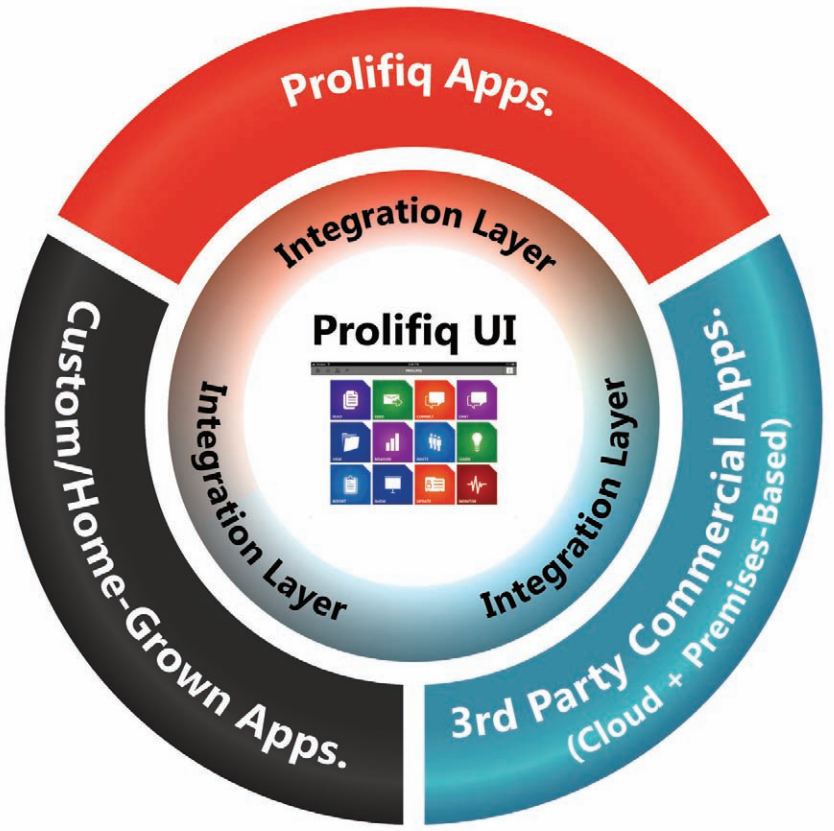
Though Prolifiq was founded in 1999, its original focus was elsewhere; the company's Life Sciences offering was launched in the fall of 2009. Life sciences now accounts for three-quarters of Prolifiq's revenue and is driving 50-plus percent growth year-on-year. Observers outside healthcare are taking notice; Prolifiq was selected as one of America's 20 most promising young companies by Forbes the same month it moved into life sciences, and was chosen as one of the analyst company Gartner's "Cool Vendors" of CRM sales just a few months afterwards.

"Prolifiq's iPad and iPhone applications allow pharmaceutical and medical device sales reps to quickly and easily find, show, share, and measure documents, images and videos to help them represent and demonstrate their products to doctors, nurses, and other healthcare providers and to establish real-time video and screen-sharing sessions with expert resources elsewhere in their company," says Jeff Gaus, Prolifiq's CEO. "Prolifiq has combined the speed and simplicity users expect from mobile applications with the governance and control needed to comply with federal and state rules and regulations."

The original vision of the founders of Prolifiq was to simplify the use of rich media in daily business communications. The company began by serving large West Coast-based technology companies with sophisticated sales processes. But a bit of serendipity intruded that wound up pushing Prolifiq towards the world of healthcare.

"[We] saw an opportunity to introduce its technology to the life sciences industry because one of our customers used the Prolifiq platform to defend themselves in a Federal unapproved-use-case marketing prosecution – this event crystallized for our management team a very real problem we knew how to address and solve," Mr. Gaus says.

Prolifiq establishes relationships with pharma companies through trade shows, webinars, digital marketing, print advertising, and thought leadership speaking engagements. Through these routes, the company's representatives encounter what Mr. Gaus calls "champions" – "Typically a 'champion' emerges who is trying to solve a specific problem or create a competitive advantage. They want to deploy, or have deployed, iPads or mobile devices and are looking for solutions above and beyond just 'building an app.' Or they are frustrated by the lack of customer engagement tools within their CRM applications. Or they recognize that the role of the field sales rep is changing and want to facilitate this change through mobile technology. Or they are launching a new brand and believe there is a better way to do so. Or they have had a compliance violation, or are operating under a corporate integrity agreement and are seeking a way to comply with rules and regulations while enabling their employees to do their jobs."



Prolifiq's architecture allows for the integration of the company's own native apps, third-party apps, and clients' legacy apps so users can access all of these from anywhere.

In all of these cases, Prolifiq's capacity for customization alongside maintaining data to regulatory standards is a differentiating characteristic. The company's rules engine for good promotional practices allows each pharma company to incorporate its own standard operating procedures and workflows so the system maintains the "personality" of each brand and company and ensures the proper data is used and generated by users while fulfilling information requests by healthcare providers. But to succeed in life sciences, Prolifiq's developers knew that they needed to go beyond mere compliance.

"Prolifiq entered the life sciences industry with a robust platform that passed government scrutiny," Mr. Gaus says. "We knew how to address this issue – unapproved-use-case marketing – and we believed this was the driver for our customers' purchase decision. To use an automobile metaphor, what we quickly learned was the compliance solution is the 'airbag' and that our customers wanted the 'whole car.' Yes, 'safety' was important – in fact, a cost of market entry – but they wanted speed, handling, comfort, onboard navigation, precise instrumentation and amenities. This insight led to the broad expansion of the 'tiles' – applications – and capabilities we offer in our platform."

Prolifiq's home screen is common across all devices and provides action-oriented tiles that allow users to quickly accomplish specific tasks.

Prolifiq's user interface looks familiar to any long-time smartphone user. The platform provides an intuitive, "one-stop-shop" screen that is common across all devices (PC, tablet, smartphone) and provides action-oriented "tiles" allowing users to accomplish specific tasks. From this screen the user can access Prolifiq applications, third-party applications (CRM, ERP, CMS, LMS, et cetera), and customers' legacy applications in a single location. The platform's integrated tiles include CONNECT, which alerts reps as to company experts' availability to immediately connect customers to answer questions or resolve issues via CHAT (another tile), voice, or video conference. Reps can also READ company and industry news, VIEW the latest, approved marketing content, SEND materials to customers, INVITE customers and manage attendance at company events, CHAT with colleagues, SHOW interactive presentations, MEASURE their customer interactions, REPORT real-time field events, and UPDATE customer databases, plus whatever other third-party or legacy apps each client might desire. All this is built on top of a .NET enterprise application architecture and delivered through an enterprise-class cloud infrastructure. And all devices really means all devices; in May 2011, the company launched its enhanced mobility suite, expanding access to the platform to all tablets and smartphones.

Given the exploding demand for digital solutions to communications bottlenecks in sales organizations, not to mention the exploding size of pharmaceutical organizations, Prolifiq's leaders are quite optimistic about the future of their company and its platform. The company recently established its first beachhead in Europe, and Mr. Gaus expects further moves into Latin America and Asia in the not-too-distant future. He also expects continued broadening of the platform by providing additional "tiles" to address specific information needs of the field workforce as the full effect of tablets and the "applification" of enterprise software progresses. And while the platform's center of gravity remains in the sales force area for now, this may not remain the case.

"We see the expanded use of our platform for additional workers within life sciences companies – medical affairs, reimbursement specialists, field service, et cetera," Mr. Gaus says. "Ultimately, a very exciting trend for Prolifiq is the extension of our platform directly to healthcare providers, payers, and ultimately to patients, and providing a private, secure communications experience to effect better patient outcomes." MEDADNEWS

TAKING MOBILE GLOBAL

To successfully deploy content in mobile ways in emerging markets, pharma needs to keep in mind the type of technologies available and assess the true needs of physicians and patients.

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

The explosive growth in the number of mobile phone users represents an opportunity for communicating with patients and physicians in more ways than ever before. Experts predict that in many countries in the emerging markets, mobile use will exceed desktop use, and pharma companies will need to account for differences in technology and mobile usage and plan their campaigns accordingly. And in places where the handsets are less fully featured and few people can afford top-line smart phones, pharma should not overlook the value of basic technology such as texting.

Looking outside of mobile health, strong precedents already exist for the use of mobile phones to obtain products and services. According to Marc Michel, partner, Greater Than One Europe, in developing countries such as the Philippines, Kenya, and Nigeria, where up to 80 percent of the population does not even have a bank account, mobile phones are key for money transfers and mobile payments. Often cited as the example for the emerging world, 68 percent of Kenyans have used mobile money transfers, with 19 million accounts active and one quarter of Kenya's GDP transacting on the m-pesa network.

"In fact, the financial services sector in these parts of the world will be substantially different than the developed world," Mr. Michel says. "GTO helped design the front-end for MFS Africa's portal launch in Madagascar with telco partner Orange. Mobile payments will make healthcare accessible in ways that were not possible before, by allowing people to pay for services, pay for transport to/from clinics, by being able to access micro loans to pay for treatments, or receive reminders and tips about their health all from their mobile device."

According to PricewaterhouseCoopers' report "Emerging mHealth: Paths for Growth," almost 6 billion mobile phones were in use worldwide by late 2011. "The ubiquity of mobile technology offers tremendous opportunities for the healthcare industry to address one of the most pressing global challenges: making healthcare more accessible, faster, cheaper, and better," says David Levy, M.D., Global Healthcare Leader for PwC.

PwC experts say that in the emerging markets they surveyed, patient awareness and expectations of mHealth are higher than those in developed countries, with 59 percent of emerging-markets patients using at least one mHealth application or service, compared with 35 percent of those patients from the developed world. In emerging markets, 61 percent of patients surveyed were familiar with the terms mobile health or mHealth, compared with 37 percent of patients in developed markets; 64 percent of those surveyed from emerging markets say they expect mHealth will change how they seek information on health issues; 54 percent say mHealth will change how healthcare providers or services send general healthcare information; 57 percent say it will change how they manage their overall health; and 55 percent say it will change how they manage their medication.

For emerging-markets patients who do not yet use mHealth, 57 percent said they would be interested in apps or services that could help them track their own well-being through entering data manually and 46 percent said they would be interested in such apps that got their data automatically. By contrast, only 37 percent and 28 percent of developed-markets patients, respectively, were interested in such apps. 61 percent of emerging-markets patients said the were interested in apps that would help them communicate better with healthcare professionals, compared with 54 percent of developed-markets patients. And 57 percent of emerging-markets patients expressed interest in apps or services that would gather general healthcare information, including drugs, compared with 44 percent of developed-markets patients.

PwC also says that payers and doctors in emerging markets are also more interested in mHealth than those in developed markets. For example, 43 percent of respondents from emerging markets say their payers cover telephone-based consultations, compared with 29 percent of respondents from developed markets. Additionally, 37 percent of emerging-markets respondents say payers will cover text-based consultations, compared with 23 percent from developed markets.

According to PwC, the overwhelming need in emerging markets may explain the faster adoption of mHealth. Not only are fewer physicians available per patient, most of these physicians are concentrated in urban areas, leaving rural patients with little access to doctors. This is especially a problem in India, China, and South Africa, where much of the population lives in the countryside and medical care is often provided, if at all, by those with only the most basic medical training.

Where will some of the innovations in mobile health campaigns be seen? Mr. Michel believes there will be high usage of smartphone and new strategies in South Korea, Taiwan, Malaysia, and Turkey. Cell phones will still dominate in developing countries such as China and India and African markets where mobile is enabling people to be connected for the first time. "As smartphone price points drop to below $50, then we will see a dramatic shift as entire populations can get onto the Internet for the first time ever," he says. "At the current price point most people in developing nations still can not afford a smartphone device."

Smart phones, feature phones, and dumb phones

Roberto Ascione, president of Razorfish Healthware International, says in established markets, mobile has to be a totally integrated component of marketing programs. Marketers have to keep in mind that people will want to access content from several platforms, and as users move from platform to platform throughout the day, marketers will have to provide content that keeps them engaged all around.

"Years ago, you had to care about the reach of channels, but today, you have to worry about the switch of technologies or platforms or access devices, because that's our reality," Mr. Ascione says. "During the day, I have the PC in front of me, and then I have the phone, then maybe I move to another room and I have the tablet, because it's more comfortable on the couch than the PC. I shouldn't break my experience as I switch between the different platforms."

In emerging markets, however, mobile could be the first tactic, and in some cases the only tactic. But in some of these cases, mobile doesn't mean the same thing as mobile in the United States or another developed market.

For example, Razorfish Healthware is partnered with a charitable group in India, HealthPhone, that is putting videos on newborn care and child care onto inexpensive chips that are installed in popular low-cost models of mobile phones. Razorfish Healthware is providing content through Videum – Health in Any Language, a new video portal that allows users to access health and wellness content in any language.

HealthPhone's topics include timing births, safe motherhood and newborn health, child development and early learning, breastfeeding, nutrition and growth, immunization, diarrhea, hygiene, malaria, HIV, child protection, and injury prevention. Because the content is provided on pre-loaded chips, the phones do not need signals nor is there a download cost.

"It's an incredibly smart use of mobile, but it's a very different mobile than we have in our minds because of what we use today," Mr. Ascione says. "And through that we are able to reach people who would be normally unreachable, and I think that's incredibly smart. It's not something we'd do in the States."

Kurt Mueller, chief digital and science officer at Roska Healthcare, says one of the things that pharma companies should be thinking about is what mobile means, and how they see the audience engaging with it.

"In many cases outside the United States, even though you have a smart phone, text is huge, text is still really big," Mr. Mueller says. "And I think pharma shouldn't lose sight of that. As the smart phones become prevalent, we should not lose sight of the effectiveness of text. Some of the research that we saw showed the highest use in communication was text. At EyeforPharma, there was a presentation on what the most common form of communication on a smartphone was, and it wasn't e-mail, it wasn't social networking, it was text. I thought that was pretty compelling. There's a lot that pharma can do with text messaging that's very effective."

A prime example of text use in a mobile campaign is Text4Baby, the public-private partnership founded by **Johnson & Johnson**, the National Healthy Mothers, Healthy Babies Coalition, Voxiva, CTIA – The Wireless Foundation, and Grey Healthcare Group. However, this free program is strictly in the United States.

Larry Mickelberg, partner and chief digital officer at Havas Health, says mobile growth across categories, not just health, is being driven in particular by Brazil, China, and India. But he says pharma marketers must keep in mind that the mobile devices in these countries will be different than what we typically think of as a smart phone.

"The smartphones in India and China aren't going to look like [an iPhone]," he says. "The purchasing power is different, and consumers, although they want and will get access to these devices, they're going to be much, much cheaper. I don't know if they will be much less functional, but they will be different than the smartphones we know today in the Western world. I think it's a bit of an innovation challenge for handset manufacturers in particular to come up with a new generation of phones that meet the need of this new middle class. So we'll see some great change in the space in terms of the devices themselves."

Mr. Mueller says in emerging markets, smart phones will be outnumbered by "dumb" phones, without video/photo, music, gaming, and e-mail capabilities, and feature phones, which may support photos/videos, music, and gaming, but will not have e-mail or Web browsing.

"That's why I brought up text, that will work on a dumb phone, a feature phone, and a smart phone," he says. "There's an instance where if they have a base phone, that's at least at that minimum level, just about everybody can get text. And some of the studies we are looking at in large cases, where they're on the older technology, that's the best technology that they've got, besides calling somebody. That's why I said text is perhaps getting undervalued and not looked at, as the newer technologies come aboard, and I think that's really a mistake. I think that we should have a renaissance going back to that, going back to basics in the emerging markets."

But according to Mr. Mickelberg, games, particularly in places such as Egypt, Africa, and India, are counting for a growing percentage of use, greater than music, social networking, search, and e-mail. He says using text for mobile campaigns, while prudent, is a short-term strategy, and pharma marketers need to be thinking ahead.

"I think the innovations in these markets will make for far more feature-laden phones to come to market than before, even

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at much lower price points," he says. "We're going to see a great innovation moment in terms of handsets. So designing to the terms of the lowest common denominator might be prudent for today, but definitely not the wave of the future."

Account for human need (it may not be an app)

Industry experts stress that pharma marketers should always determine what the ultimate need of the customer is before offering a solution. "At GTO we always think that the customer-centric approach is key to any digital strategy and it is important to understand the use case to roll out the solution," Mr. Michel says. "So if it is providing access to care to rural citizens of the developing world by supporting mobile payment upstarts and funding projects in money transfer that will ultimately be used to access healthcare and healthcare insurance, to creating patient adherence programs or HCP tools for smartphones, it is important to build the human element in the digital age."

One example cited by Mr. Michel of an innovative outreach program is Gamreen Health, which has partnered with **Pfizer**, GE Healthcare, and Mayo Clinic to find new ways of funding healthcare through sustainable business models. "In fact, through projects such as these, and innovating in markets very different from the developed world, there are opportunities to bring innovation back home for profit," he says. "The trend of reverse innovation has strong supporters, such as GE CEO Jeffrey Immelt, and there are many examples of GE Healthcare putting this to work."

Mr. Mickelberg says that significant differences exist between physicians in Asia, Brazil, and Russia, and the United States and Europe, in terms of the penetration of smart phones and tablets and the way that physicians in these different markets use them during the course of their clinical workday.

"There are definitely differential modes of use throughout the course of their day, whether they're in between patient consultations and what their needs are in that mode – things like staying up to date about treatments, managing questions that patients have, finding information quickly – or during patient consultations, when they're dealing with practice management or EMR, they're looking up formulary information, those kinds of things are different across regions in terms of devices physicians use to do that," Mr. Mickelberg says. "So what we're seeing is a rise of multiple screen users, it's really a three-screen world, between a laptop, a tablet, and a smartphone. They're all mobile in some way, shape, or form, but tuning programs to a deep understanding of how physicians by region consume information is important. I think it will dictate changes in how companies go to market."

Mr. Ascione says every client his agency works with has to fill out a "value equation," in which they must figure out what the customer's needs are. "What we are trying to prove here is to say, ask yourself what's needed from a service standpoint, and the message and the campaign will come as a consequence, but not as the tweaker for the need, because that's your need, that's not the end user's needs," he says.

That evaluation is particularly critical when the client wants to create an app, because so many apps get used once, then abandoned. When it comes to determining the need for the apps, "we're trying to push a lot more customer centricity, even more than what we normally do when it comes to a Website or another digital product, because the mobile phone is something that you literally have available seven days a week, 24 hours a day," Mr. Ascione says. "If you are really able to engage with the user with something that makes a difference, then you can be incredibly successful. Otherwise, it will be a gimmick and probably be something that's used once; a cool design, but something that will basically be ineffective."

Mr. Mickelberg believes that pharma companies are starting to pay attention to the digital behaviors of their audiences, whether physician or consumer. But, "they have to create far more distributed strategies to get information or experiences, or services, into the hands of their customers," he says. "They have to take the time to understand the nuances between customer types across regions, even across therapeutic categories, and create distributed strategies to make sure that you reach them where they're looking for information or where they expect to get information. You're not going to drive them to a brand-dotcom, or even a mobile brand dotcom; you have to actually be a little bit craftier in terms of strategies. Gaming is one example, and there are others in terms of apps and other platforms and other means to syndicate content, that are part of the overarching content strategy today."

Mr. Michel points to what **Merck** & Co. is doing with Univadis as an example of how a pharma company is trying to meet the needs of the customer. Univadis is an online medical community for physicians in 38 countries worldwide. "In the past two years they have had more healthcare practitioners sign up in China alone than the rest of the world," Mr. Michel says. "They are undergoing a comprehensive overhaul of their Website and launching a mobile friendly responsive design Website that will meet user needs. They also have a road map for developing specific tools and solutions on the mobile for different markets. This is the understated heavyweight in pharma communications on a global basis with over 1.2 million HCPs registered to their unbranded, independent editorial Website."

To meet customer needs, content will have to be provided in a way that can be played on any platform, Mr. Mueller says. This requires the use of responsive design and tactics. "If they're on a smartphone, they'll be on a small screen, they probably only want to have things that are most important to them and not the rest, and basically shorten up everything else," Mr. Mueller says. "Through code, we can control it in such a way that, you have really one Website, but depending on the device that hits it, the content that gets served to the device and the way that it's laid out is optimized for that device. So rather than creating 61 different Websites, there's only one, and through programming, you can tell the Website what to serve." ■ MEDADNEWS

RISKY BUSINESS:

Will the REMS program survive?

There is growing pressure on FDA to revamp a controversial effort to bolster safety.

By Ed Silverman ed.silverman@ubm.com

For nearly five years, the pharmaceutical industry and FDA have been grappling with an experiment designed to bolster safety standards for newly approved medications. But after drug makers have spent countless dollars and hours, the agency is facing criticism that the Risk Evaluation and Mitigation Strategies program has fallen short of its overarching goal of improving public health.

The REMS program was authorized by the Food and Drug Administration Amendments Act of 2007 in the wake of various safety scandals – notably the Vioxx debacle in which Merck withdrew its widely used painkiller after links were established to heart attacks and strokes. In fact, the episode helped usher in a new era of safety-conscious regulators.

By creating the REMS program, Congress and FDA hoped to ensure that manufacturers similarly adopted a new awareness toward safety that emphasized greater communication and education for physicians and patients. For drug makers, this required an added layer of investment in order to win agency approval for their medications.

Now, though, some say the effort requires serious rethinking. Even as FDA, itself, takes a closer look at the process in which drug makers must submit assessments of their specific REMS programs, there is a growing call for the agency to examine the entire REMS campaign and consider scrapping this in favor of something that does more than demand souped-up medication guides.

"The question is really whether we're achieving our goals," says Mary Mease, senior director for risk management at Quintiles, the contract research organization. "A lot of money is put into REMS evaluations and comprehension tests. But the goals should be to affect the outcome and have fewer adverse events. But I don't think that's been the goal. Instead, it seems that the goal is to communicate understand the REMS materials.

"Why do we need REMS to communicate this information to healthcare providers? The material has already been out there. I would hope we don't need REMS to require a prescriber to read about a drug they're going to prescribe. That's part of 'do no harm.' For patients, it's a slightly different story, but I don't think it needs to be part of REMS," she continues. "Why does a company need to be forced to prepare materials that will simply be evaluated? I would say we probably don't need them in most circumstances."

Since March 2008, FDA has approved approximately 200 REMS programs for individual products, according to agency statistics. Of those, 125 required only a medication guide and 40 had patient communications plans as a primary component, although many have since been released, which means a REMS is no longer required. This took place partly in response to lobbying two years ago from different groups, but also physicians, who complained that REMS requirements were often onerous and robbed them of valuable time. As of last spring, there were 86 REMS programs in existence.

However, 36 of the original 200 or so programs carried the more demanding Elements To Assure Safe Use requirement, which involves several additional steps, including training for healthcare providers who write prescriptions; certification for pharmacies; restrictions on where drugs can be dispensed or administered; patient monitoring and enrolling patients in registries.

The programs that carried the ETASU requirement were originally the most controversial aspect because these were seen as a kiss of death – any drug that demanded so much training and monitoring may be perceived as unnecessarily risky not only by prescribers, but also payers. And such a perception could tarnish the prospects for a new medicine, especially in a competitive therapeutic category.

Given that only three dozen drugs were approved with ETASU stipulations, that fear has not materialized to the degree that some had expressed at the outset of the REMS era, suggesting the agency has quietly found a way to acknowledge the issue. In fact, one industry watcher notes that the agency has noticeably required fewer REMS, in general, over the past couple of years.

"FDA is actually using them less and less frequently," says Mike McCaughan, founding member of the Prevision Policy consulting firm and editor of The RPM Report. "The risk that a new product would have a REMS peaked two years after the program started and really declined rapidly, because a lot of people in the healthcare system pushed back and didn't like it. There were concerns about barriers to access and FDA, itself, has concerns about what these programs are supposed to do."

Just the same, there is no indication, for the moment, that the REMS concept will be abandoned, even though some say the effort has lost its direction. Instead, there is a growing movement calling for using REMS programs to ease approvals for drugs for rare diseases or where there is a lack of therapies, but something less than the usual amount of necessary data. In such cases, a REMS could be used to advance approval and justify the sort of conditions found in ETASU requirements.

In fact, a September report on drug discovery, development and evaluation by the President's Council of Advisors on Science and Technology suggested a similar notion. One approach could be for FDA to implement a mechanism under which sponsors could choose to seek approval of new drug under a new designation called Special Medical Use, or SMU, according to the report.

Under this concept, a drug maker would "propose a development process to address the benefit-risk balance in a specific subpopulation at high risk from the disease, using the same standards for efficacy and safety as the existing approval pathways – traditional or accelerated – and demonstrate that clinical trials in the larger population of patients would require much longer to complete or would not be feasible. If sponsors decide to complete broader studies, they could broaden their market and approved indication by submitting additional evidence to FDA. The initial designation, however, would give them an early foothold in a market for a narrow population or indication," the report states.

Whether this approach or something like it will become reality remains to be seen, but the concept articulated in the White House paper underscores a growing concern with drug development, the overall drug approval process and the increased emphasis on providing therapies for unmet needs. By implementing a REMS program of some sort, the result would, ideally, provide some balance between an ongoing concern for safety and getting drugs – or at least drugs for certain ailments – to patients faster.

There is a political dimension to this approach, reflecting growing frustration in the pharmaceutical industry with the pace of drug approvals, even though FDA has displayed data showing approvals have been increasing over the past year or so. But many conservatives have been itching to find ways to hasten the process and frequently cite treatments for unmet needs as a starting point for debate.

At the same time, Mr. McCaughan notes that, thanks to the user fee imperative, there has been talk of a more standardized approach that would eventually develop into off-the-shelf REMS plan for many drugs. Meanwhile, a real-world experiment, of sorts, is starting to play out thanks to the recent approval of two prescription diet pills – **Qsymia**, which is sold by **Vivus**, and **Belviq**, which is sold by **Arena** Pharmaceuticals. However, only Qsymia has a REMS program.

The REMS was required because the pill can harm a fetus. The drug contains phentermine, which is the surviving half of the fen-phen weight-loss cocktail, and topiramate, the active ingredient in the **Topamax** seizure medicine, which generated concern over cardiovascular and teratogenic risks – specifically, cleft palates – and prompted the agency to reject the drug in 2010. And since Qsymia can increase heart rate, the effect on patients at high risk for heart attack or stroke is not known.

While industry lobbies and Congress contemplate, the dueling diet pills may provide a much-needed window into the extent to which a REMS program can make a difference not only in bolstering safety, but also in determining when a plan is truly useful. And drug makers can be expected to watch closely, because one company will be able to argue that REMS is a positive if payers will provide coverage, while the other may say REMS is a disadvantage with additional barriers to access.

This brings us back to the fundamental argument over the value of having the current REMS framework. One expert says REMS need not be an all-or-nothing proposition,

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CURRENTLY FDA-APPROVED INDIVIDUAL REMS WITH $600+ MILLION IN 2011 SALES

Product	Date REMS Approved	REMS Components (All REMS include timetable for assessment)	Primary Disease/ Medical Use	2011 Sales ($ in millions)	2011 Reporting Company
Actemra (tocilizumab) Injection	1/8/2011; modified 4/15/2011, 6/20/2012, 10/11/2012	Communication plan	Rheumatoid arthritis, systemic onset juvenile idiopathic arthritis	697	Roche and Chugai Pharmaceutical
Androgel (testosterone) Gel	9/18/2009; modified 3/10/2011, 11/30/2011	Medication guide	Hypogonadism	874	Abbott Laboratories
Androgel (testosterone) 1.62% Gel	4/29/2011; modified 9/7/2012	Medication guide	Hypogonadism	874	Abbott Laboratories
Aranesp (darbepoetin alfa) Injection	2/16/2010; modified 6/24/2011, 5/31/2012	Medication guide, communication plan, elements to assure safe use, implementation system	Anemia	2,303	Amgen
Chantix (varenicline) Tablets	10/19/2009; modified 4/22/2010, 7/22/2011	Medication guide	Smoking cessation	720	Pfizer
Epogen and Procrit (epoetin alfa) Injection	2/16/2010; modified 6/24/2011, 5/31/2012	Medication guide, communication plan, elements to assure safe use, implementation system	Anemia	3,663	Amgen (Epogen) and Johnson & Johnson (Procrit)
Forteo (teriparatide [rDNA origin]) Injection	7/22/2009; modified 3/13/2012	Medication guide, communication plan	Osteoporosis	950	Eli Lilly
Revlimid (lenalidomide) Capsules	8/3/2010; modified 5/9/2012	Medication guide, elements to assure safe use, implementation system	Multiple myeloma, myelodysplastic syndrome	3,208	Celgene
Soliris (eculizumab) Injection	6/4/2010; modified 9/23/2011	Medication guide, elements to assure safe use	Paroxysmal nocturnal hemoglobinuria, atypical hemolytic uremic syndrome	783	Alexion Pharmaceuticals
Stelara (ustekinumab) Injection	9/25/2009; modified 12/30/2009, 10/20/2010, 5/2/2012	Communication plan	Plaque psoriasis	738	Johnson & Johnson
Tasigna (nilotinib) Capsules	3/15/2010; modified 6/17/2010, 1/14/2011, 10/26/2011, 11/18/2011	Medication guide, communication plan	Chronic myeloid leukemia	716	Novartis
Tracleer (bosentan) Tablets	8/7/2009; modified 2/19/2010	Medication guide, elements to assure safe use, implementation system	Pulmonary arterial hypertension	1,718	Actelion
Truvada (emtricitabine and tenofovir disoproxil fumarate) Tablets	7/16/2012	Medication guide, elements to assure safe use	HIV infection	2,875	Gilead Sciences
Tysabri (natalizumab) Intravenous Injection	10/7/2011; modified 1/20/2012	Medication guide, elements to assure safe use, implementation system	Multiple sclerosis, Crohn's disease	1,511	Biogen Idec and Elan
Victoza (liraglutide) Injection	1/25/2010; modified 5/18/2011	Communication plan	Type 2 diabetes	1,119	Novo Nordisk
Zyprexa Relprevv (olanzapine) Extended-Release Injection	12/11/2009; modified 7/8/2010	Medication guide, communication plan, elements to assure safe use, implementation system	Schizophrenia	4,622	Eli Lilly

Note: Sales are for entire product line
Sources: Fda.gov and eKnowledgeBase.com

but urges FDA to rework the effort so that physicians are not burdened and that more useful information is gathered in order to determine whether additional post-marketing studies would be needed.

"Most of the post-marketing surveillance requested from FDA is in the form of clinical trials. But I think we should do more with registries, but they first need to be defined better and we also have to overcome concerns FDA has that these are suspect, because the agency believe these can be used as a marketing tool, which they can," says Uwe Tigor, executive VP and chief medical officer at Palio, an advertising agency that works with drug makers to develop REMS plans.

"Right now, all you're doing in a registry is tracking information and then compiling that, but there's no need to prove or disprove a final hypothesis. Coming out of a registry, you could have some hard evidence in a real-world setting that needs to be studied in a clinical trial.With experience of five years of REMS implementation, FDA has to look at what's worked and what's hasn't. And they need to show the pendulum can go both ways.

"If everybody gets a REMS, it's a problem, because it gives the impression every drug is unsafe. You know, if everybody's in the club, then nobody is," he continues. "It's been significantly overdone at the front end. The communication tools are so generic and regurgitate what's in the production information, so what's the production information for? And how well are we educating everyone? What I'm saying is we need a better designed post-marketing system." ■ MEDADNEWS

Opportunities abound

Patent expirations around the globe are impacting some of the CNS field's best-selling medicines as drug developers look to new uses for blockbuster brands as well as internal and external pipeline products to sustain and improve category growth.

By Andrew Humphreys andrew.humphreys@ubm.com

The central nervous system category is one of the industry's largest and fastest-growing therapeutic markets worldwide. High levels of unmet medical need exist throughout the CNS segment, creating many commercial opportunities for drug developers. On the other hand, CNS is considered one of the riskiest therapeutic groups in terms of clinical development. Meanwhile, some of the top brands have lost major-market exclusivity during 2011 and 2012. Some leading drugs also have been affected by rising pricing pressure from generics as well as safety issues.

CNS disorders/diseases include major depressive disorder, Alzheimer's disease, schizophrenia, bipolar disorder, multiple sclerosis, epilepsy, insomnia, Parkinson's disease, attention-deficit hyperactivity disorder, and migraine. Many of the leading pharma companies have a stake in the CNS arena in terms of marketed products and pipeline assets. Though some companies are moving away from R&D in this therapeutic field to concentrate on other disease areas with less development risks, they may pursue additional CNS product opportunities via external alliances.

Antipsychotic medicines represent the largest central nervous system drug class. According to IMS Health data, prescription antipsychotic products generated $18.2 billion in 2011 U.S. sales, which was a $2.1 billion increase versus 2010. There were 57 million prescriptions filled for antipsychotic drugs in the United States during 2011, up 2.4 percent year over year. Sixty percent of those filled scripts were for prescription medicines.

Besides antipsychotics, other CNS drugs produced significant growth during 2011. ADHD therapy sales in the United States improved 17 percent versus 2010 to $7.9 billion. MS treatments advanced 22.5 percent to $7.1 billion compared to 2010 U.S. sales. Antidepressant sales fell 5.8 percent to $11 billion in 2011, though they represented the most prescribed class of drugs among all therapeutic categories in 2011 with 264 million prescriptions filled according to IMS Health data.

The global antidepressant market is dominated by selective serotonin re-uptake inhibitors and serotonin norepinephrine re-uptake inhibitors. With rising payer pressure and the necessity to show clear value, new medicines must either demonstrate superior efficacy versus existing treatments or clear efficacy in well-defined patient segments, such as treatment-resistant depression.

Due to an increase in patients taking antidepressants and antipsychotics as well as a rise in generic competition for CNS therapeutics in 2013, the necessity is growing for new drugs with novel mechanisms of actions and molecular targets. A strong and vast market exists to support such development – despite the clinical and safety risks publicized in recent years – as shown by the growth of CNS drug sales and prescriptions dispensed.

CNS product sales leaders: antipsychotics

The top four selling CNS medicines during 2011 were psychotherapeutic agents, accounting for about $20 billion in worldwide sales during that year. Leading the way was **AstraZeneca** Plc.'s **Seroquel**. Seroquel IR is approved for treating adult schizophrenia and bipolar disorder, and in the United States the drug is additionally approved for treating acute manic episodes in bipolar disorder in children and adolescents ages 10 to 17 years, and for schizophrenia in adolescents 13 to 17 years old.

Seroquel XR has been approved in at least 76 countries for schizophrenia, 66 countries for bipolar mania, 55 countries for bipolar depression, 41 countries for bipolar maintenance, 42 countries for major depressive disorder, and six countries for generalized anxiety disorder. Seroquel XR was granted EU clearance as an add-on treatment for major depressive episodes in patients with major depressive disorder.

The Seroquel franchise generated worldwide sales of $5.83 billion in 2011 for AstraZeneca (astrazeneca.com). Tokyo-based **Astellas** Pharma Inc. reported Seroquel sales of ¥27.8 billion ($337 million) for the fiscal year ended March 31, 2012.

AstraZeneca's Seroquel sales totaled $2.33 billion during the first nine months of 2012 compared to $4.28 billion in the corresponding one-year-earlier period. The year-over-year sales plummet was due to the U.S. loss of exclusivity for Seroquel IR during March 2012, with sales dropping from $3.19 billion during January-September 2011 to $1.2 billion for the first three quarters of 2012. Seroquel XR sales, on the other hand, improved from $1.09 billion to $1.13 billion during the same time frame.

The No. 2 CNS drug in 2011 was **Abilify**, approved for treating schizophrenia, bipolar mania disorder, and major depressive disorder. Marketed by **Bristol-Myers Squibb** Co. and **Otsuka** Pharmaceutical Co. (otsuka.co.jp), global 2011 sales of Abilify were in the $5 billion territory. Bristol-Myers Squibb (bms.com) reported January-September 2012 Abilify sales of $2.01 billion, down 1 percent compared to the first three quarters of 2011.

Zyprexa was the third best selling CNS medicine of 2011, with worldwide sales of $4.62 billion. Initially approved by FDA in September 1996, Zyprexa is marketed for treating schizophrenia, acute mixed or manic episodes associated with bipolar I disorder, and bipolar maintenance. The product generated more than $4 billion in annual sales from 2003 through 2009. In 2010, Zyprexa produced peak-year sales of $5.03 billion for **Eli Lilly** and Co. The 8 percent drop-off in global sales from 2010 to 2011 was mainly attributed to the drug's loss of exclusivity in certain major markets. In the first nine months of 2012, worldwide sales continued to decline, down 66 percent to $1.32 billion.

Lilly (lilly.com) also markets **Cymbalta**, which was the No. 4 CNS product in 2011. The company reported sales of $4.16 billion for the drug. **Shionogi** & Co. of Osaka, Japan, reported ¥6.6 billion ($80 million) for Cymbalta during the fiscal annual period ended March 31, 2012. Lilly and Shionogi jointly market the medicine in Japan. During 2012, Cymbalta surpassed Zyprexa as Lilly's best-selling product. For the first nine months of 2012, Cymbalta sales for Lilly increased 20 percent year over year to $3.57 billion.

Alzheimer's disease

On a global scale, 35.6 million people have dementia and the figure is projected to exceed 115 million by 2050. Alzheimer's disease is the most common cause of dementia and is the No. 6 cause of death in the United States. The best-selling drugs in this disease category are **Aricept**, **Namenda**, and **Exelon**.

Aricept is the most commonly dispensed medicine to treat Alzheimer's disease symptoms. Discovered and developed by Tokyo-based **Eisai** Co., the product is jointly promoted with **Pfizer** Inc. in the United States and several other countries. Pfizer has an exclusive license to sell Aricept in certain other countries.

Aricept generated global sales of more than $2 billion during 2011 between Eisai and Pfizer. For the fiscal year ended March 31, 2012, Eisai reported Aricept sales of ¥147.1 billion ($1.78 billion). Pfizer's alliance revenue for Aricept totaled $450 million during 2011 and $249 million for January-September 2012.

Namenda is marketed by **Forest** Laboratories Inc. for treating moderate and severe Alzheimer's disease. The Namenda franchise generated sales of $1.4 billion for the company's fiscal year ended March 31, 2012 (fiscal 2012). Forest reported Namenda sales of $736 million during the six-month period ended Sept. 30, 2012, up about 12.1 percent versus the company's first two quarters of fiscal 2012. As of mid-October 2012, Forest anticipated Namenda's fiscal 2013 sales will grow 11 percent compared to the previous fiscal term (versus a previous guidance announced during April 2012 of a 17 percent year-over-year improvement). Company managers say new initiatives to improve dementia care in nursing homes, while primarily directed toward cutting down on antipsychotic use, appear to have reduced demand for Alzheimer's medications. Namenda sales for full-year fiscal 2013 are projected to decrease by $85 million.

Available since 1997, Exelon capsules are marketed in 90-plus countries for mild-to-moderate Alzheimer's disease dementia. Exelon was initially approved in April 2000 by FDA as a capsule and oral solution for treating mild-to-moderate dementia of the Alzheimer's type. Exelon Patch, the first transdermal therapy for Alzheimer's disease, was approved in 2007. **Novartis** (novartis.com) announced in September 2012 that FDA approved a higher dose of Exelon Patch for treating mild-to-moderate Alzheimer's disease. The Exelon family produced 2011 sales of $1.07 billion. Sales for the first nine months of 2012 reached $784 million, down 2 percent year over year.

The potential of the Alzheimer's disease market is enormous, and industry observers believe that a drug that can reduce memory loss could generate yearly sales of $5 billion.

The beta amyloid inhibitor **bapineuzumab** is being developed as a subcutaneous formulation for treating mild-to-moderate Alzheimer's disease. Phase III clinical trials of an intravenous formulation of the drug were halted during 2012. The co-primary clinical endpoints – change in cognitive and functional performance compared to placebo – were not met in the Phase III study of intravenous bapineuzumab in patients with mild-to-moderate Alzheimer's who do not carry the ApoE4 genotype.

Before the Phase III program was discontinued, some industry analysts had heralded bapineuzumab as a potential multi-billion peak-year sales generator. Bapineuzumab I.V. was developed by a collaborative effort between Pfizer (pfizer.com) and the **Johnson & Johnson** company Janssen Alzheimer Immunotherapy R&D LLC.

Solanezumab is another highly touted potential blockbuster for Alzheimer's disease that has produced varying degrees of clinical-result success. In October 2012, Lilly revealed detailed results showing primary endpoints – cognitive and functional – were not met in either of two Phase III, double-blind, placebo-controlled trials in patients with mild-to-moderate Alzheimer's disease. Lilly says the next steps for solanezumab's clinical development will be determined after discussions with FDA.

In more positive news, **TTP488** has demonstrated some promise for disease modification in Alzheimer's patients. The novel, orally administered drug has shown clinical evidence of slowing of cognitive decline during 18 months of therapy in patients with mild-to-moderate Alzheimer's disease, according to data revealed in October 2012. The small-molecule drug is the first to demonstrate clinical benefit from research on the receptor for advanced glycation end products, which is a new biochemical target in Alzheimer's disease treatment. High Point, N.C.-based **TransTech** Pharma Inc. discovered, developed, and owns all rights to TTP488.

Multiple sclerosis

Multiple sclerosis is a chronic inflammatory disease of the central nervous system that destroys and scars the sheaths covering nerves. About 2 million people around the globe suffer from multiple sclerosis.

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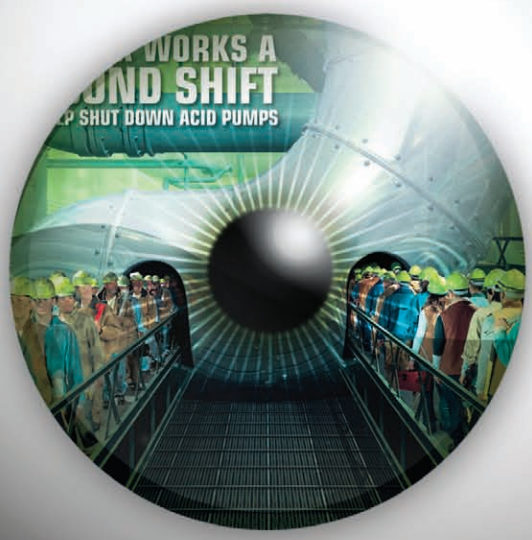
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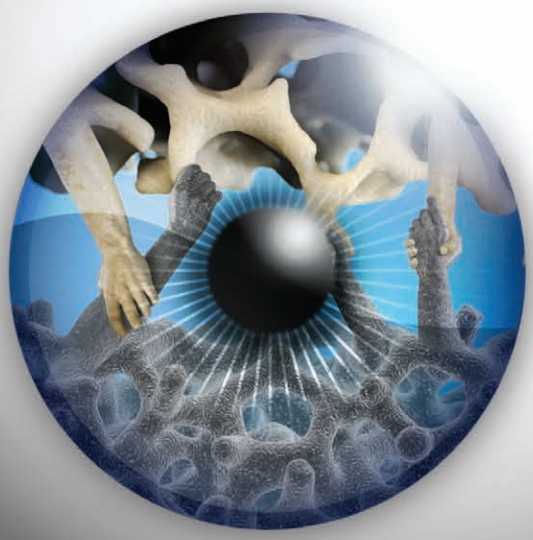
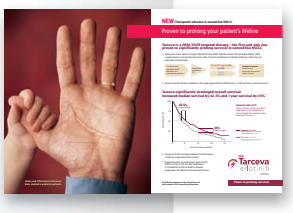
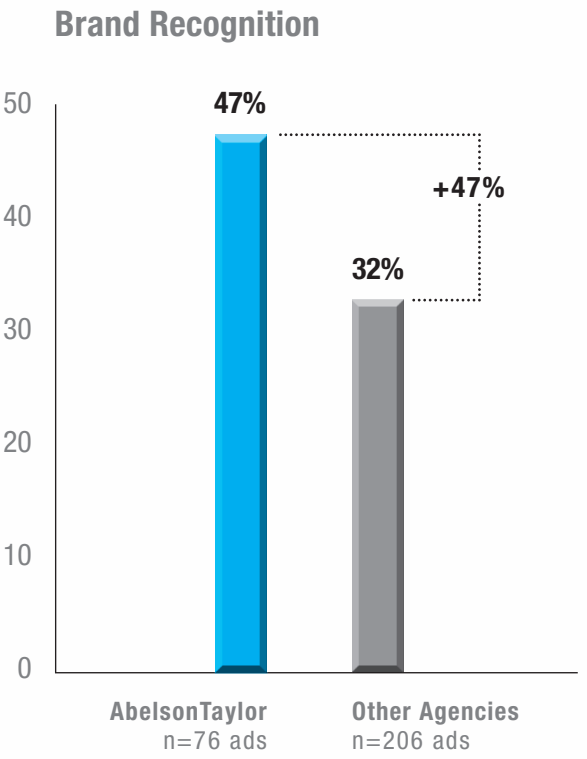


Branding more doctors recall seeing.





Can one agency's communications provide a proven advantage over another's? That's the question Kantar Health investigated with regard to product recognition. And the results were eye-popping. Physicians could identify AbelsonTaylor's brands 47% more than those of other agencies—giving those products a recognizable advantage in the market. To get a glimpse of your brand's potential and see what we can do for you, call Dale Taylor at 312.894.5657 or visit abelsontaylor.com.

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Copaxone is the leading MS therapy in the United States and worldwide. **Teva** Pharmaceutical Industries Ltd. reported Copaxone sales of $3.57 billion for 2011 and $2.94 billion during the first nine months of 2012. **Sanofi** reported Copaxone sales of €436 million ($607 million) for 2011. The French pharma giant transferred Copaxone sales to Teva (teva.com) during first-quarter 2012. The drug is predicted to produce 2012 global sales of about $4 billion.

Gilenya represents the first in a new class of multiple sclerosis compounds known as sphingosine 1-phosphate receptor modulators. The drug is the first approved oral disease-modifying treatment for multiple sclerosis in the United States. Gilenya has been cleared for marketing in 60-plus countries, including the United States, the European Union, and Japan. The compound is licensed by Novartis from **Mitsubishi Tanabe** Pharma Corp. Gilenya generated sales of $316 million in third-quarter 2012 and $846 million during the first nine months of the year.

Dimethyl fumarate/BG-12 represents a promising MS treatment. The **Biogen Idec** Inc. immunomodulator is awaiting approval in the United States, European Union, Australia, Canada, and Switzerland for treating relapsing-remitting multiple sclerosis. Dimethyl fumarate is the only known investigational compound for treating RRMS that has experimentally shown activation of the Nrf-2 pathway.

In October 2012, Biogen Idec (biogen-idec.com) announced that FDA extended the initial PDUFA date for its review of the new drug application for dimethyl fumarate. The three-month extension – a standard extension time line – was needed to allow extra time for review of the application.

In a June 2012 report, EvaluatePharma cited BG-12 as the second most valuable R&D project in the industry with a net present value of $9.08 billion. Those analysts projected global 2018 sales of $3.4 billion for the drug.

Teva is developing **laquinimod**, a novel pill option for MS. The drug has been heralded as a future blockbuster brand, but delayed clinical-development progression and the buzz created by the anticipated rival BG-12 have tempered some industry-observer expectations. During 2011, despite results from a Phase III clinical study in which laquinimod failed to meet its primary endpoint – achieving it only after a statistical correction – Teva reportedly said it could file a new drug application and start marketing the product in late 2012 or early 2013. That time line has been pushed back, though, as the drug continues to undergo Phase III development as of October 2012.

Teva and **Active Biotech** AB are jointly developing and commercializing the drug. Laquinimod is also undergoing Phase II trials for Crohn's disease and lupus. ■ MEDADNEWS

TOP-SELLING CNS PRESCRIPTION MEDICINES OF 2011

Medicine	2011 sales ($ in millions)	2010 sales ($ in millions)	2009 sales ($ in millions)	2012 first nine-month sales ($ in millions)	2011 reporting company	Primary disease/medical use	First approval date/launch date
Seroquel	6,165	5,622	5,152	2,579 (estimate)	AstraZeneca and Astellas Pharma	Major depressive disorder, bipolar disorder, schizophrenia	U.S. approval: Sept. 27, 1997 U.S. launch: October 1997
Abilify	4,991	4,761	4,541	3,656 (estimate)	Bristol-Myers Squibb and Otsuka Pharmaceutical	Major depressive disorder, bipolar disorder, schizophrenia, autistic disorder	U.S. approval: Nov. 15, 2002
Zyprexa	4,622	5,026	4,916	1,317	Eli Lilly	Bipolar disorder, schizophrenia	EU approval: Sept. 27, 1996 EU launch: Sept. 30, 1996 U.S. launch: Oct. 1, 1996
Cymbalta	4,241	3,514	3,075	3,660 (estimate)	Eli Lilly and Shionogi	Major depressive disorder, generalized anxiety disorder, diabetic neuropathic pain, fibromyalgia, chronic musculoskeletal pain	U.S. approval and launch: August 2004 Japan launch: April 2010
Copaxone	4,177	3,673	3,201	2,970	Teva Pharmaceutical Industries and Sanofi	Multiple sclerosis	U.S.approval: Dec. 20, 1996 U.S. launch: April 1997
Lyrica *Note: Eisai reports Lyrica co-promotion income.*	3,693	3,063	2,840	3,026	Pfizer	Neuropathic pain, partial-onset seizures, postherpetic neuralgia, fibromyalgia	EU approval: July 6, 2004 U.S. approval: Dec. 30, 2004 U.S. launch: Sept. 21, 2005 Japan launch: June 22, 2010
Lexapro/Cipralex	3,244	3,401	3,264	982 (estimate)	Forest Laboratories and H. Lundbeck	Major depressive disorder, generalized anxiety disorder	Lexapro U.S. approval: Aug. 14, 2002 Lexapro U.S. launch: Sept. 5, 2002 Cipralex approval: 2002
Avonex	2,687	2,518	2,323	2,160	Biogen Idec	Multiple sclerosis	U.S. launch: May 17, 1996 U.S. launch: May 1996
Rebif	2,356	2,324	2,141	1,926 (estimate)	Merck KGaA	Multiple sclerosis	Canada launch: February 1998 U.S. approval: March 7, 2002 U.S. launch: March 11 2002
Aricept	2,234	3,975	4,350	1,221 (estimate)	Eisai and Pfizer	Alzheimer's disease	U.S. approval: Nov. 25, 1996 U.S. launch: January 1997
Risperdal Consta	1,583	1,500	1,425	1,067	Johnson & Johnson	Schizophrenia, bipolar disorder	U.S. approval: Oct. 29, 2003 U.S. launch: December 2003
Betaseron/ Betaferon	1,556	1,680	1,691	1,236	Bayer	Multiple sclerosis	Betaseron U.S. approval: July 23, 1993 Betaseron U.S. launch: 1993 Betaferon EU approval: Nov. 30, 1995
Tysabri	1,511	1,230	1,059	1,198	Biogen Idec and Elan	Multiple sclerosis	U.S. approval: Nov. 23, 2004 Original U.S. launch: Nov. 29, 2004 U.S. and EU relaunch: July 2006
Keppra/E Keppra	1,489	1,322	1,272	982 (estimate)	UCB, GlaxoSmithKline, Otsuka Pharmaceutical	Partial-onset seizures	Keppra U.S. approval: Nov. 30, 1999 Keppra U.S. launch: April 2000 E Keppra Japan approval: July 2010
Namenda	1,400	1,267	1,115	1,104 (estimate)	Forest Laboratories	Alzheimer's disease	U.S. approval: Oct. 16, 2003 U.S. launch: January 2004
Provigil	1,179	1,124	1,025	392	Cephalon and Teva Pharmaceutical Industries	Sleepiness	U.S. approval: Dec. 24, 1998 U.S. launch: Feb. 15, 1999
Ambien/Stilnox/ Myslee	1,110	1,538	1,569	825 (estimate)	Sanofi and Astellas Pharma	Insomnia	Stilnox EU launch: Feb. 15, 1988 Ambien U.S. approval: Dec. 16, 1992 Myslee Japan launch: Dec. 13, 2000
Exelon and Exelon Patch	1,067	1,003	954	784	Novartis	Alzheimer's disease, Parkinson's disease	Exelon Sweden approval: 1997 Exelon U.S. approval: April 21, 2000 Exelon U.S. launch: June 21, 2000 Exelon Patch U.S. approval: July 6, 2007
Geodon/Zeldox	1,022	1,027	1,002	322	Pfizer	Schizophrenia, bipolar disorder	Geodon U.S. approval: Feb. 5, 2001 Geodon U.S. launch: March 2001 Zeldox EU launch: May 2002

Sources: eKnowledgeBase.com and industry reports

Notes: This chart presents the top-selling CNS medicines in order by their full-year 2011 sales. Certain products are represented by more than one company due to joint-marketing or joint-promotion accords. Joint-promotion profit or royalty revenue is not included in product sales totals.

* 2012 sales represent the first nine months of the year; some figures are actual and others are estimates based on data available as this magazine edition went to press.

*All foreign product sales are reported in U.S. dollars using Federal Reserve or company-provided exchange rates. 2011 exchange rates were used to translate all figures.

*First approval date or launch date = anywhere worldwide; in some instances, the first approval or launch date and region of occurrence are provided.

*All Japanese company 2011 product sales are for the fiscal year ended March 31, 2012 (2010 = year ended March 31, 2011; 2009 = year ended March 31, 2010).

*Forest Laboratories 2011 product sales are for the fiscal year ended March 31, 2012 (2010 = year ended March 31, 2011; 2009 = year ended March 31, 2010).

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A framework for healthcare reform risk assessment

By Will Suvari and Lujing Wang

While politicians debate about how best to address U.S. healthcare challenges, reform efforts are under way and will not be stopped. Suppliers of pharmaceutical products are going to have to adapt to the new market realities in order to succeed. Company leaders need to get under the hood of their organization and assess every facet of their business to truly understand where they are most vulnerable to risk. Though a complete assessment of how healthcare reform will affect operations must go much deeper, thinking about risk across three domains – portfolio risk, market risk, and implementation risk – can provide a basic framework for approaching the analysis.

Most pharmaceutical suppliers have adopted a wait-and-see posture with respect to the potential impacts of reform on their development investments, their markets, and ultimately their business models. However, the time for waiting is over. While the direct effects of reform as dictated by the Patient Protection and Affordable Care Act (PPACA) are relatively minor, the indirect consequences of PPACA-driven reform on insurers and providers will have far-reaching consequences for drug manufacturers.

Healthcare reform has already gained too much momentum to be completely reversed, regardless of how politics plays into the implementation of PPACA provisions. Change one way or another is largely inevitable. The degree to which leaders in life sciences choose to prepare and plan to adapt to reform will have just as significant an impact on top and bottom line growth tomorrow as product mix, strategy, and execution ability do today.

Portfolio risk

Portfolio risk assessment considers the ways in which a company's range of products may be particularly exposed to reform and whether, as a whole, the portfolio is either biased for or against certain reform-sensitive therapeutic areas. The analysis is important to determine adjustments the company may need to make for its in-line brands and to prioritize R&D and development costs for the future.

Diagnosing portfolio risk assesses at-risk revenue, potential shifts in patient populations, pricing and market access pressures, evolving evidence requirements, and competitive overlap. Diagnosing at-risk revenue could measure the number of on-market and development projects a company has in its portfolio by therapeutic area as well as indication diversity within a particular therapeutic area.

As healthcare reform brings insurance coverage to the uninsured and underinsured, new people are introduced into the risk pool. A company's ability to benefit from this infusion of insured patients depends on the therapeutic areas covered by the portfolio. While companies need to balance revenue risk against the population shift and change in quality of coverage, payers will be doing the same calculations. As a result, there is likely to be pricing and market access pressure in certain therapeutic areas and not others.

Companies must measure how well competing companies are positioned against healthcare reform risks. A good reform diagnostic will measure therapeutic area/indication overlap, generic efficiency in target therapeutic areas, and post-reform pricing and market access advantage.

Market risk

Inevitably, the changes that will come from healthcare reform will pass market risk on to manufacturers in some fashion. The winners will be those who first figure out how to take on some of the risk in a fair and sustainable way.

The impact of healthcare reform will vary widely across geographic markets. PPACA mandates the creation of state exchange markets where individuals with incomes between 100% and 400% of the federal poverty level can purchase insurance at federally subsidized rates. Companies will need to consider how they are going to operate on state exchanges and how they are going to get covered on exchange-related insurance offerings.

Meanwhile, a redesign of payment structures and service delivery models between payers and providers that shifts the management of both clinical and financial risk from payers toward providers will drive further consolidation among providers toward existing integrated delivery networks. A number of accountable care organization pilots are also already under way and proving viable alternatives to traditional fee-for-service models.

For pharmaceutical companies, this means being aware of the local markets around the country where these trends are under way or are likely to occur. These changes can take place suddenly, so it is necessary to understand how they happen or where organizations are in the process of change in individual markets.

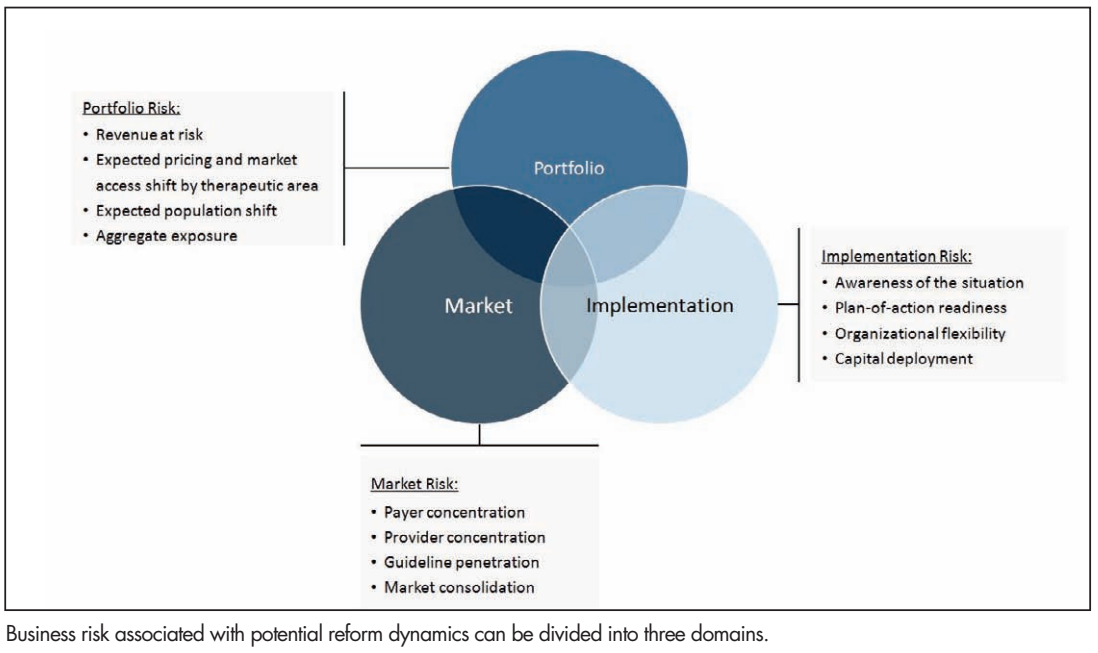
Implementation risk

Implementation risk is a function of a pharmaceutical company's nimbleness in reacting to the effects of healthcare reform. This includes how well informed the company's people are generally about reform and how prepared they are to adjust for the changing market dynamics.

Currently, public awareness of the implications of healthcare reform is extremely low. To assess the awareness of personnel, the first thing a company needs to do is to get a sense of the organization's understanding of how reform will impact their customer base. The company needs to measure the degree to which functional groups and individuals understand reform dynamics, customer implications, and the potential impact on long-range planning.

When something does happen in the local market, a company must be prepared to pivot on a dime and change the organization to better react to a more reform-oriented market. Local market dynamics may require significant changes to market-facing resources, and existing/legacy reporting structures may not allow for rapid adaptation.

Finally, most capital and budget structures are built to reflect existing market dynamics, and organizational decision-making processes limit redeployment agility. Many drug companies have considerable capital tied up in R&D that could be reallocated against engaging with accountable care organizations, payers, or integrated delivery networks. Before they get to the point of having to react, companies need to identify places from which money could be diverted to effect necessary changes in terms of human capital, marketing expenses, or contracting costs.



Business risk associated with potential reform dynamics can be divided into three domains.

Editor's note: This article is an excerpt from the Campbell Alliance white paper, "Reform Readiness Toolkit: Diagnostic Tools to Assess Healthcare Reform Risk." Will Suvari is VP, Pricing and Market Access, Campbell Alliance. He can be reached at wsuvari@campbellalliance.com. Lujing Wang is Managing Director, Commercial Center of Excellence, Pricing and Market Access, Campbell Alliance. He can be reached at lwang@campbellalliance.com.

FACTS & FIGURES

One in four U.S. healthcare executives say that government mandates are the biggest barriers to achieving sustainable cost reductions in their organizations, according to a study by HealthLeaders Media. **Almost 90 percent** say their organizations lack the clinical and financial data necessary to identify opportunities for cost savings.

According to HealthLeaders analysts, government mandates were the number-one obstacle in cost containment efforts (cited by **27 percent**), followed by physician-hospital relationships (**19 percent**), and unsupportive organizational cultures (**15 percent**).

For those executives who have been able to implement successful cost containment initiatives, purchasing (**32 percent**) and labor efficiencies (**21 percent**) were mentioned most frequently as providing the highest dollar-value reductions.

Other study findings include that **89 percent** of healthcare leaders lack the integrated clinical and financial data they need to target cost savings; **four in 10** healthcare leaders say they still need to cut **6 percent or more** from their annual operating budgets; continuous improvement techniques (**68 percent**) are the most popular tools that executives use to foster cost containment initiatives; and IT is the biggest area of non-clinical FTE growth, with **32 percent** of healthcare leaders expecting to add to their IT staff.

Physicians move to a new location, retire, or pass away at an average rate of **14 percent** per year, according to a five-year study by SK&A, A Cegedim Company. The ongoing study reveals the turnover rate of office-based physicians in the company's OneKey, Powered by SK&A database of healthcare providers. The latest results show the move rate for 2012 to be **12.1 percent**, up slightly from **11.8 percent** in 2011.

The move-rate report also tracks physicians who make professional changes, including a redefinition of practice specialty or change in employment status. In the five years since SK&A began the study, the annual change rate has fallen from a high of **18.2 percent**. The continuous decline indicates stability of employment among medical workers who, like professionals in other sectors, are unwilling or unable to make changes against the backdrop of a weakened economy.

Move rates were more pronounced for specialists than for primary care doctors. Specialists such as hematologists (**20.4 percent**), oncologists (**15.6 percent**), and emergency medicine specialists (**14.4 percent**) were more likely to move than primary care physicians (**11.9 percent**), a group that includes family practitioners, general practitioners, internists, and pediatricians.

"The move-rate results from SK&A underscore the importance of monitoring the status of your target physicians and acknowledging that professional profiles change often," says Dave Escalante, senior VP OneKey and Marketing. "If left unchecked for a period of two years, your customer master database could age by nearly **25 percent**, contributing significantly to campaign waste."

Sources: HealthLeaders Media (healthleadersmedia.com), SK&A (skainfo.com).

MOST-RECOGNIZED BRANDS

ONCOLOGY AND HEMATOLOGY

The most-recognized oncology and hematology brand in North America is **Procrit**. The brand was most recognized by 3.8 percent of physicians in a survey conducted by **Brand Institute** Inc. during second-quarter 2012. Procrit, comprising epoetin alfa, is marketed by Janssen Biotech Inc., a subsidiary of **Johnson & Johnson** (jnj.com). The product was first approved by FDA in December 1990 for a variety of anemia and renal failure indications and received an additional approval in June 2004 for the treatment of anemia associated with cancer chemotherapy.

Taxol and **Avastin** are the second most-recognized oncology and hematology brands in North America. About 3.5 percent of physicians recognize these brands the most. Taxol, comprising paclitaxel, is marketed by **Bristol-Myers Squibb** (bms.com). The drug was first approved by FDA in December of 1992 for treatment of ovarian cancer that had not responded to standard chemotherapy, and subsequently received indications for breast cancer, non-small cell lung cancer, and AIDS-related Kaposi sarcoma. Avastin, comprising bevacizumab, is marketed by Genentech, a subsidiary of **Roche** (roche.com). The drug was first approved by FDA in February of 2004 in combination with intravenous 5-fluorouracil-based chemotherapy for the first-line treatment of patients with metastatic carcinoma of the colon or rectum, and has since received several additional cancer-related indications.

The most-recognized oncology and hematology brand in Europe is Avastin. The brand was most-recognized by 3.3 percent of surveyed physicians.

The second most-recognized oncology and hematology brands in Europe are **Herceptin** and **Glivec**. About 2 percent of physicians recognize these brands the most. Herceptin, comprising trastuzumab, is marketed by Roche. The drug was first approved by the European Commission in August 2000 to treat HER2-positive metastatic breast tumors, and has since received several additional breast and gastric cancer indications. Glivec, comprising imatinib, is marketed by **Novartis** (novartis.com). The drug was first approved by the EC in November 2001 for the treatment of adult patients with Philadelphia chromosome positive chronic myeloid leukemia in chronic phase after failure of interferon-alpha therapy, or in accelerated phase or blast crisis, and has since added additional leukemia indications as well as others in gastrointestinal cancer, gastrointestinal stromal tumors, and dermatofibrosarcoma protuberans.

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

Congress floats a draft for the supply chain

By Ed Silverman

Here is a trick question for those who enjoy watching the doings on Capitol Hill – when is a bill not a bill? The answer is … when it is a discussion draft. But that is what the U.S. Senate Health, Education, Labor and Pensions Committee issued Oct. 24 in a bid to develop what it calls a "consensus policy" on shoring up the pharmaceutical supply chain.

The move was motivated by ongoing disagreement over the steps needed to create a system that can somehow thwart distribution of counterfeit or adulterated medications. As we have reported previously, a key problem has been a long-standing lack of agreement among the many players – drugmakers, wholesalers, and pharmacies – about a suitable approach.

In fact, conflicting efforts prevented a so-called track-and-trace provision for medications from being included in the FDA Safety and Innovation Act that was passed by Congress earlier this year. Track and trace, you may recall, refers to a proposed method of following medications through the supply chain.

The effort is designed to implement a uniform system that would allow each player to follow each shipment in the supply chain, but this requires an investment to purchase equipment, such as scanners for warehouses, trucks, and pharmacies to read bar codes placed on every bottle in each lot that is shipped.

More than 30 states have passed laws requiring so-called pedigrees, a reference to steps taken to prove proper possession of medicines along the supply chain. Only California, though, has passed a law that requires a universal standard for track-and trace technology at the unit level. But a national system is lacking and since the California law goes into effect in 2015, drugmakers, wholesalers, and others fear that other states may follow suit in the interim, creating an unwieldy patchwork of regulations across the country that would increase costs. And Congress worries such a development would not improve oversight and safety.

Which brings us to the draft discussion, which is lengthy and filled with various technical possibilities for inching the parties closer to agreement. For instance, the document proposes creating a form of FDA licensure for wholesalers, as well as third-party logistics providers, which do not take ownership of products, but facilitate shipments.

What else? Drugmakers would have to serialize nearly all medicines; serial numbers and National Distribution Codes would be encoded; and drugmakers and repackagers would be required to create a database of all serial numbers they produce. There is also a definition of transaction history and reference to a transaction statement that each seller must provide each buyer along the chain.

And as Dirk Rogers of RxTrace consulting notes, FDA would be required to conduct at least one pilot program of a full unit-level track-and-trace system with the industry. Afterwards, FDA may propose a system to replace the initial transaction history, which is another way of saying pedigree.

"My impression is that this is a very interesting approach that attempts to blend the desires of all parties," he writes us. "It is, effectively, a phased approach because the initial lot-level requirements have some similarities with the PDSA's RxTEC proposal, but it eventually gets replaced with a more complete unit-level serialization-based track and trace system."

He is referring to a proposal made earlier this year by the Pharmaceutical Distribution Security Alliance, a coalition of drugmakers, wholesalers, and pharmacies, that lacked a mandate for a unit-level tracking system. This put the group at odds with others in the industry, including drugmakers, wholesalers and pharmacies.

"In general, it establishes an interim national system that would result in tracking of drugs at the lot-level. It also lays out a potential path to a permanent unit-level tracking system. And it establishes a framework that would ensure uniform licensure standards for pharmaceutical wholesalers," says Allan Coukell, a pharmacist and director of the medical programs at the Pew Health Group.

"It represents a great deal of work that has gone into clarifying definitions and important concepts. It also lays out a wide range of potential implementation timelines and dozens of policy choices that will have to be made in order to move forward. The question is will the various stakeholders commit to that second phase. That's really essential for patient safety."

Depression rising, gastro falling

A pair of analyses by the business intelligence provider GBI Research are projecting improvement in the market for antidepressants while prices are expected to drop for drugs to treat gastrointestinal disorders as patents run out.

Further research into the disease etiology of a number of mental health disorders would open up considerable scope for improvement in the development of antidepressants, according to the first report. GBI analysts project that the global market for major depressive disorder, obsessive-compulsive disorder, generalized anxiety disorder, and panic disorder, estimated at $11.9 billion in 2011, is forecast to generate $13.4 billion in sales by 2018.

According to the GBI report, some of the weaknesses of the popular SSRI and SNRI classes may offer companies opportunities for innovation. Many patients fail to respond adequately to these classes, while a significant number of patients also discontinue therapy due to unwanted side effects. Latency is also a factor in drug compliance, as the positive effects of antidepressants may only be seen after around six weeks, leading to more instances of treatment discontinuance due to frustration and lost confidence in the drug. Without breakthroughs in scientific understanding, development activity in this therapeutic area will be restricted. However, this does leave considerable scope for improvement over current treatment options if understanding of the disease etiology improves.

Drugs to treat gastrointestinal disorders, on the other hand, are facing more difficult times over the next few years. The expiration of patent protection for products like Aciphex and Nexium is expected to generate a decline in the annual cost of treatment, from $291 in 2011 to $261 in 2018, at a negative compound annual growth rate of 1.5 percent, although the launch of novel biologics will stabilize this drop.

The gastro market, though, is projected to experience steady growth from 2015 onwards due to the anticipated entry of innovative new drugs. According to GBI analysts, about 269 clinical trials are ongoing in the gastrointestinal disorders therapeutics market, with the main focus being on Crohn's disease and UC. 42 percent of all ongoing clinical trials are in Phase II and 22 percent are in the late stages (Phase III and NDA-filed). This robust pipeline increases the chance of getting new drugs to market and may represent better treatment options with fewer side effects.

Interactive&DigitalMarketing

By *Med Ad News staff*

Patients and understanding: Commitment to the patient perspective

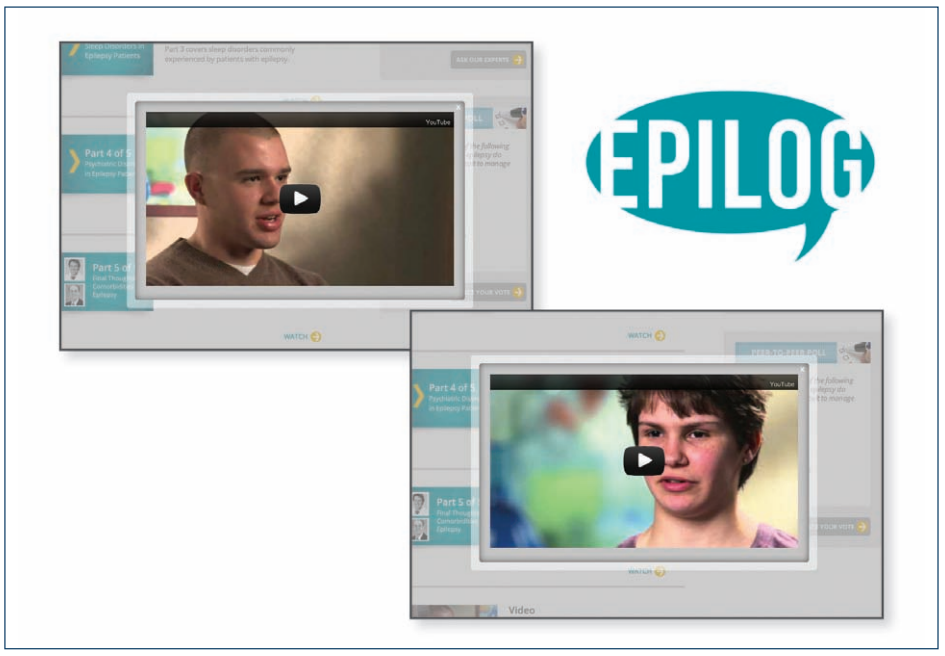
By Patrick O'Shea

Samantha is a 17-year-old college student living with epilepsy. Like many who live with epilepsy, Samantha also lives with comorbid conditions – hers are ADHD and anxiety/depression. Despite the complexity of treating epilepsy, neurologists, who also treat many other central nervous system disorders, often do not have enough time to keep up with the latest published literature about the disease and its many complications. This can affect the length and content of the physician/patient dialogue in terms of addressing these underlying issues, which may directly or indirectly impact subsequent treatment decisions and approaches. **Upsher-Smith** Laboratories Inc. recognized this as an opportunity to partner with and support the treating community.

Upsher-Smith is a privately held pharmaceutical company with a mission of improving lives through innovative products. Their portfolio has historically included products in women's health, dermatology, and cardiology. More recently, however, the company has pursued product development opportunities in the CNS arena for disorders such as epilepsy, Parkinson's disease, and Alzheimer's.

The challenge was how to position Upsher-Smith, a company with limited to no prior association with the CNS community, in a way that would provide a meaningful and impactful partnership with physicians to help them understand the critical questions that can lead to better treatment decisions.

At the 2011 American Epilepsy Association convention, Upsher-Smith initiated its position as an industry partner among epileptologists and neurologists when it launched Epilog.us, a peer-based, unbranded online community to help neurologists and allied health practitioners better understand and treat epilepsy. The site, driven by some of the nation's leading academic and clinical epileptologists, has been a useful springboard for bringing the patient perspective to the fore.



Upsher-Smith's patient video testimonials, focusing on multiple comorbid conditions affecting epilepsy patients, were developed to help the neurology community gain a deeper understanding of questions that can elicit responses leading to better epilepsy treatment options.

Epilepsy is a complicated neurological disorder with no definitive treatment formula. The fact is, the success or failure of a given epilepsy treatment can be greatly impacted by the questions neurologists ask during a patient's appointment. It also depends upon the information patients recall and share with their physician. In short, many critical questions aren't always asked, and information is not always proffered, creating the potential for a critical gap in the treatment continuum.

To help bridge this gap, Upsher-Smith brought this important issue to light by partnering with people living with epilepsy and creating a series of patient video testimonials. Because as many as 84 percent of epilepsy patients have at least one comorbid condition, the video series focuses on multiple comorbid conditions affecting epilepsy patients. These videos supplement a five-part Epilog video series on Epilepsy and Comorbidities in Practice, featuring two of Upsher-Smith's educational consultants: Dr. John Stern, co-director of the Seizure Disorder Center at the Geffen School of Medicine at UCLA, and Dr. Christopher Skidmore, director of neurology residency at Jefferson Medical College of Thomas Jefferson University.

Through its relationship with the Epilepsy Foundation of Minnesota, Upsher-Smith asked to be introduced to patients at different points along the epilepsy spectrum who were willing to be filmed speaking about their epilepsy, comorbidities, and resulting quality of life. The Epilepsy Foundation introduced the company to Matt, a 21-year-old college student living with epilepsy and ADHD, and Samantha, whose epilepsy is compounded by anxiety, depression, and ADHD.

Matt, Samantha, and their families were invited to Upsher-Smith's headquarters to meet the company's personnel and to share their personal stories about daily life with epilepsy and comorbidities. The discussions and resulting videos created a framework to help shape neurologists' discussions with epilepsy patients. The videos also demonstrate the varying degrees of information patients disclose to their neurologists regarding their epilepsy, symptom severity/frequency, and the impact comorbidities have on their daily lives.

According to Dr. Stern, about 30 percent of people living with epilepsy suffer from comorbid depression. In fact, he recommends that depression screening be a routine part of epilepsy treatment. Yet when asked if her doctors ever mentioned that her anxiety/depression and ADHD could be related to her epilepsy, Samantha said, "I don't think they ever did. I didn't ask, and they didn't bring it up, so I kind of heard it on my own."

She also said that, although her comorbidities seriously affect her epilepsy, she doesn't always remember to tell her doctors. "I get so anxious and depressed sometimes that I sometimes feel like I'm going to have a seizure … I don't always bring that up, which I should."

Matt, however, said his epilepsy is well controlled on his antiepileptic seizure medication and that epilepsy really doesn't impact his daily life. He also said that now that his epilepsy is controlled, his ADHD also seems to be under control. When asked whether or not his doctors have indicated that his epilepsy and ADHD could be related, he was uncertain. "I don't know if they're related … I can't answer that."

These videos gave patients an opportunity to talk, at length, about living with epilepsy and gave practitioners an opportunity to better understand and treat patients with epilepsy. Additional patient videos will be added to Epilog.us, covering a variety of topics impacting epilepsy patients. The first set of videos accomplished three important goals. First, the neurology community gained a deeper understanding of questions that can elicit responses leading to better epilepsy treatment options. Second, Upsher-Smith personnel gained critical awareness of and appreciation for the types of patients their anticipated CNS product pipeline may help. And third, Upsher-Smith strengthened its partnership with epilepsy practitioners, further demonstrating its commitment to serving as a go-to resource among neurologists in the epilepsy community.

The videos were launched via push marketing to a targeted list of neurologists. Since their launch, the videos have quickly become among the most watched on the Website.

It is unclear why epilepsy and comorbidities often go hand in hand. What is clear is that to accurately and successfully treat the many aspects of epilepsy a thorough patient perspective is critical.

Patrick O'Shea works in account service for Finger-Paint Marketing.

FACTS & FIGURES

About **two-fifths** of pharmacists say that they spend more time providing care and support for patients, such as recommending a pharmaceutical company Website or app to their patients, than they did two years ago, according to a survey by Manhattan Research. The top conditions for which retail pharmacists provide the most care and support are **diabetes**, **cardiovascular disorders**, **pain**, **respiratory diseases**, and **psychosis/depression**.

More than three-fourths of pharmacists would like access to online patient education materials from pharma. Additionally, **64 percent** of retail pharmacists would like patient assistance or vouchers, provided by pharma companies, through their EHR systems.

About **two in three** retail pharmacists, **three in five** hospital pharmacists, and **three in four** specialty pharmacists own or use a smartphone for professional purposes. About **half** of retail and hospital pharmacists and **three in five** specialty pharmacists have used pharma product Websites or apps in the past 12 months.

When talking to patients or caregivers, about **seven in 10** retail pharmacists and **three in five** hospital and specialty pharmacists typically discuss adherence related issues, such as taking treatment as recommended. Among pharmacists who interact with patients or caregivers, these numbers increase to **100 percent** for retail pharmacists, **90.4 percent** for hospital pharmacists, and **98 percent** for specialty pharmacists.

Only **50 percent** of surveyed pharmaceutical companies' information technology teams are involved in developing their companies' mobile health initiatives, according to a study by Cutting Edge Information.

The study also found that drug and device companies are beginning to incorporate the efforts of marketing, medical affairs, and IT functions within their mobile health teams. Of surveyed companies reporting the number of FTEs involved on their cross-functional mobile health teams, **88 percent** report involving FTEs from marketing, and **63 percent** involve their medical affairs teams.

According to Cutting Edge analysts, pharmaceutical and device companies can promote mobile health strategy and develop new initiatives by moving beyond the traditional scope of individual departments. Dedicated groups with sole focus on the mobile, as well as digitally based strategy development, help to secure mobile health campaigns' success.

"Centers of excellence generate value by incorporating multiple perspectives and capabilities," says Michelle Vitko, senior research analyst at Cutting Edge Information. "These centers also offer companies the unique opportunity to consolidate their mobile strategy team under one roof while promoting end user engagement."

Sources: "Taking the Pulse Pharmacists 2012", Manhattan Research (manhattanresearch.com); "Pharmaceutical Mobile Health: Transforming Brand Marketing, Healthcare Communication, and Patient Adherence", Cutting Edge Information (cuttingedgeinfo.com).

Online sourced patient-recruited outcomes are reliable: study

A new pilot study from Quintiles' Digital Patient Unit has confirmed the reliability of patient-reported outcomes collected via patients recruited over the Internet, demonstrating the viability of a new method for observational research that combines patient-reported outcomes and medical record data.

Quintiles' findings demonstrate that patients can be recruited, screened, and enrolled directly from online patient communities for observational studies that collect patient-reported-outcomes and clinical data with about 75 percent of physicians contributing medical record information.

"Results of this pilot study are a positive step forward in confirming the viability of the PRO+MR direct-to-patient study approach," says Elisa Cascade, study co-author and Quintiles Digital Patient Unit VP. "This pilot validates the use of patient-reported outcomes when collected in this manner. It is a foundational step toward broader use of this design in collecting real-world, observational data."

A Quintiles-authored article on the study, "Conducting Research on the Internet: Medical Record Data Integration with Patient-Reported Outcomes," has been published by the peer-reviewed *Journal of Medical Internet Research*. The study profiled in the article found that patients can be recruited directly for observational study designs that include patient-reported outcomes and clinical data with about three-quarters of physicians contributing medical record information. In the study pilot, nearly all charts confirmed patient-reported diagnoses.

"Utilizing direct-to-patient techniques for real-world data collection not only work in pilot, but we are also leveraging in practice," says Rich Gliklich, M.D., president of Quintiles Outcome. "Given the widespread demand for rapid data collection, direct-to-patient studies will become an increasingly important component of real world evidence development for understanding appropriate cohorts from treatment patterns to safety information." ■ MEDADNEWS

AdAgencyUpdate

By Joshua Slatko joshua.slatko@ubm.com

An ad universe where creativity is still allowed to flourish

By Jay Carter

Creativity is a key ingredient of effective healthcare advertising, the thing that grabs and holds attention, simplifies the complicated, delivers a relevant message, and makes a vividly remembered association with your product.

Our agency has been honored with many awards for creativity, a distinction that's especially sweet considering that the bulk of our work is in pharma, where strict regulatory requirements can seem like the enemies of imagination.

We've had our share of great concepts that were reduced to shadows in the name of compliance. We've had clients opt for the safe road rather than take the less-traveled scenic route. But in the past few years, as we've expanded into other areas of healthcare, we've discovered an advertising universe where creativity is still allowed to thrive and flourish. That place is diagnostics.

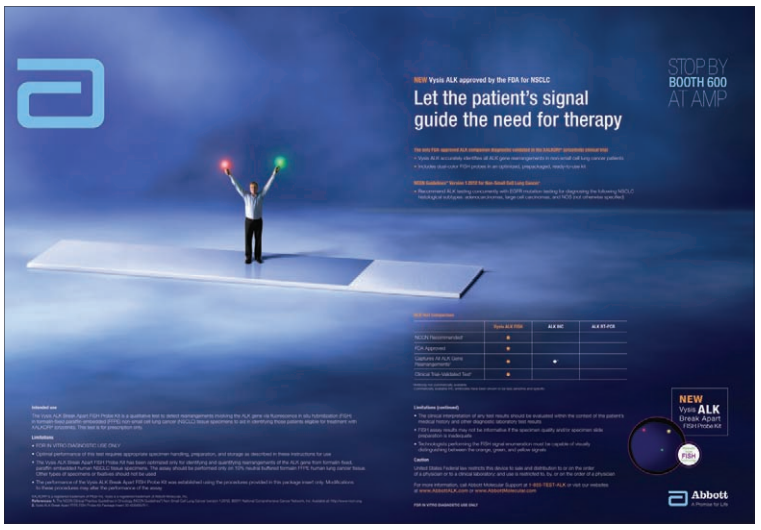
Because medical diagnostics are less invasive and involve fewer risks than pharmaceuticals, the regulatory climate is different. There are fewer requirements for fair balance and no mandate to run "brief summary" copy listing all risks in the FDA-approved product information. This leaves more room for creativity and more freedom to use graphics to drive the message.

Another cause for excitement in the field of diagnostics is the expanding number and variety of products being introduced. Advances in research and technology are moving us closer to personalized medicine, which uses an individual's unique clinical, genetic, genomic and environmental information to predict that person's susceptibility to disease and how the disease might progress. An important aspect of personalized medicine is the development of companion diagnostics that identify which patients are most likely to respond to target therapies. This opens the door to fresh opportunities for creatively introducing and branding a new generation of diagnostics.

The strength and stability of the medical diagnostics market also tend to foster creativity. Diagnostics have weathered the economic downturn better than some other healthcare sectors and the market is poised for continuing growth. Most analysts value the global in vitro diagnostics market -- the largest segment -- at $44 to $45 billion, with projections that it will reach $50 billion by 2014.

With that growth comes greater sophistication and accountability, which also favors more creative advertising. Many diagnostics ads are a throwback to an era when visual imagery was only about the functional -- the machine, test tubes and photos of packaging. There's a need to communicate more complex information in a meaningful and memorable way, and creativity is the tool for doing that.

Two cases in point:



A patient stands tall on a lab slide, raising bright lights into the darkness, to communicate the strong signal sent by this test to detect rearrangements in the ALK gene in non-small cell lung cancer. The lights suggest the orange and green probes a pathologist sees through a microscope.

SENDING A CLEAR SIGNAL

For Abbott Molecular, we helped commercialize the first genetic test to detect rearrangements in the ALK gene in non-small cell lung cancer (NSCLC). The test, known as the Vysis ALK Break Apart FISH Probe Kit, was developed as a companion diagnostic to identify patients eligible for treatment with Xalkori (crizotinib), a Pfizer ALK inhibitor used to treat patients with advanced NSCLC who have a tumor with a specific molecular abnormality.

Our creative campaign focused on the key differentiator of the test -- its strong signal. We showed a patient standing tall on a lab slide, holding bright signal lights in the dark blue twilight. The orange and green lights are evocative of the probes a pathologist sees when peering into a microscope, and the blue background represents a DAPI counterstain. The copy is simple and succinct: "Let the patient's signal guide the need for therapy."

One of the things that makes this ad effective is bringing the patient into the picture, sending a subtle reminder that NSCLC patients are in a race against time for survival and can't afford a trial-and-error approach to treatment. The ad speaks directly to pathologists, showcasing their ability to quickly pinpoint which patients are most likely to benefit from treatment with an ALK inhibitor. This elevates their role as an essential part of the patient's treatment team and underscores the importance of the information the new test allows them to discover.

The Vysis ALK Break Apart FISH Probe Kit launched in August 2011 and exceeded its annual sales target in less than seven months, making it Abbott Molecular's most successful diagnostic launch of the year.

IMPARTING INSIGHT

For Genomic Health, we created a way of vividly communicating an important clinical insight related to the Oncotype DX test for patients recently diagnosed with early stage, estrogen receptor positive breast cancer. The test helps physicians and patients decide on a treatment plan by generating a Recurrence Score that identifies the probability that a cancer will return. The score also indicates the degree of benefit a patient might receive from chemotherapy.

The message we drove home is that in a meta-analysis involving 900 patients, physicians changed their treatment decisions one-third of the time when they used the Oncotype DX test. This resonated strongly with clinicians, who found the number surprisingly high. Our creative campaign used a striking graphic to link this important insight to the things oncologists already knew about the test -- it's for women, it's genomic, and it comes in orange packaging.

We believe that the resulting ad is bold and impactful, dominated by the image of a woman composed of orange DNA strands. The copy calls out the findings of the meta-analysis with the tagline "Uncover the Unexpected."

Low users of ODX increased use after exposure to the promotion.

This ad is all about the unexpected. A woman made up of strands of orange DNA associates what clinicians commonly know about this breast cancer assay (it's genomic, for women and comes in an orange package) with the surprising finding that clinicians change their treatment plans a third of the time when they use the test.

FUTURE PROSPECTS

What we've learned from our work in diagnostics is that, as in pharma advertising, it's rewarding to help drive products that improve patient care. But it's also fun and stimulating to create campaigns without the fetters of pharma regulations. A growing market, exciting new products and a less-stringent regulatory climate make diagnostics a very attractive field for healthcare advertisers looking to flex their creative muscle. And there's plenty of room for breakthrough creativity.

Just as the Hytrin Balloon ad caused a resurgence of iconic work for pharma brands, I hope that our work and the work of other agencies will create a renaissance in diagnostics advertising.

Purohit Navigation assists in charitable drug donation from Sagent

In a continuation of the agency's longstanding commitment to community, **Purohit Navigation** President/CEO Ahnal Purohit has helped assist a charitable drug donation from Sagent Pharmaceuticals to the people of Sierra Leone, West Africa. Accepting the donation was Ambassador Bockari Stevens of Sierra Leone. The chemotherapy medication donated, topotecan, is used to treat small cell lung cancer. The ceremony took place at the Chicago office of the Consulate of the Republic of Sierra Leone.

Sagent Pharmaceuticals, Inc., headquartered in Schaumburg, Illinois, is a specialty pharmaceutical company that develops, manufactures, sources, and markets pharmaceutical products, with a specific emphasis on injectables. The company donated 840 vials of topotecan.

"I humbly accept this generous donation on behalf of the people of Sierra Leone," Ambassador Stevens said upon the presentation. "My appreciation is only exceeded by the spirit of those who will benefit from this contribution. I extend our gratitude to Sagent for making this needed medication available to us, and also to the Purohit Navigation/AWASH team for assisting in the endeavor.

Purohit Navigation helped establish the AWASH Foundation (Africa Women's Alliance in Support of Health), whose mission is to be a constant, ever-present source of community and support for women and to provide healthcare services irrespective of the patient's race, religion, language or political affiliation. The organization plans to establish a presence in Sierra Leone and expand to other parts of Africa. To structure and service the operation, a proper staff of physicians and nurses has been retained, and private donors and volunteers are sought regularly.

Purohit Navigation received *Med Ad News*' inaugural Heart Award in 2009 for its work in Sierra Leone.

"One of our foundation's objectives is to provide medications and devices that people of West Africa, specifically Sierra Leone, cannot afford," Ms. Purohit says. "We feel privileged to connect globally minded pharmaceutical companies like Sagent with people in need, like those in Sierra Leone."

Euro RSCG Life becomes Havas Life

As part of a global rebranding operation aiming to underline a simpler and more transparent corporate structure and a unified culture, Havas has renamed the Euro RSCG Worldwide network and its agencies as Havas Worldwide, and the Euro RSCG Life agencies as Havas Life.

"Rebranding the Euro RSCG Life network to Havas Life is a natural step in streamlining the Havas Health structure and, for clients, more clearly demonstrates our unified offering and shared culture," says Donna Murphy, global CEO, partner, Havas Health. "For any message to stick with today's customers, they need a singular, consistent brand experience, and the new branding is as strikingly memorable and unified as we are."

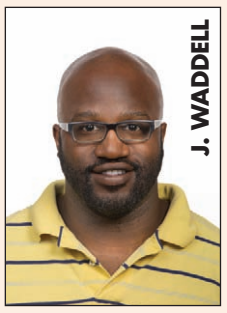
The Havas group will now consist of two main brands: Havas Media, which includes all global media agencies, and Havas Creative, which includes the Havas Health networks, including Havas Life and Health4Brands (H4B), the Havas Worldwide network, the Arnold Worldwide micro-network, and all other communications agencies.

Havas' main focus is to deliver the most unified offer and one that drives greater effectiveness, consistency and value for its clients. According to its leaders, the network has implemented a unique business model with a simple, clear, and agile structure placing digital at the core of all its activities and agencies, unifying creative and media assets and strengthening visibility of its global brand by renaming its largest network.

As of Sept. 24, all Euro RSCG Life agencies, with 60 offices in 50 countries, have been renamed Havas Life. Some of these include Havas Life Metro (formerly Euro RSCG Life LM&P NY and Chicago); Havas Life New York (formerly Euro RSCG Life MetaMax); Havas Life Medicom (formerly Euro RSCG Life Medicom); and Havas Life Digital (formerly Havas Drive). The rebrand did not create any changes in leadership.

"A decade ago, we set ourselves apart by being the first major communications holding company placing digital at the core of all our creative agencies," says David Jones, global CEO of Havas. "I think we're once again pioneering through the integration of creative, media and digital. Today with the rebranding we're making a small change, but it's one we want to use as a catalyst for driving big change through Havas and the broader industry."

AGENCY PEOPLE ON THE MOVE



■ AbelsonTaylor

Dan Lathitham and **Jenny Beaumont**, previously account supervisors, have been promoted to the position of senior account supervisor at AbelsonTaylor (abelsontaylor.com). Mr. Lathitham, who joined the agency in 2006 from Ketchum Public Relations, has 14 years of experience in healthcare advertising and public relations, medical education, integrated communications, issues, and event management. Ms. Beaumont joined AbelsonTaylor in 2001 after graduating from college. **Kathy McCracken** has been promoted to senior account executive and **Barbara N. Seigfreid** and **Christina Mirro** have been promoted to account executive. Ms. McCracken, previously an account executive, joined AbelsonTaylor from Apex Systems Inc., an IT staffing company, in 2009. Ms. Seigfreid, promoted from account coordinator, joined the agency from Panthera Global Inc. in 2011. Ms. Mirro, previously an account coordinator, came to the agency from Aerotek in 2011. **Katerina Babinski** is promoted to manager of new business development. Ms. Babinski, with AbelsonTaylor since 2004, was previously senior account executive. **Eric Cale** is promoted to senior account supervisor. Mr. Cale joined the agency in 2008 from Ideon Healthcare Communication, the medical education division of Williams Labadie. **Mary Clare Mooney** and **Samantha Hickey** are promoted to account executive. Ms. Mooney and Ms. Hickey both joined AbelsonTaylor in 2011. **Jill Hogan** and **Justin Mroz** become senior interactive producers. Ms. Hogan, with the agency since 2005, was promoted from producer. Mr. Mroz joins AbelsonTaylor from Burrell Communications, a multi-cultural ad agency, where he was senior executive producer.

■ Cambridge BioMarketing

Michael Gatti becomes creative director, experience, Cambridge BioMarketing (cambridgebmg.com). Prior to joining the agency, Mr. Gatti spent six years with The Barbarian Group, most recently as a creative director.

■ The CementBloc

Robert Roth is named group account director, The CementBloc (thecementbloc.com). Mr. Roth was previously with JWT New York. **Michael Stolper** becomes account director. Mr. Stolper joins the agency from Ogilvy Healthworld. **Rachel Mansfield** is named account manager. Ms. Mansfield recently graduated from Muhlenberg College. **Katarina Hellstrom** is named VP, account planner. Ms. Hellstrom was previously with Kaplan Thaler Group. **Darryl McNeil** becomes director, analytics and operations. Mr. McNeil joins the agency from International Business Times. **Jon-Eric Waddell** is named senior analyst. Mr. Waddell previously worked at Forest Laboratories. **Hui Tang** becomes research analyst. Ms. Tang is a recent MBA graduate from Case Western Reserve University. **Sanjay Gupta** is named associate director, multichannel product management. Mr. Gupta was previously with Echo Torre Lazur. **Annette Kosaka** becomes senior multichannel project manager. Ms. Kosaka joins the agency from Digitas Health. **Stephen Whelan** is appointed multichannel project manager. Mr. Whelan was previously with Area 23. **Debora Shiokawa** is named associate creative director, digital. Ms. Shiokawa joins the agency from H4B Chelsea. **William Ricchini** becomes associate creative director, copy. Mr. Ricchini comes from GlaxoSmithKline. **Richard SanFilippo** is appointed group copy director. Mr. SanFilippo was previously with Euro RSCG Life MetaMax. **Michael McSwain** becomes senior copywriter. Mr. McSwain joins the agency from Saatchi & Saatchi Health. **Thu-Nhi Nguyen** is named senior art director. Ms. Nguyen was with Cline Davis & Mann.

■ Kane & Finkel

John Flaherty is appointed to the role of European director, Kane & Finkel Healthcare Communications (kaneandfinkel.com), based out of the agency's London office. Mr. Flaherty's agency experience includes leadership positions at GSW Worldwide, Lowe Healthcare, Sudler & Hennessey, and Huntsworth Health.

■ Sudler & Hennessey

James Hammond is appointed to the newly created role of chief strategy officer, China and Japan operations, Sudler & Hennessey (sudler.com). Mr. Hammond joins the agency after serving as president of McCann Healthcare China.

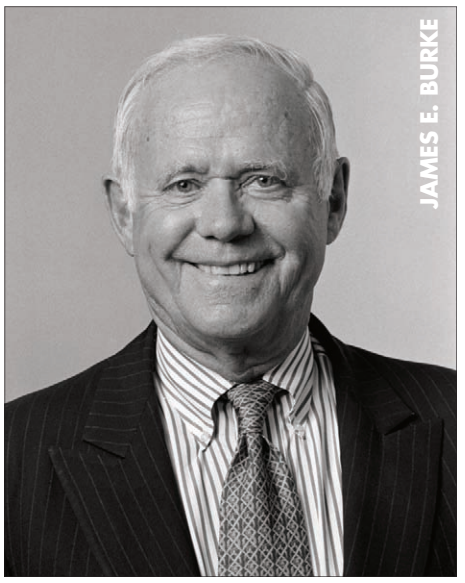
■ Topin & Associates

Justin Smith is named web developer, Topin & Associates (topin.com). Prior to joining the agency, Mr. Smith worked for several companies in the Chicago area including Star Events, an event production company that has spent more than a decade developing events in and around Chicago.

People on the Move

By Joshua Slatko joshua.slatko@ubm.com

Former J&J CEO Burke dies at 87



Former J&J CEO James Burke, best known for his role in managing the company's response to the Tylenol poisonings of 1982 and 1986, died Sept. 28 at 87.

Former Johnson & Johnson Chairman and CEO **James E. Burke**, whose long career in the private and public sectors earned him the Presidential Medal of Freedom, died Sept. 28 at the age of 87.

"Jim Burke was among the greatest leaders in the history of American business," says Alex Gorsky, CEO of Johnson & Johnson. "His commitment to the values expressed in our credo served as the foundation for everything Jim did throughout his remarkable career. He will forever inspire the people of Johnson & Johnson."

Born in Rutland, Vt., in 1925, Mr. Burke grew up in the small upstate New York town of Slingerlands. After commanding a landing craft tank in the Pacific during World War II as an ensign in the United States Navy, he completed his college education and graduated from Holy Cross in 1947 and the Harvard Business School in 1949. In 1953, Mr. Burke joined Johnson & Johnson as a product director. He would spend 37 years at J&J, 16 of them as president (1973-1976) and then chairman and CEO (1976-1989).

During Mr. Burke's tenure as chairman and CEO, Johnson & Johnson's sales grew more than threefold to $9 billion; net income increased nearly fivefold; the company's market capitalization nearly tripled; and it expanded its presence from 37 to 54 countries, all while focusing on meeting significant unmet needs of patients and consumers around the world. In addition to this, Mr. Burke's career will likely be best remembered for his steady leadership of the company during the Tylenol poisonings in 1982 and 1986.

After retiring from Johnson & Johnson in 1989, Mr. Burke assumed the chairmanship of the Partnership for a Drug-Free America (now The Partnership at Drugfree.org), a non-profit organization founded by the American Association of Advertising Agencies. The Partnership created advertising designed to change social attitudes about illicit drugs. Mr. Burke rallied thousands of media and communications professionals to support the cause. Campaigns were created pro bono by hundreds of advertising agencies; media companies donated millions of dollars in broadcast time and print space to carry the campaigns. Under Mr. Burke's leadership, the Partnership would grow to become one of the most effective organizations combating substance abuse in the United States.

At a ceremony held in the East Room of the White House on Aug. 9, 2000, President Bill Clinton awarded Mr. Burke the Presidential Medal of Freedom in recognition of his outstanding corporate and civic leadership. The Presidential Medal of Freedom is the nation's highest civilian award, reserved for individuals the President deems to have made extraordinary contributions to the country.

In a letter to President Bill Clinton offered in support of Mr. Burke's nomination for the Presidential Medal of Freedom, President George H.W. Bush wrote, "Jim deserves the award not only for his tireless and unselfish work in the fight against drugs, but also for his exemplary business leadership when he was CEO of Johnson & Johnson."

"Jim Burke believed 100 percent in the Johnson & Johnson Credo, as he exemplified when he took Tylenol off the shelves (in 1982 and 1986)," said Thomas S. Murphy, former chairman and CEO of Capital Cities/ABC. Mr. Murphy met Mr. Burke at the Harvard Business School; they were roommates for many years, and became lifelong friends. "Jim also was a great believer in America. To me, he was a wonderful friend."

Mr. Burke and his wife, Didi, had been longtime residents of Princeton, N.J. He is survived by his wife; his son James Burke, of Princeton; his daughter, Clo Burke of San Antonio, Texas; a sister, Phyllis Burke Davis of Bridgehampton, New York; and four grandchildren.

PHARMA

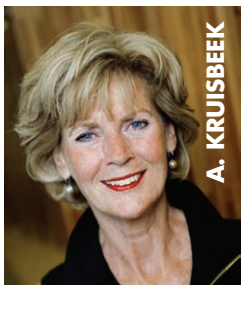
■ **Frances Heller** becomes senior VP, business development, Bristol-Myers Squibb. Ms. Heller previously served as executive VP, business development at Exelixis and head of strategic alliances at Novartis Pharmaceuticals.

BIOTECH/BIOPHARMA

■ **Christian Weyer**, M.D., is appointed president and CEO, Fate Therapeutics Inc. Dr. Weyer joins the company after a 12-year tenure with Amylin Pharmaceuticals Inc., where he most recently served as senior VP of research and development until the completion of its acquisition by Bristol-Myers Squibb in August 2012. Fate Therapeutics is a biotechnology company developing first-in-class therapeutics with novel points of intervention in the field of adult stem cell biology.

■ **Neil Belenkie** is named CEO, Sirona Biochem Corp. Mr. Belenkie is the founder of the strategic management consulting company GrowthPoint Group. Sirona is a biotechnology company developing diabetes therapeutics, cancer vaccine antigens, skin depigmenting and anti-aging agents for cosmetic use, and biological ingredients.

■ **Marcel Zwaal** is appointed CEO and Dr. **Anthony Hall** becomes chief medical officer, DCPrime. Dr. **Ada Kruisbeek**, founder of DCPrime and active in a dual role as CEO and chief scientific officer since the launch of the company, will continue to build and expand the company's product platform technology as chief scientific officer. Mr. Zwaal has been promoted from the position of chief business officer; Dr. Hall has 18 years of experience in clinical drug development, in particular in orphan drug indications. DCPrime develops off-the-shelf dendritic cell-based vaccines for a broad range of cancer types, based on its unique, proprietary technology platform, DCOne.



■ **Carl Harald Janson**, M.D., Ph.D., becomes CEO, Axelar AB, a Karolinska Development AB portfolio company. Dr. Janson previously worked as VP, portfolio management at Karolinska Development from 2008 to 2011. Axelar is a Swedish biotech company developing insulin-like growth factor-1 receptor inhibitors for the treatment of cancer and other diseases.

■ **Jane Wasman** is named president, international, Acorda Therapeutics Inc. Ms. Wasman most recently served as the company's chief, strategic development, and general counsel. Acorda is a biotechnology company focused on developing therapies that restore function and improve the lives of people with MS, spinal cord injury, and other neurological conditions.

■ **Cynthia M. Patton** becomes senior VP and chief compliance officer, Amgen. Before joining Amgen, Ms. Patton served for seven years as the general counsel of a California HMO. Amgen discovers, develops, manufactures, and delivers innovative human therapeutics.

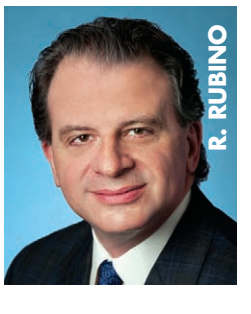
■ **Linda C. Hogan** becomes VP of business development, Tolera Therapeutics Inc. Ms. Hogan has more than 25 years of experience in the healthcare industry, having served as VP of global business development for Aventis in addition to various roles in medical affairs, strategic planning and finance, new business market intelligence, and licensing for its predecessor companies of Marion Laboratories, Marion Merrell Dow, and Hoechst Marion Roussel. Tolera is developing and commercializing therapies for the immune modulation market with the goal of addressing unmet medical needs with safer, more targeted solutions to reduce the risk of serious and toxic side effects often associated with immunotherapy.

■ **Deborah A. Thomas**, Ph.D. is promoted to VP, regulatory affairs, and **Gene C. Jamieson** is promoted to VP, chemistry, manufacturing, and controls, Sunesis Pharmaceuticals Inc. Dr. Thomas joined Sunesis in November 2011 as executive director, regulatory affairs after joining the company from BiPar Sciences, where she was VP, regulatory affairs. Mr. Jamieson joined Sunesis in December 2010 as executive director, CMC. He came to the company from AllyCMC, a CMC services company, where he served as principal partner. Sunesis is a biopharmaceutical company focused on the development and commercialization of new oncology therapeutics for the treatment of solid and hematologic cancers.

■ **Tim Freeborn** is named finance director, Silence Therapeutics Plc. Mr. Freeborn previously worked at Xcap Securities, where he was head of research. Silence Therapeutics is a biotechnology company dedicated to the discovery, development, and delivery of targeted, systemic RNA interference (RNAi) therapeutics for the treatment of serious diseases.

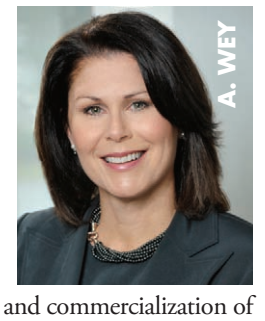
SPECIALTY

■ **Richard J. Rubino** is named chief financial officer, Aerie Pharmaceuticals. Prior to joining Aerie, Mr. Rubino spent nearly 20 years at Medco, holding positions of increasing responsibility, including chief financial officer and chief accounting officer. Aerie is a privately held clinical-stage biotechnology company dedicated to the discovery and development of novel treatments for glaucoma.



■ **Robert Rosen** is appointed senior VP and chief commercial officer, A.P. Pharma Inc. From 2005 to 2011, Mr. Rosen served as global head of oncology at Bayer HealthCare, where he was responsible for the development of the global oncology business unit for regions that included the Americas, Europe, Japan, and Asia Pacific. A.P. Pharma is a specialty pharmaceutical company developing products using its proprietary Biochronomer polymer-based drug delivery platform.

■ **Allison Wey** is named VP of investor relations and public affairs, Durata Therapeutics. Before joining Durata, Ms. Wey served as VP, investor relations and corporate affairs for Par Pharmaceuticals until its recent acquisition by TPG. Durata is a pharmaceutical company focused on the development and commercialization of novel therapeutics for patients with infectious diseases and acute illnesses.



■ **Hyunna Coelho** is promoted to VP, commercial excellence, Merz Inc., the U.S. affiliate of Merz Pharma Group. Ms. Coelho most recently served as area business director – East for Merz Aesthetics. The companies of Merz Pharma Group are focused on medications for treating neurological and psychiatric illnesses and thereby assume a leading role in the field of Alzheimer research.

■ **Karin L. Walker** becomes VP of finance and chief accounting officer, Affymax Inc. Prior to joining Affymax, Ms. Walker served as VP of finance and corporate controller at Amyris Inc. Affymax is a biopharmaceutical company with

a mission to discover, develop, and deliver innovative therapies that improve the lives of patients with kidney disease and other serious and often life-threatening illnesses.

■ **Bill D'Agostino** is named senior director of manufacturing and engineering, InVivo Therapeutics Holdings Corp. Mr. D'Agostino most recently spent seven years at Angiotech Pharmaceuticals as VP, engineering. InVivo is utilizing polymers as a platform technology to develop treatments to improve function in individuals paralyzed from traumatic spinal cord injuries.

■ **Jorgen Winroth** joins Sobi to lead the company's investor relations activities. Mr. Winroth served as director, investor relations for AstraZeneca North America for the past sixteen years. Sobi is an international healthcare company dedicated to bringing innovative therapies and services to improve the lives of rare disease patients.

SERVICE SUPPLIERS

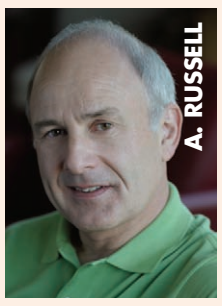
■ **Cathy Wolfe** is named president and CEO of Wolters Kluwer Health's Medical Research business, effective Jan. 1, 2013. Ms. Wolfe has been with the company since 1996 and served as CEO of Wolters Kluwer U.K. since 2007. Wolters Kluwer Health is a global provider of information, business intelligence, and point-of-care solutions for the healthcare industry.

■ **Gary J. Gatyas**, Jr., is appointed senior VP, global marketing and communications, Kantar Health. Mr. Gatyas joins Kantar Health from IMS Health, where he directed global media relations and played a key role in launching the IMS Institute for Healthcare Informatics, as well as executing its media relations and marketing programs. **Louise Tamblin** is named group director. Ms. Tamblin was head of research with Strata Research. Kantar Health is a global, evidence-based decision support partner to the world's leading pharmaceutical, biotech, device, and diagnostic companies.

■ **John Kritzmacher** joins WebMD Health Corp. as senior VP business operations, organizational planning and structure. Prior to joining WebMD, Mr. Kritzmacher was executive VP and chief financial officer of Global Crossing until its acquisition by Level 3 Communications. WebMD is a leading provider of health information services, serving consumers, physicians, healthcare professionals, employers, and health plans through its public and private online portals, mobile platforms, and health-focused publications. ■ MEDADNEWS

RUSSELL TO RETIRE; SHIRE NAMES CEO-DESIGNATE

The board of directors of Shire has announces the retirement in 2013 of CEO **Angus Russell** after 13 years with the company and 32 years in the pharmaceutical industry. **Flemming Ornskov**, M.D., will join the Shire board as chief executive designate Jan. 2, 2013 following completion of his notice period with his current employer.



After a handover period of several months to ensure a smooth transition, Dr. Ornskov will become CEO April 30, 2013, the date of the Shire annual general meeting. As chief executive designate, Dr. Ornskov will spend time with all three Shire businesses and will have a special focus initially on the Specialty Pharmaceuticals business. He will be based at Shire's offices outside Philadelphia during this period.

Dr. Ornskov joins the company from Bayer where, as chief marketing officer and global head, strategic marketing for general and specialty medicine he oversees the full pharmaceutical product portfolio, with sales of more than 10 billion euros from global marketing units in Europe, China, and the United States.

"Shire stands out in the industry," Dr. Ornskov says. "I'm motivated and inspired by the company's vision and excited to bring the combination of my medical, multi-national, and entrepreneurial business background to lead Shire to the next phase of its development."

Prior to his present role at Bayer, Dr. Ornskov served as global president, pharmaceuticals and OTC for Bausch & Lomb Inc. from 2008 to 2010. Before that, he was chairman of the board of directors of Lifecycle Pharma A/S from 2006 to 2008, stepping in as CEO to take the company through an IPO. From 2005 to 2006 Dr. Ornskov was president and CEO of Ikaria Inc., a privately owned biotech company in Seattle, a majority stake of which was sold to a private equity firm. The company was then merged with Ino Therapeutics Inc.

THELASTWORD Act like a man! Really?

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

HANNA ROSIN'S BOOK "The End of Men" which was excerpted in the *New York Times Magazine*, has caused a huge stir. One of my favorite columnists, David Brooks, based an entire column on the idea entitled "Why Men Fail." Debra Spar, president of Barnard College and a former professor at Harvard Business School, chimed in with a *Newsweek* essay: "American Women Have it Wrong."

A few years ago these stories about gender wars in business were still new, but today it's looking like the dust has settled and the white flags are flying. Brooks points out that men are coming up short – only 40 percent of bachelor's degrees are earned by men and the same holds true for master's degrees. In my Leadership class at Fordham University's Graduate School of Business, I see the same: 60:40 for women, whereas only a decade ago the reverse was true. And I don't have to tell you who are often my hardest working MBA students!

Brooks says that what's turned the roles around is adaptability. Men, who once ruled the roost, are slower to accept change, but women adapt faster to new paradigms. Brooks makes an analogy with immigrants – some adapt and thrive in their new homeland; others never learn the new language and customs, remaining expats all their lives.

Of course, some retort that this is all hogwash and women are still underpaid and undereducated (see Stephanie Coontz's article "The Myth of Male Decline" in the *New York Times*). But there's no arguing the fact that there has been a shift. In the last 30 years, the percentage of managers and administrators who are women has grown from 26 percent to 34 percent, and 70 percent of managers of medicine and health occupations are women, up from 50 percent just three decades ago.

Over the years I've worked with some of the brightest people in pharma; many of these happen to be women. I've also met and followed the careers of many women in other areas of business who have risen to the top of their organizations.

Curiously, not all of them succeed. Some are fired, others burn out, and many simply stagnate. It's not clear why. Debora Spar observes that to succeed many women plunge into years of working 60+ hours a week; but crash when they find they still cannot be perfect parents, perfect wives and perfect everything else. On the other hand, Brooks offers the theory that the relative disparity of women at what he calls the "tippy top" of business is due to the fact that they take time off to raise children.

I have a different thought. Perhaps many women can rise through the ranks because, in addition to their smarts, skills and passion, they also have the ability to adapt better to the profound changes that are inherent in any large organization. But when they reach the pinnacle, they succumb to the illusion that now they must act like the leadership patriarchs of old – and, forgetting what got them to the top, begin to "act like a man."

This might explain the unexpected falls after meteoric rises that we often see with women in the business world. And, looking across the aisle at men, it might also explain why acting childishly and unprofessionally now hamper men on every level of the ladder. "Acting like a man" doesn't mean acting like a boy. It's a new world, and it pays to learn the territory. ■ MEDADNEWS

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