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AGENDA 2013

Caution: future approaching

The impending components of U.S. healthcare reform, the growth of "Big Data," an increasing demand for pink slips, and a drive to go beyond the pill will all shake a rapidly restructuring pharmaceutical industry in the coming year.

By Joshua Slatko joshua.slatko@ubm.com

While 2012 should go into the history books as a year of uncertainty in the pharmaceutical world, 2013 is expected to clear up many mysteries. With President Obama re-elected, the various tendrils of his signature healthcare reform legislation will continue to move forward. Although the full scope of the act's impact remains unclear, at least industry players know the rules of the new game. Downsizing, restructuring, outsourcing, and other euphemisms for layoffs are expected to continue in the new year, but the pace should slow as companies approach a happy medium of suitability for the new marketplace. "Big Data," more a buzzword than a useful tool in the past, should evolve in value as marketers and their data teams figure out new ways to take advantage of the enormous sources of information at their fingertips. And the practice of going "beyond the pill" by offering complementary services, a trend that is mostly present in just a few therapeutic areas and categories, will expand further into the marketplace as brand managers seek ways to offer more value to patients, payers, and other stakeholders.

The election

A year ago, both the results and the impact of the upcoming U.S. presidential and congressional elections were matters of intense speculation. The "results" bit is now out of the way, but President Obama's re-election has not ended the debate over how politics and policy will impact the pharmaceutical marketplace. At the forefront of this discussion, of course, is the growing influence of the Patient Protection and Affordable Care Act, with some of the Act's provisions already in effect and many others coming over the horizon.

"The biggest impact from the election is that the Patient Protection and Affordable Care Act will now be implemented," says Nancy Lurker, CEO of PDI Inc. "PPAC is going to have an enormous impact on the healthcare landscape, effecting patients, physicians, and the biopharmaceutical industry. Gradually, this implementation will create a profound impact on how the biopharmaceutical industry interfaces with government, payers, patients, and healthcare providers. Those companies who are able to innovate within this change will gain enormous opportunities, and those who don't will lag behind, operating in the old paradigm."

Rarely has any piece of legislation, at least since FDA was created, changed the equation for pharma makers and marketers more broadly than PPAC will. According to Ms. Lurker, everything from the Sunshine Law to rebates, and eventually accountable health organizations, the exchanges, formularies, electronic health medical records – all will be put into play, some in ways far outside the obvious. For instance, the implementation of electronic health medical records over time will have a significant impact on how the industry tracks prescription use and interfaces with physicians. This ability to track use and aggregate "big data" will offer an invaluable real-time assessment of the benefits and side effects of pharmaceutical medicines in the community, giving the industry a platform from which to better tailor medicines for different patients and develop better solutions to health issues.

With these sorts of opportunities in mind, many industry-watchers emphasize that pharmaceutical executives need to prepare for a post-reform environment where the focus of reimbursement is shifting to value over volume and where customers – consumers, physicians, and payers – have significantly different expectations of value.

"Pharmaceutical companies must reassess their strategies and work to demonstrate their value by improving health outcomes and/or reducing the overall

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This month on PharmaLive.com

WEBCAST: Specialty Pharmacy, Benefit Investigation and Copay Programs - February 13th, 12:00pm ET

Benefit investigation and reimbursement activity has become a marketing requirement for many new drugs in addition to various FDA requirements that can include limited distribution through specialty pharmacies. Purchasers in the commercial market don't understand the complexity or clinical issues associated with specialty products, but have more awareness of benefit design and coverage considerations since they pay for health care. As a result, current reimbursement hub solutions are necessary, but require significant resources, are driven by manual and inefficient processes, lack transparency and require cumbersome workflows from patients and physicians or other providers.

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By Christiane Truelove chris.truelove@ubm.com

"**Somewhere** along the way, we're forgetting that men and woman who create products, develop training programs, and design the services of next-generation pharma companies must themselves feel honored, protected, and viable."

Happy New Year. I can't believe it's 2013, but not for the obvious doomsday reasons. Despite the endless speculations about the "Mayan prophecy," Dec. 21, 2012, was not the end of the world; for me, though it did mark the end of my Christmas shopping and cookie baking, and my kitchen did look like an apocalypse hit it (the aftermath of baking reminds me why I rarely do it – the product is delicious, but scrubbing cookie sheets is tedious and tiring).

With the new year comes change and new resolutions, and speculation of what is to come. In Agenda 2013, our cover story, Managing Editor Joshua Slatko asked editorial board members and other industry experts what they think the future holds for the pharmaceutical and healthcare advertising industries. One of our favorite comments came from Denise DeMan, chairman and CEO of the executive search company Bench International.

Ms. DeMan says 2013 needs to be a time of corporate soul-searching in the pharmaceutical industry; although the number of workers shed was fewer in 2012 than in previous years, the hits were particularly deep on the R&D side.

"I fear that leaders, once again, have failed to consider the toll that these predictable waves of layoffs, cresting every Christmas, corporate emotional intelligence, complete absent of institutional courage and conviction," she writes. "What becomes of bravery, and the will to invest in new medicines? 'Merry Christmas. We are having a big layoff. Now the rest of you who dodged the bullet be prepared to start the New Year refreshed, revitalized, and excited to take on the challenges of the New Year.'"

As one pharmaceutical executive put it to Ms. DeMan, "Our raison d'être is to make people well, yet we are made to feel vulnerable, insignificant, and physically ill in the process."

Ms. DeMan argues that the industry is forgetting the human beings that populate it. "How can we focus on the patient, create important products, and get them to sick/hurt individuals if our companies are populated with fearful, sick, insecure people?" she says. "Somewhere along the way, we're forgetting that men and women who create products, develop training programs, and design the services of next-generation pharma companies must themselves feel honored, protected, and viable."

I would say that feeling of being honored, protected, and viable is missing from a lot of industries, not just the pharmaceutical industry. Artists have felt like that for decades – and being asked to perform for free is flattering, but doesn't pay the bills or put food on the table. Journalists who have spent years honing their craft and going from regional paper to regional paper find those regional papers are disappearing and the practice of news reporting has been replaced by people on the street Tweeting out iPhone videos or Websites where "content" is provided by aggregators who pay anonymous stringers $5 per article.

And then there is the sad story of the book giant Barnes & Noble, which is closing locations down in major cities – some experts are saying the company will be out of business in two to three years. The company that crowded independent booksellers out of business by undercutting prices will now be leaving those markets without any book stores at all, reducing the options for authors to share their works. I've seen stats that say B&N holds 80 percent of the print book market, so if you know any aspiring authors, you might want to help them rethink their career paths.

So, we're coming to a world where no one values books – and authors and editors – because people won't really see any of them. As Dennis Johnson says on the publisher Melville House's blog, "In short, B&N's scorched earth policy of the 1990s has ultimately left us with, well, scorched earth. If the book is going to survive it, it's going to take some real revolutionary activity, indeed."

And if there is going to be a viable pharmaceutical industry, it will also take some revolutionary activity. Companies' fixation on the bottom line has led to the cuts that have disheartened everyone from the scientists to the sales reps. The time is now to take the steps that truly prove the value of new medicines, by embracing Big Data efforts (see my story on page 20) and the building of relationships with patients from clinical trial recruitment to post-marketing studies. Hopefully, this can also improve pipelines (see Managing Editor Andrew Humphreys' evaluations of the top 10 pharma/biotech pipelines on page 12). And perhaps if the focus shifts away from the bottom line to the people, everyone will feel like what they do matters.

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ON THE COVER

AGENDA 2013 • CAUTION: FUTURE AHEAD
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WHAT'S ONLINE

WEBCAST: SPECIALTY PHARMACY, BENEFIT INVESTIGATION, AND COPAY PROGRAMS

February 13th at 12:00pm ET

The growth in biologics and specialty pharmacy products has evolved new business practices, benefit coverage issues, and cost offsetting programs related to health product marketing, especially pharmaceuticals and some medical devices.

Benefit investigation and reimbursement activity has become a marketing requirement for many new drugs in addition to various FDA requirements that can include limited distribution through specialty pharmacies. Purchasers in the commercial market don't understand the complexity or clinical issues associated with specialty products, but have more awareness of benefit design and coverage considerations since they pay for health care. As a result, current reimbursement hub solutions are necessary, but require significant resources, are driven by manual and inefficient processes, lack transparency and require cumbersome workflows from patients and physicians or other providers.

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WHAT'S IN PRINT

continued from page 1

cost of care, an economic outcome," says Todd Evans, director, pharmaceutical and life sciences practice, PwC. "When healthcare providers are paid for the quality of care they deliver, they'll apply the same criterion to the therapies they prescribe. That means payers will only pay a premium for medicines that offset or reduce costs from elsewhere in the care pathway. Pharmaceutical companies must be able to develop products that are clinically and economically superior to what already exists, and they must be able to prove it to payers, providers, and patients with hard, real world data expressed as outcomes. In essence, if there is no outcome, then there is no income."

Because of this, Evans expects pharmaceutical companies to regard the values of their candidate assets in development using outcome valuation logic and reset their net present values. "We can also expect that as the various economic implications of the ACA take hold, pharmaceutical companies will refocus and recast the logic of their global planning for both mature and growth markets, since the overall rates of growth and margins earned from U.S. sales is now responding to a very different drumbeat," he says.

Calculating those new values, though – and, more broadly, figuring out what will work and what won't in the new PPAC environment – is still a matter of some doubt, if well past the burning entrails phase. The center of gravity for the discussion all along has been payers and providers, and as those

"Pharma will need to shift its go-to-market model from share-of-voice promotion to one centered on meaningful dialogues with institutions about meeting their overall care and cost objectives."

stakeholders strive to improve outcomes and reduce costs, both challenges and opportunities for pharma will arise.

"On the challenge side, we expect an increased portion of consumers to opt-in to low price products with less benefits and choice than are typical in most employer plans," says Greg Rotz, partner and lead of the North American life sciences sector, Booz & Company. "On the opportunity side, the fact that many drugs can reduce, or avoid altogether, higher-cost events is more important than ever. The question is which drugs will be favored in this environment, and what's required to succeed? Generics will be a natural beneficiary. Branded pharma will need to enhance its efforts around comparative effectiveness, build real-world evidence capabilities, aggressively pursue personalized medicine strategies, and collaborate with stakeholders to drive value versus just driving drug utilization. And to deliver on this, pharma will need to shift its go-to-market model from share-of-voice promotion to one centered on meaningful dialogues with institutions about meeting their overall care and cost objectives."

Those dialogues will have to justify themselves too, just like the drugs will. With the force of momentum behind it, outcome-based decisionmaking may well spread beyond actual product choice into other places, such as marketing itself. "Pharma will find itself having to be far more financially rigorous, with increased accountability and transparency," says Rob Rebak, CEO, QualityHealth. "Spending in areas like marketing, long supported by analysis but often determined by the discretion of the brand team, will be tied to the outcome of the marketing activity. I am encouraged that this will accelerate a larger scale shift to performance-based marketing services, which I have been evangelizing for several years now."

From a sales strategy perspective, the long coat tails of PPAC may well exacerbate one of the industry's long-standing challenges – the availability, or lack thereof, of physicians for personal promotion. But this too, like most of the act's effects, could be an opportunity disguised as a challenge.

"The combination of an influx of newly covered patients in the market for healthcare as a result of Affordable Care Act provisions and a lower percentage of new physicians going into family practice or GP specialization will exacerbate field sales' challenges to reach HCPs for personal promotion during office hours," says Karen Lichtig, senior VP, alliance management and partner enablement, CMI/Compas. "To help balance the patient load, NPs and PAs will need to be prepared to address a wider range of indications to support a busy FP/GP office. This offers us an opportunity – non-personal promotion strategy (especially point of practice and digital channels) will become even more important to reach and inform this increasingly influential audience as well as capture whatever still remains of the physicians' share of mind. I predict that in 2013 we will see both a dramatically increased effort to reach out to NPs and PAs, and we will enhance our measurement tools to capture the impact of this group."

Another existing trend that may be pushed along further by the impact of PPAC is demand for health information through easily accessible digital sources.

"Looking forward, more people will have access to healthcare coverage," says Marc Weiner, managing partner, Ogilvy CommonHealth Worldwide. "That means more patients competing to see a finite number of healthcare professionals. Quite simply, it's getting harder to schedule a visit with a physician.

"Patients are already turning to the web for more information, but we believe they want more than text. Patients at all levels respond to video-based learning, and we anticipate that the need for video will continue to increase.

"Doctors will have less time to train (and retrain) patients to participate in their own health and wellness. As such, patients are likely to 'fill in the gap' by watching videos that answer questions exactly when they need answers."

A well-produced video, Weiner believes, can demonstrate a technique that transcends educational, cultural, and language barriers. A busy caregiver may want to access a longer, more detailed video series from a desktop. Later, that same caregiver may need a quick refresher from an iPhone, if he or she is on vacation.

"We're seeing increased queries about scalable video projects," Weiner says. "Specifically, brands want to create one asset that can be leveraged across markets, translated into multiple languages, and formatted for multiple digital channels. Look for more videos being distributed across public platforms like YouTube, but also through private channels like physician portals."

PPAC isn't quite the end of the story for policy-watchers in 2013, though. The ongoing "fiscal cliff" discussions, however they are resolved, have the potential to add another variable to the industry's equations, especially in the pricing area.

"The outcomes of fiscal cliff discussions will impact pharma more immediately," says Ganesh Vedarajan, principal and leader of the oncology and specialty therapeutics practice, ZS Associates. "If Medicare payments are cut dramatically in 2013, then this will trigger increased pricing pressures and cause pharma to adjust its pricing and discounting strategies for buy-and-bill products."

BEYOND THE PILL

One of the key marketing stories of 2012 was how pharma brand managers have been pushing "beyond the pill" by adding complementary services to their brands to try to play a larger role in the entire patient care continuum. Although a few product categories experienced this trend full-force in the past year, the new year is expected to send it broader and deeper into the marketplace. But as with most hot marketing trends, brand managers should be wary not to fall in love before they know a bit more about their intended.

"There is no question this is a trend we see with our clients, and one we expect to continue," says Rick Edmunds, senior partner and leader of the global health practice, Booz & Company. "However, we should be wary of looking to the past as a guide to a future model. Certainly there have been individual successes, especially where we have seen platforms that help patients engage in their disease more productively. This includes past efforts like patient support services to enable adherence during the rough start-up of drugs in MS, as well as more recent examples using gamification, to engage groups of patients to better understand their disease implications and treatment requirements. At the same time, though, a lot of money has been spent on 'beyond the pill' offerings that do not add value, nor do they enhance the financial results of the drug brand."

The key to getting this right, Edmunds believes, is an end-to-end, multi-stakeholder (patient, physician, payer, et cetera) view of the clinical, economic, and experiential pain points each stakeholder faces as the patient progresses through the disease. This understanding will provide the insight to assess whether adherence services, educational apps, e-diagnostic services, in-home delivery, or other such services will make a difference. "Digital technology holds great promise in providing these solutions, and in the New Year we will be supporting the creation of breakthrough digital platforms to greatly enhance 'beyond the pill' offerings," he says.

Implementation of successful "beyond

The leader of an executive search company offers her perspective on "behind the pill"

The popularity of the catchphrase "beyond the pill" tells us that large numbers of people recognize the need for change in our industry. Among other signs, there is the transformation of the traditional sales force, marked by role consolidation as pharma slashes sales and marketing staff. As head of Bench International, an executive recruitment company focused on life sciences, I've seen the birth of a new skill set. Call it the super MSL (medical science liaison). The core competency is the ability to represent a product across a broader swath of the medical community. That may entail reframing the product, not just to physicians but to patients, advocacy groups and insurers. Individuals who possess these skills, many of them M.D.s and Ph.D.s, must confidently represent or advocate for patients in a disease state as well as for the pharma and device sector seeking the privilege of serving them. The idea is not brand new, but the tide in this direction is noteworthy. From the vantage of attracting and retaining talented leaders, the human asset in most demand is no longer the detailers' direct sell to physicians. It's the deep scientific, medical, or procedural knowledge base offered to pharma and device industry "clients," be they providers, payers or patients. The conversation truly has moved beyond conventional sales and marketing. We're talking about significant technical achievement and skill, provided to pharma by a smaller pool of executives than in the past. They enter at a higher pay grade, and they also may prove to be harder to retain. This is a reformation in the skill set necessary at the pulse, where the product is delivered and consumed.

There is a second nuance to the phrase "beyond the pill." It describes a trend in which healthcare companies – drugmakers among them – devising apps for iPhones or Android devices that remind patients to take their meds. To me, this is simply substituting one type of product for another, and doesn't get at the heart of the word "reformation." Why? Because companies really need to think about leveraging the assets they have by being so narrowly product focused. Brand focus is their tip of the tip of their iceberg.

I don't dispute that medication non-adherence is a problem for patients and for pharmaceutical companies. The U.S. drug industry loses $188 billion a year because patients fail to fill or refill their prescriptions, according to Capgemini consulting. I guess it's encouraging to see drug companies developing health-related apps to keep patients compliant. At a site called Pocket.MD, you can click on any pharma company and call up lists of their smartphone offerings. And it's not just about prescription adherence. Digital health apps, which now number more than 17,000 according to Frost & Sullivan, are becoming a new drug-marketing channel. My point is that commentators who are huge fans of mobile e-health may be missing the point – at least in reference to the drug industry. The revolution we want to see in healthcare isn't the discovery of new marketing channels, with or without sexy devices and software. It's finding better, more effective ways of putting the patient first.

A model leader of a pharma company who thinks well beyond pharma is Clive Meanwell, M.D., the chairman and CEO of The Medicines Company. Clive, at his core, is a futurist as well as a hands-on businessman. Meanwell tackled the puzzle of why critical care units of some hospitals experience different patient outcomes who have experienced the exact same illnesses and procedures. Beyond devising and marketing heart medicines, he set about raising the overall level of patient care in CCUs. In a recruitment context, I'm struck by Meanwell's ability to turn these ideas into core values for attracting "thinking and doing differently talent." You don't get hired at the Medicines Company unless you know that it is your responsibility is to improve the life of patients' lives.

- Denise DeMan, chairman and CEO, Bench International

the pill" offerings so far has been spotty, with most of the notable successes coming from high-price brands like oncology and large molecules, as well as chronic areas like diabetes and multiple sclerosis. According to Pratap Khedkar, managing principal and leader of the global pharmaceuticals practice at ZS Associates, brands like this come with a built-in related services advantage because the patient so obviously needs assistance dealing with the complexities of both the drug and their condition. Small molecule brands have been another matter, but their day may be coming.

"Many pharma companies have added related services for staff and patients (e.g., reimbursement services, patient tools, nurse educators, et cetera)," Khedkar says. "Most oncology and specialty [large molecule] companies do this often and well, largely because the customer clearly needs help. Small molecule brands have struggled to create complementary services, and have largely created alternate channels to deliver traditional value propositions, including information and patient resources. These will find more traction in 2013-2015 as companies harmonize the channels and the roles. This will be a scaling – not a change in value. New value-add will come from in-home devices and monitoring to directly address the patient, but pharma may not have a monopoly on this."

Khedkar and his colleagues at ZS also expect a bump in the use of companion diagnostics.

"Companion diagnostics associated with the use of a product are not very prevalent; 1 percent of brands have one today," he says. "But clinical trial pipelines indicate that 30 percent to 50 percent of treatments will need biomarkers in the coming years. As more products launch with a biomarker diagnostic, the 'dual' launch will be more complex, as companies are not experienced in this."

Beyond that, companies are offering or considering an array of products, including pills, devices, and services, to serve the full needs of the customer, typically within a disease area or for a specialty. This, Khedkar says, may include services far removed from a drug product (e.g., practice management). But customer-centric solutions by pharma companies have not realized their potential so far, due to compliance concerns, margin dilution, and the inability to merge silos between product divisions.

Another barrier to going beyond the pill has been a lack of payer support and complex reimbursement, especially when it comes to adding companion diagnostics or owning multiple solutions in a disease area. "Payers, with their siloed budgets and focus on cost, have not supported such linkages," Khedkar says. "As reform creates ACOs and providers willing to focus on outcomes, this may change, but it is still a few years away."

Coordinating a solution that connects disparate parts of the delivery system with a treatment package that can prevent or substantially delay increasingly intense levels of patient care, reduces incidences of redundant care, and reduces total costs of care to the risk bearing entity seems like it should become a winning combination; doing so, however, far exceeds the traditional label indication and will require some rewiring, both in the minds of marketers and marketees.

"Pharma companies are going beyond the pill, adding complementary services to their brands to assist in patient compliance, disease management, nutritional habits, and other services that serve to coordinate patient management while on therapy," Evans says. "This type of packaging and the reimbursement of an outcome also implies that these are not subsidized extras, but in fact are required parts that drive an outcome solution with a very different price to value than the traditional unit based sale."

In 2013, Evans expects remote monitoring via mobile devices to support patient adherence and to better understand the effects of a particular remedy on a particular patient will continue to grow, as will the data that can be added to the EHR. Pharma will also continue to move more aggressively into the health management space, with compliance programs, nutritional advice, wellness promotion, health screening and other such services, with a broad range of partners in order to forge closer relationships with the patients who use their products and services and to create outcomes that align with their provider and payer incentives.

"We believe a golden era lies ahead for pharma, but pharma companies have to decide to thrive in it," Evans says. "Those that do will have to face the crucial need to marry the pipeline with the new market definition of value. The industry has spent billions to develop new drugs, but it continues to focus on 'me-too' or small population, high-price specialty treatments, even though outcome demand and customer expectations around chronic disease and population management are changing dramatically. Pharma companies need to shift from a mass-market, one-size-fits-all approach to a targeted, segment specific value delivery approach that aligns with and responds to the new incentives and business models that their customers are adopting."

According to Will Reese of the ad agency Cadient Group, the most impressive complementary services pharma companies have added to their brands so far have been in the multiple sclerosis and diabetes categories.

"Providing the ability to connect with nurses and diabetes educators and receive greater peer social support has become an important differentiator and driver of consideration in chronic disease categories," Mr. Reese says. "The most successful brands have balanced their investments in specific services with the efforts needed to ensure the services are integrated across marketing efforts, including professional, and easily accessible across customer channels."

One recommendation Reese has for prospective beyond-the-pill adherents is to look outside. "Successful organizations will partner with strong, well-established patient service groups and build valuable programs versus building their own services from the ground up," he says.

Jessica Brueggeman, VP of the health behavior group at the ad agency Micro-Mass Communications, has observed this very development in the marketplace.

"We've seen the development of initiatives and formalized partnerships at the corporate-level that combine pharma's expertise with unique products and services from external partners (e.g., integrated delivery networks, advocacy groups, technology products)," Ms. Brueggeman says. "Examples of this trend include Merck's patient engagement collaboration with Geisenger Health System, which looks at innovative ways to drive shared decision making and adherence to treatment plans. Another example is the partnership between Boehringer Ingelheim and Healthrageous to develop a pilot program targeting lifestyle and behavior modification in patients with type 2 diabetes."

With the story having barely started, significant room seems to exist for beyond-the-pill initiatives to become even more valuable than they are today. "Many programs, whether initiated at the brand or corporate level, are still very product or disease centric, addressing just one aspect of patient care," Ms. Brueggeman says. "This limits their ability to be embedded broadly as real world solutions. In the future, we anticipate that pharma companies will go beyond an external focus and partnerships. They'll take on the more difficult task of looking inward at their own capabilities, not just for the ability to generate insights to market products effectively, but to really examine and build the internal skills, processes and priorities to effectively and broadly impact patient outcomes."

One dangerous temptation for marketers may be wanting to tack on services later along in a brand's lifespan when the idea of an integrated approach should have been built in from the beginning. Cavan Redmond, the CEO of WebMD and a former top leader at Pfizer, cautions against this sort of short-term thinking.

"First and foremost the biggest challenge for pharma companies in moving beyond the pill is avoiding the impulse to simply 'add on' services."

"First and foremost the biggest challenge for pharma companies in moving beyond the pill is avoiding the impulse to simply 'add on' services," Redmond told *Med Ad News*. "The industry should seek to offer truly integrated approaches to the healthcare experience that brings value all along the spectrum. Embedding holistic, innovative thinking from the beginning is essential. Therefore, the best opportunity of success is likely to be seen in those products seeking approval where, from the very outset, there has been a device or companion diagnostic integrated into the continuum to improve the overall health benefits."

RESTRUCTURING

Uneasy has lain the head that wears any job in pharma over the past year, for fear of receiving a pink slip. Companies big and small alike have busied themselves with resizing, outsourcing, and all the other euphemisms for letting people go. With the age of the traditional blockbuster nearly over, the viability of large research organizations prominently in question, and sales strategies shifting away from the face to face approach, this trend shows no sign of ending in 2013, though the pace may slow somewhat.

"Sales forces and corporate expenses have been cut at a furious pace driven largely by the patent cliff," Khedkar says. "While 2012 saw the most significant drop in patent coverage, the next two years will see more restructuring as additional products go off patent. After a 45 percent reduction in sales personnel over the last few years, however, we expect restructuring to occur at a slower pace before we turn the corner in 2014-2015."

Hiring will bounce back as pipelines pick up, Khedkar expects, although it will only be a modest bounce given concentrated customer bases. Operating at a lower cost at headquarters, however, will become the long-term norm, since this trend is also driven by strong payer pressure on profits, emerging markets' needs, and centralization of services.

"We expect more companies to outsource multiple aspects of commercial operations, sales, and even marketing," Khedkar says. "This is true of big pharma as it tries to cut costs and emerging small pharma as it tries to contain costs. In addition, the combination of specialization and scale helps third parties deliver supporting services at lower costs and higher quality. This, in turn, enables pharma to focus on its core competency of molecule development and customer promotion."

Ms. Lurker agrees with Khedkar's estimate of the coming pace of restructuring. "We have absolutely not reached a 'happy medium' in headcount reduction and continued outsourcing," she says. "As we look forward, we see patent cliffs continuing to roll on in 2013 and beyond. As a result, restructuring with continue, but not at the same pace as in prior years. Becoming more efficient is not something new. We are simply following trends set by other industries before us, such as finance and retail. And like other industries, we are beginning to embrace technology trends. Leveraging our ability to reach patients and physicians through technology, coupled with enormous cost pressures will continue. The ability to deleverage and create flexible organizations will be the industry's model of the future."

In the rush to "right size," though, pharma organizations may be tossing away a good deal of what has made them innovative in the first place, not to mention the morale of their own employees. Denise DeMan of the executive search company Bench International believes that this increasing pressure to shed numbers is making the beginning of 2013 a critical time for corporate soul searching.

"On the one hand, drug companies shed workers at a slower pace in 2012 than the year before," Ms. DeMan says. "Our industry lost a little under 13,000 jobs in the January-November period, compared to more than 20,000 in the same period of 2011, according to employment consultants Challenger, Gray & Christmas. On the other hand, these layoff numbers are still very high, with a weighting in critical R&D activities, and with a devastating impact on the social ecology pharma and the device sectors."

Ms. DeMan fears that the industry's leaders have failed to consider the toll that these waves of layoffs are taking on their companies.

"What becomes of bravery, and the will to invest in new medicines?" she says. "Merry Christmas. We are having a big layoff. Now the rest of you who dodged the bullet be prepared to start the new year refreshed, revitalized, and excited to take on the challenges of the new year. I'll never forget what I was told by one of my clients, a senior executive in pharma. 'Our raison d'être is to make people well,' he said, 'yet we are made to feel vulnerable, insignificant, and physically ill in the process.'"

It is true, Ms. DeMan believes, that the industry lived too long with bloated payrolls, under the doctrine that bigger is better. "We now know that better is better and size does matter, though not the way we thought. The lesson, for some managers, is to shrink and become more nimble. Yet slash-and-burn cuts into the soul of the

organization, the values, the belief system, and the sense of trust and connection."

The sense of vulnerability created by this approach can lead to retention breach. "Consider an employee who has proven critical to a business and has been advanced quickly," Ms. DeMan says. "We see that these very employees start to falter, to deliver less, or to make errors in judgment. Companies must ask themselves if they have caused the burn-out or disenfranchised key human assets."

The question for rapidly resizing companies is how to avoid these scenarios, though Ms. DeMan is reluctant to answer, since doing so would be against her own business interest. "How does a company protect the health and well-being of the talent that's developing the products on which they depend?" she asks. "It's important to add that this vulnerability is a clarion call to recruiters. Headhunters win by listening to the pain, by recognizing the unresponsive workplace, by hearing the questions valued staff quietly pose to themselves. Maslow kicks in and their disenfranchisement leaves the employer vulnerable because talent will be stolen from under their noses."

Resizing without irreversible trauma in an era of increasing cost pressure will require complementary thinking; trying to cut costs while at the same time keeping the company's best minds happy and preparing for future growth. The consultants at Booz & Company call this approach "Fit for Growth" – "A more strategic approach to costs that helps companies save but still prepare to grow," Rotz says. "To borrow an analogy, the idea is to move from 'crash diet' cost saving initiatives – e.g., restructuring to address a wave of patent losses – to an ongoing cost fitness regimen where you can build muscle and lose weight at the same time."

Before any significant decisions about resizing are made, Rotz suggests that companies should address two prior questions: "Where should we grow?" and "What are the few truly difference-making capabilities we need?"

"Armed with answers to these questions, executives are well-equipped to align resources, including how to reduce spending on capabilities, and headcount, outside those areas deemed to be 'difference-making,'" he says. "It also presses executives to determine where business model changes – and the capabilities required to deliver on them – can deliver more substantial productivity compared to current efforts that try doing the same thing with less."

Whatever strategy companies choose, Ms. DeMan believes that the year 2013 could be a turning point in pharma's grand effort to figure out what human resources it really needs and how they should be cared for – the time for the industry to get away from slash and burn and back to fundamental principles. Otherwise companies may pay a high price for their lack of vision.

"It's a time to learn that those of us who have chosen a life path of human health, either attempting to manifest it, or to be a service company supporting them, we are all servant leaders, we are servants of a population that wouldn't turn to us if they weren't sick," she says. "How can we focus on the patient, create important products, and get them to sick/hurt individuals if our companies are populated with fearful, sick, insecure people? Somewhere along the way, we're forgetting that men and women who create products, develop training programs, and design the services of next-generation pharma companies must themselves feel honored, protected, and viable."

BIG DATA

"Big Data" may well have been the buzzword(s) of the year for pharma technologists in 2012. Marketers seem to have no trouble at all collecting mountains of data on whatever topic or audience they wish – or, at least, talking about the mountains of data they plan to collect and how it all will help them reach some heretofore unattainable level of targeting nirvana – but actually processing and responding to all this information is another matter.

"Access to more data doesn't necessarily result in better insight," says Stephen Wray, president and CEO of the Cadient Group. "The value of 'Big Data' will remain marginalized until we focus upon making it actionable, by aggregating the most essential findings, visualizing key strategic insights, and making those insights portable across various levels of strategic stakeholders within organizations. Unless we focus on converting big data into a more user-friendly information flow, the pain points that have handicapped the industry's analytics process will only be exacerbated by the increasing volumes of data available for analysis."

In order to do this, Wray suggests that companies should begin to look to take advantage of advanced business intelligence tools that will allow them to access numerous data sources simultaneously, mash up data from numerous channels, and visualize the data in a user-friendly manner. Performance indexing and competitive analysis must also be enabled in one integrated process.

Even the best tools, though, won't necessarily help separate the useful from the rest; that is a judgment that real people need to make. Adam Budish, senior VP of sales at Epocrates and a decided "Big Data" skeptic, calls this Real Data.

"'Big Data' may have been a hot topic for 2012, but it didn't generate much action," Budish says. "Focusing on the amount of data is counterintuitive to what actually needs to be done with quality data. We should be drilling down to the precise moment that a physician is making a life-saving decision and focusing on the information they need at that point in time. Real Data will tell you what they are looking up and what information would be relevant to be delivered to them."

Embracing Real Data, Budish believes will help pharma companies gain a better understanding of physicians'needs and behaviors while helping them see which resources may be most beneficial to which audience at what time and on which channel.

This will enable pharma marketers to provide more targeted and dynamic content to their target audiences based on Real Data and real world scenarios, ultimately generating – another Budish catchphrase – Real ROI.

"Currently, in the absence of market standards for data evaluation and sharing, it's on the companies to ask for Real Data versus a large pile of 'Big Data,'" Budish says. "Making the distinction will lead to better decision-making and optimized campaigns, and proven ROI will follow suit."

The leaders at Veeva Systems, a company that plays with data all day long, take a similar view, meanwhile warning of the dangers of that old business bugbear of balkanization. "New technologies have certainly made it much easier for pharmaceutical companies, marketers in particular, to collect mountains of data from vari-

"We're forgetting that men and women who create products, develop training programs, and design the services of next-generation pharma companies must themselves feel honored, protected, and viable."

Top 10 of 2013

PwC's Health Research Institute has identified ten issues as the top focus for the health industry in the year ahead.

1. States on the frontlines of Affordable Care Act implementation
Over the next year, state officials must decide how to run insurance exchanges, whether to expand Medicaid coverage, and what type of insurance market regulation is needed. The biggest challenge states may face in 2013 will be information technology. Designing infrastructure to create a single, seamless entry point to the exchange will require some states to undergo a major overhaul of existing Medicaid eligibility systems.

2. Consumer revolution in health coverage
Consumers' rising voice on how they spend their healthcare dollars, coupled with state insurance exchanges, is prompting the health industry to compete on attributes similar to the retail industry: convenience, price and transparency. HRI found signs that consumers already are warming up to new ways of purchasing insurance: nearly one-quarter (23 percent) of consumers surveyed said they are likely to buy health insurance from non-traditional sources such as a retail store, up from 18 percent in 2011.

3. Medtech industry braces for excise tax impact
A 2.3 percent excise tax on medical device companies takes effect on January 1, 2013, representing potentially $29.1 billion to the federal government over the next 10 years. The $380 billion global medical device industry is unlikely to be able to pass the tax on to its customers, but could look to its suppliers to share in the burden. Some companies could owe more in taxes than they generate in profits, making them less attractive to investors but more enticing to larger companies looking to expand their portfolio. The tax impact should kick start new innovation, industry consolidation and operational recalibration in the medtech sector.

4. Caring for the nation's most vulnerable: dual eligibles
Dual eligibles – people who qualify for both Medicare and Medicaid – make up many of the 16 million people the ACA will add to Medicaid rolls by 2019. The cost of care for duals is skyrocketing – much of it wasted due to a lack of care coordination between the two programs – and 70 percent of state Medicaid spending on duals goes to long-term care support services, such as nursing homes. Cash-strapped states are increasingly turning to the expertise of managed care companies to better coordinate care, and they are seeking innovative solutions, such as from the technology sector, to better support home-based care and caregivers.

5. Bring your own mobile device: convenience at a cost
Doctors and nurses are bringing their own mobile devices to work, but many hospitals do not yet have a secure enough environment to protect sensitive patient information. Sixty-nine percent of consumers surveyed said they are concerned about the privacy of their medical information if providers were able to access it on their mobile devices. According to PwC, only 46 percent of hospitals have a security strategy to regulate the use of mobile devices.

6. Goodbye cost reduction, hello transformation
With reimbursement resetting under the ACA and pressure from the federal budget crisis and price-conscious consumers, hospitals are scrambling to further reduce their costs. HRI research found that 40 percent of consumers postponed care in 2012 because of the costs. Having already plucked low-hanging fruit with labor productivity and supply cost reductions, more hospitals in 2013 will embark on full-scale transformation efforts to redesign how they deliver care.

7. Customer ratings hit the pocketbooks of healthcare companies
Paying for performance will take on new meaning in 2013 as consumer reviews generate penalties and bonuses for hospitals and insurers. This could mean a bonus payout of more than $3 billion for insurers and a hold back of $850 million for providers in 2013. Healthcare companies will need to invest in consumer research and education in order to take full advantage of the new payments.

8. Meeting the new expectations of pharma value
Physicians, once the primary arbiters of pharma value, now have less say in payment decisions than insurers and large providers. The final hurdle in the long, expensive path to drug and device development is not regulatory approval, but rather reimbursement. Though pharmaceutical and medical device companies play a pivotal role in health outcomes, they will have to prove it to earn it by demonstrating their value and comparative effectiveness.

9. Bigger than benefits: employers rethink their role in healthcare
For nearly 70 years, employer-based coverage has been a cornerstone of U.S. healthcare - but healthcare and employers may not be inseparable. With the Supreme Court ruling to uphold the ACA and the re-election of the President, employers have an opportunity to re-examine their long term role in providing healthcare coverage and explore alternative approaches provided by state and/or private exchanges. In 2013, CEOs will ask tough questions about how and why so many resources are going to something that is not core to the business. The answers will vary by company, some of which are likely to transition away from healthcare coverage while others will redesign their benefit strategies.

10. The building blocks of population health management
Medicare's accountable care organization and patient-centered medical home initiatives laid a foundation for improving population health, but other collaborations are fueling growth in population health management. In 2013, more companies are likely to form partnerships to build their population health IT infrastructures and to share responsibility for patient outcomes and satisfaction, data collection and analysis, member education and engagement, with a focus on at-risk populations.

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ous channels – all promising huge insight," says Paul Shawah, Veeva's VP of multichannel CRM. "This is good, but collecting relevant data is better. However, many marketing organizations are struggling to realize the benefits of big data due to the difficulty in integrating data from multiple channels, all siloed. At best, cross-channel interaction data is stitched together after the fact, but that is often delayed and only a partial view. At worst, it is not captured at all. The marketing team, therefore, never gets a complete perspective of the physician across all channels and the process is grossly inefficient."

In 2013, Shawah suggests that the pharma technologist's focus is going to turn from "Big Data" to Relevant Data – "In other words, how can pharma capture and consolidate data from all of the interactions that a physician has with the company through all channels AND put it into context.

"Also, how do you simplify this analytics process for marketing teams? New technologies will emerge to enable both consolidation of interaction data and orchestration of sales and marketing tactics from across all channels. The result will be better, real-time customer insight and a more orchestrated customer engagement approach across channels. Marketing will be able to answer the question, 'How do I spend my limited budget for maximum return?'"

Asking the question is easier than answering. One industry analytics specialist offers the industry-perplexed three potential areas of focus.

"'Big Data' enables evidence-based reasoning on a broader and deeper scale, with more data being analyzed and brought to bear in clinical, behavioral, and marketing decisions," says Scott Nesbitt, executive VP, analytics, insight, and strategy, PatientPoint. "To better manage the information, marketers need to focus on three areas: first, a move toward actionable insight; second, expanded personnel skillset; and third, better data relationships."

Regarding Nesbitt's first area, the field of data analytics is continuing to evolve from the reporting of data to the interpretation and understanding of data. "Just spewing out data in reports, charts, and tables is no longer the end point for the pharma technologist," he says. "The challenge is to provide actionable insight. The industry needs to convert 'Big Data' into 'Big Insight.' For example, it is not enough to know that 'we need to improve adherence.' The insight is that 'we can improve adherence by proactively analyzing and identifying patterns leading to non-adherence and suggest regimen changes that lead to better adherence and improved outcomes.'"

Next up, the expanded personnel skillset. A new hybrid of data analyst has evolved, one that is in high demand and short supply. This analyst can decipher the data and think like a business person.

"Because of the complexity of 'Big Data' and the millions of paths down which it can lead, a need now exists for an empowered analyst as thought/business leader," Nesbitt says. "Analysts no longer simply report the data and 'pull crosstabs' for the marketing department. Instead they need to understand and learn all aspects of the business and focus on providing both actionable insights and business solutions – not just data."

And finally, better data relationships. Healthcare is arguably the most complicated topic in the world. The inter-relationship of genetics, personal history, medication, and lifestyle, among other factors, means that each person's health is individualized to an impressive degree.

"The movement toward the integration of all the data into longitudinal patient-centric relational databases is paramount to developing the right solutions for each patient," Nesbitt says. "Insights gained from proper use of 'Big Data' will help physicians and pharmacists better match and fine tune regimens to specific patient needs, leading to improved patient outcomes and reduced healthcare costs."

One potential source of insight that some companies may be overlooking in their rush to all the data that comes from electronic health records in hospitals, insurers' claims and cost data, pharmaceutical clinical trials, health risk assessments, and the rest is that which comes with another of the industry's buzzwords: social media.

"Social media is a rich source of data and an opportunity for health organizations to interact with communities of both consumers and clinicians," says Andrew Gunn, director, pharmaceutical and life sciences advisory, PwC. "A recent PwC Health Research Institute survey found that one-third of consumers are using social media for health-related matters. Yet social media has largely been used in healthcare as a tool for one way education and promotional activity, which represents unique challenges for pharmaceutical companies."

"Inasmuch as marketing has a responsibility to communicate the value of the medicine, 'Big Data' is likely to make life more difficult."

As marketers become more sophisticated in their use of data, Gunn suggests that social media will become a more valuable source of actionable business intelligence about consumer preferences, expectations and behavior, prescription adherence, product performance-quality and safety issues, unmet clinical needs, and emerging health concerns as well as sources for clinical trial participation.

Whatever the source, though, marketers should prepare themselves for many sleepless nights of figuring out the implications of all the data they were so overjoyed to access. In an inversion of the usual cliche, "Big Data" may well be a challenge disguised as an opportunity.

"Inasmuch as marketing has a responsibility to communicate the value of the medicine, 'Big Data' is likely to make life more difficult," Rotz says. "Whereas historically the manufacturer had good control and visibility of the clinical trial data that underpins the product's value proposition, the rise of 'Big Data' – and specifically real-world data on the products – will make shaping the value story much more difficult. A significant implication of Big Data is that pharma companies will need to create a forward-looking real-world evidence capability, which is inherently a cross-functional undertaking spanning commercial and medical. While control of the 'value message' for the product is just one implication, more generally, we need to remember 'Big Data' itself does not create wisdom or insight. Given all of the possibilities, pharma marketers will need to be even sharper on the questions they want to answer and how they will use those answers to drive performance." ■ MEDADNEWS

Three new predictions for pharma marketers in 2013

By Bill Drummy

Nate Silver of the *New York Times* astounded the political world by predicting the results of the 2012 elections with uncanny accuracy, while many so-called experts, including the revered and/or feared Karl Rove (who George W. Bush referred to as the "architect" of his 2004 re-election) were dramatically, historically, and embarrassingly wrong.

This brings to mind the promise and peril of the prediction business. I have been making predictions about the future of pharma marketing for more than a decade; sometimes I've come out looking like a svelte and psychic Silver; other times I resembled a rotund and retrograde Rove. And yet here I go again.

For 2013, I foresee three major developments that will have dramatic impact on how pharma marketers plan and execute their marketing campaigns, with those on top of the trends enjoying superior results and burnished careers. This year, the trends are not so much revolutionary as evolutionary: crystallizations of strategies that have emerged over the last several years, and refinements of platforms that are no longer new.

Digital marketing becomes "Marketing"

I am old enough (as my partners regularly tell me) to remember lots of things that nobody else does. When I was a kid, the TV networks used to announce that popular shows like *Bonanza* were "brought to you in living color." They eventually stopped doing that, long after it seemed superfluous, even to an 8-year-old. Well, we have reached that point with digital marketing. Virtually all marketing is now (or will be by next season) "digital" in some sense, whether it's detail aids on iPads, targeted campaigns driven by "Big Data" insights, or HCP programs that reach clinicians at the moment of care through mobile devices. Digital, digital, digital. So in 2013, smart marketers will not be asking, "What is my digital marketing strategy?" but, "How should my entire marketing strategy be digitally enabled?" Artificial distinctions will disappear. Everyone knows that *Bonanza* will be broadcast in color.

But this is more than just a change in nomenclature. In a more significant way, it signifies that marketers need to change their orientation to marketing. The fundamentals don't change: you still build campaigns based on audience insights, and you still need to conceive a strategy with differentiating creative. But no longer should you think in a pigeon-holed way about marketing "channels."

Rather, you maximize the power of all your marketing by using digital as a tool for deriving key customer insights, and then by deploying assets strategically to reach your targets most efficiently and effectively. To be clear: I am not saying that every tactic will be or should be digital. There are still good reasons for slim-jims, TV spots, and print ads. But the prism through which one peers into marketing strategy must be a digital one, and every component of the strategy should include measurement that is, inherently, digital. Think of it as making all your assets intelligent, in the way that they can smartly interact with their audiences, and in how they can tell you about themselves, in other words, how they can become, in a sense, "self-aware" and thus much more relevant to the audience and illuminating to the marketer.

So my prediction is this: Marketers who take a digital-centric approach will be significantly more successful in 2013 than their old-fashioned competitors (who may still be watching *Bonanza* in black and white).

The iPad dives deeper into sales

The entire industry has gone gaga over the tablet platform. And even though Android tablets from Samsung, Google, and Amazon have begun to significantly erode iPad's market share dominance (in Q3 2012, iPad shipments accounted for 55 percent of the tablet market, down 14 points from Q2 2012), in pharma, it's pretty much an all-iPad game, and likely to remain so with the Q4 introduction of the more labcoat-friendly iPad Mini.

The news here is that pharma companies will now make the platform much more impactful in 2013, in terms of both salesforce productivity and sales detail creativity. From the productivity point of view, by integrating the devices more deeply into closed-loop marketing systems, companies will achieve significant savings and greater clarity about salesforce effectiveness.

Many companies that took halting, conservative first steps with tablets in the name of expediency and risk-avoidance are realizing just how much of the value of the device as a sales tool they have been avoiding as well. (Throwing a PDF of a sales aid onto an iPad has not impressed many doctors.) Now we are seeing clients looking to use the full power of the device to make a deeper impression on HCPs. That means taking advantage of the iPad's GPS functionality, accelerometers, and built-in cameras, as well as design principles that are tablet-centric. The result in 2013 should be breakthroughs in sales effectiveness for those companies that deploy these devices to full effect.

Filling the gap between patient and HCP

With all the focus on the HCP-sales rep relationship, the most intriguing opportunity for pharma marketers may well lay in another space entirely – the dialogue between HCPs and their patients. Of course, pharma can't practice medicine or do anything that violates the sanctity of the patient/HCP relationship. But marketers can (and should) enable that critical dialogue – by providing tools that will help the HCP better understand a particular condition, and better inform the patient of how to best manage that condition, including how to best use their drugs. This is such a rich place to play that the possibilities appear almost as broad as your imagination as a marketer.

Here are just a few non-imaginary examples:

- An app that visualizes an algorithm for oncologists to help them understand which patients are right for a particular treatment – based on industry-accepted guidelines – made functional, impactful and user-friendly by a clear-thinking pharma company.
- An app that helps both patients and doctors see how the patient is progressing between office visits, that critical time when the effect of a drug starts to become apparent, but remains invisible simply because the doctor does not see the patient's progress first-hand. The app allows the physician to follow the patient's progress remotely, thus increasing the HCP's confidence in the treatment regimen, and the patient's willingness to adhere to the therapy.
- A web appliance that makes it easy for doctors to see whether a particular drug is covered by the patient's insurance plan, and which pharmacy in the area is currently stocking the product. Simple, useful, incredibly valuable to the doctor, patient and pharma company. Win-win-win.

I could go on. (We have seen, and built, many of these apps in the last 18 months.) This is perhaps the most exciting territory of the new pharma marketing, a place where marketers can do real good for customers, for patients, for their brands, and indeed or the industry's reputation. In 2013, I predict that at least six such apps produced by pharma marketers will make a measurable impact in the marketplace.

So will you see me in December wearing a wide smile as you honor my perspicacity, or will you instead be grinning at my gaffes? Time will tell, but I am far surer about these predictions than I was about the 2012 election, which turned out not to be very close, after all.

Bill Drummy is the founder and CEO of Heartbeat Ideas and Heartbeat West.

THE SHAPE OF MARKETING TO COME

The balancing act for 2013: optimizing multi-channel marketing through a next generation "enabled" sales force, seamless digital operations, valuable content and time-tested traditional elements.

By Christopher Wooden, Cegedim Strategic Data

The new year will bring exciting opportunities and challenges for pharmaceutical marketing. An expanding audience of physicians, payers and patients is more connected and online than ever – and more subject to information overload than ever. Value-creating marketing strategies in 2013 depend on the performance of each engagement channel in a company's network of touchpoints with healthcare professionals (HCPs) as well as patients and other stakeholders.

Currently, the multi-channel strategy encompasses all personal promotion, e-detailing, social media, print advertising, digital promotion, email campaigns and integrated telephone interactions. As channels evolve to keep pace with tech innovations, 2013 will see some companies adapt and leverage these dynamic tools to their competitive advantage over those that don't.

The United States is well aware of this transition. According to Cegedim Relationship Management's 2012 US Pharma Insights Report, 74 percent of survey respondents ranked the changing commercial business model as a priority. Organizations are coming to the awareness that doctors, patients and other stakeholders view drug purchases in much the same way they might shop for consumer goods and services

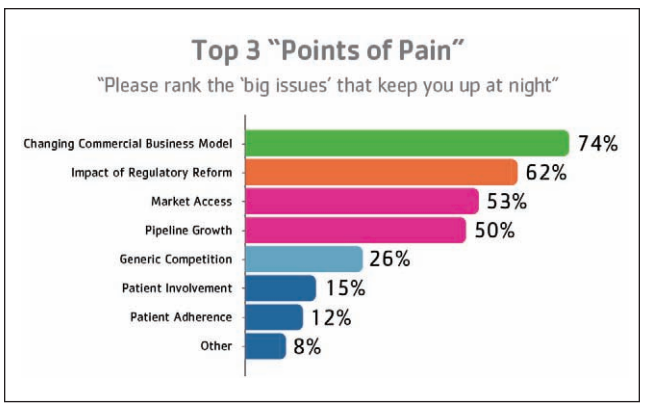
Transformations in conventional marketing underscore the need for diversified strategies. Pharma sales rep "detailing," face-to-face with individual HCPs continues a downward trend everywhere except emerging markets. Yet, this development may not be sufficient to provoke action. The flood of new technology comes with the associated potential for costly IT investments. In addition, any suggestion of "holistic" operational change may create apprehension as to revamping an existing multi-channel approach.

However, a strategic approach does not necessarily equate to a wholesale business reinvention, but merely a more intelligent merger of tools and practices that are already in play: personal interactions; traditional media; a comprehensive digital presence; operational excellence; and next generation technology.

Altered models: A condensed, more effective sales force

Facing numerous blockbuster patent expirations, current pharma industry pipelines will not yield the revenue to displace losses. Reducing sales force and budgets are unavoidable facts in this context. Accordingly, companies are forced to achieve more with less. Moreover, with one in five U.S. physicians now listed as "no-see" doctors, the traditional one-on-one marketing approach is no longer sustainable.

Nevertheless, face-to-face sales meetings will remain an essential part of the marketing channel mix. Indeed, a field user must be equipped to rapidly stimulate further engagement, tying the HCP into other valuable resources. Ideally, these will be available through a near seamless multi-channel offering. Serving as the lead-in and human side to the multi-channel environment, sales reps must be enabled to maintain high-level efficiency. Improved field practices will most likely come through upgrading tablet capabilities – cited as most companies' tool of choice (80 percent) according to Cegedim's 2012 U.S. Pharma Insights Report.



Instant-on capabilities and simple yet intuitive dashboards can save users precious moments in front of doctors with a waiting room full of patients. Further, enhancing reps' mobile toolkits can allow administrators to easily track performance, execute/modify activities, and quickly adapt to market transitions and specific budgets. Eventually, by enriching these channels with the fruits gleaned from "big data" from the right healthcare sources, companies will bring HCPs even more value.

As channels evolve to keep pace with tech innovations, 2013 will see some companies adapt and leverage these dynamic tools to their competitive advantage over those that don't.

Smooth out the digital interchange

Once a rep has aced the sales meeting and the physician accesses digital resources, or picks up the phone to close the loop, the rest is downhill – right? It is hard to believe, but many doctors agree that this channel is still far from a painless experience.

Blurry web conference meetings and accessibility issues act as powerful deterrents. Companies need to objectively evaluate web conference usability and find providers that alleviate confusion with reservations, dial-in numbers and access codes. Especially important for smaller practices, select technology that relies less on flashy interfaces and more on simple capabilities to eliminate compatibility issues for physicians with older hardware.

Extremely relevant for the e-detailing channel, webinars and webcasts – when done right – can offer clear value in terms of time saved and features offered. These interactions build on an existing, trusted relationship between a sales rep and physician – and ideally offer value which augments conventional sales calls. During a successful e-detailing session, reps can better manage the flow of information, and, because the interaction is based on a physician's schedule, can last significantly longer than traditional meetings.

Most importantly, streamlining digital communications can empower Life Sciences organizations with a clear, up-to-date voice in the current healthcare discussion. By integrating these channels, reps and other service providers within an organization can be easily reached if a doctor, patient or hospital administrator has a specific question about a disease, conference, referral, treatment or cost-benefit issue. Indeed, the right multi-channel strategy can allow pharmaceutical, medical device and biotech companies to quickly become more visible and accessible.

Building a more logical presence with resource-driven content

In the rush to boost their digital presence, many pharma company initiatives lack strategic planning and, in some cases, coherence. Best practice online depends on a logical, orderly and aesthetically consistent relationship of working parts.

Any use of social media for marketing and PR purposes requires a cohesive strategy. Understandably, the pharma industry has approached social media with caution due to regulatory scrutiny and potential public relations missteps. Yet, success with social media is possible in terms of building brand awareness and generating good PR – and several big pharma have demonstrated this admirably. But this is not accomplished quickly or without investment. Broadly speaking, those companies that have invested in well designed, content rich and accessible websites have also performed well in integrating new social media tools.

Some processes in this context should "go without saying" but incredibly, something as basic as making sure that social posts offer a well-planned click-though pathway begs to be mentioned. For example, if a physician clicks on a link from a company's Twitter feed for a page that highlights clinical results on a given drug, does that very same web page logically provide additional contacts and resources by phone, video and email? Some companies are truly "best practice" in this regard, whereas others clearly have room to improve.

Consistently left out of the multi-channel buzz, paper mail and print journals will nevertheless generate value and provide a means of increasing brand awareness. With many online publications featuring distracting, animated advertisements and less than relevant, in-your-face videos, gleaning useful information can be frustrating for many users. In this context, the now underused and it's-so-traditional-its-old-fashioned channel of print could see a comeback. Perhaps ironically, print may offer a "new" opportunity to differentiate a brand and increase visibility.

Of course, the content, services and interaction offered should always be of the highest quality and significance to the targeted stakeholders. Consider the century-old Merck Manual as a resource archetype that has successfully integrated with digital channels. Now very active on social media, this paradigm could be applied in a product-specific format for companies to generate more meaningful feedback loops with all targets in a similar fashion.

Best practices in 2013 will be a hybrid of old and new. Undoubtedly, companies that achieve cohesion between perfecting the basics, empowering field users, and streamlining their digital channels will deliver value to stakeholders and shareholders alike.

Christopher Wooden is the VP for global sales at Cegedim Strategic Data.

Top 10 pipelines

GlaxoSmithKline and Roche's extensive and diverse product pipelines are recognized as leaders in multiple categories.

By Andrew Humphreys andrew.humphreys@ubm.com

This annual special feature identifies and profiles 10 therapeutic pipeline categories covering pharma, biopharmaceutical and biotech companies as chosen by *Med Ad News* editors. Winners in each category were selected based on pipeline depth, diversity, innovation, and commercial potential. In determining the winners, with the exception of the Best Mid-Stage/Early-Stage Pipeline selection, a special emphasis was placed on late-stage products with blockbuster potential because so many mid-stage and early-stage candidates do not reach the marketplace. The information for this special report was gathered from company and industry sources as well as internal resources of *Med Ad News*. The pipeline reviews are listed in alphabetical order by company.

BEST CNS PIPELINE: BIOGEN IDEC

Biogen Idec discovers, develops and delivers innovative medicines for neurodegenerative diseases, hemophilia and autoimmune disorders to patients globally. Established during 1978, Biogen Idec is the world's oldest independent biotech entity. Worldwide, patients benefit from the Weston, Mass.-based company's leading multiple sclerosis therapies: the blockbuster brands **Avonex** and **Tysabri**.

Dimethyl fumarate (product code BG-12) represents the next promising MS treatment and anticipated mega-brand for Biogen Idec. The 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 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 other October 2012 news, a pre-specified analysis of integrated data from the Phase III DEFINE and CONFIRM trials for dimethyl fumarate demonstrated statistically significant and clinically relevant effects in reducing MS relapses and progression of disability, as well as reductions in MRI measures of disease activity. Interim safety data from a Phase III extension trial indicate that continued exposure to dimethyl fumarate did not lead to any new or worsening safety signals. Alo, the drug's safety and tolerability profiles were consistent with previous studies.

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.

PEGylated Interferon beta-1a is a chemically modified version of interferon beta-1a, and is designed to increase half-life and systemic exposure of the protein. Biogen Idec is developing the drug candidate in Phase III trials for relapsing forms of multiple sclerosis.

PEGylation extends the half-life of Interferon beta-1a, potentially enabling dosing every two or four weeks instead of the once-weekly administration of intramuscular IFN beta-1a. PEG-IFN beta-1a is anticipated to offer efficacy at least equivalent to that of intramuscular Interferon beta-1a 30 µg. Because PEG-IFN beta-1a may help address unmet patient needs, U.S. regulators granted this product candidate Fast Track designation.

The investigational, once-monthly subcutaneous therapy **daclizumab** high-yield process (DAC HYP) is being developed by Biogen Idec in Phase III for treating relapsing-remitting multiple sclerosis. A humanized antibody specific for the interleukin-2 receptor, daclizumab is being developed under a collaboration with **Abbott** Biotherapeutics. The drug is believed to work by selectively binding to and inhibiting the high-affinity IL-2 receptor on activated T cells (immune cells) without resulting in T-cell depletion.

Ocrelizumab is in Phase II trials for relapsing-remitting multiple sclerosis. This humanized anti-CD20 mAb is being developed in a collaboration with **Genentech**, a wholly owned member of Roche. For more details, please see the Roche Best Biotechnology Pipeline entry.

Anti-LINGO 1 is a monoclonal antibody in Phase II trials. Data from animal models have demonstrated that the product candidate promotes remyelination and axon survival. Proof-of-concept studies in optic neuritis were anticipated to begin in fourth-quarter 2012, and in second-half 2013 for multiple sclerosis.

Biogen Idec struck a deal with **Isis** Pharmaceuticals during December 2012 on a worldwide collaboration. Biogen Idec and Isis plan to discover and develop antisense drugs against three undisclosed targets for treating neurological or neuromuscular disorders. The companies are developing antisense products to treat spinal muscular atrophy and myotonic dystrophy type 1 under previously established collaborations.

Biogen Idec has several development programs for amytrophic lateral sclerosis (ALS). The company in 2012 entered into a research collaboration with Duke University and HudsonAlpha Institute to sequence the genomes of up to 1,000 people with ALS during the next five years to gain a better understanding about the fundamental genetic causes of the disease. Biogen Idec also established a research consortium in collaboration with several top academic research centers to identify new approaches to treating ALS. The company has dedicated significant funds to the University of Massachusetts Medical School ALS Champion Fund to spur awareness of amytrophic lateral sclerosis, and support basic and clinical science research into potential treatments for ALS and other neurodegenerative diseases.

BEST BIOTECHNOLOGY PIPELINE
ROCHE
BEST CNS PIPELINE
BIOGEN IDEC
BEST DIABETES PIPELINE
NOVO NORDISK
BEST INFECTIOUS DISEASE PIPELINE
GILEAD SCIENCES
BEST LATE-STAGE PIPELINE
GLAXOSMITHKLINE
BEST MID-STAGE/EARLY-STAGE PIPELINE
PFIZER
BEST ONCOLOGY PIPELINE
ROCHE
BEST RESPIRATORY PIPELINE
GLAXOSMITHKLINE
BEST VACCINE PIPELINE
GLAXOSMITHKLINE
MOST INNOVATIVE PIPELINE
NOVARTIS

BEST INFECTIOUS DISEASE PIPELINE: GILEAD SCIENCES

Gilead Sciences of Foster City, Calif., is a research-based biopharma company that discovers, develops and commercializes innovative medicines in fields of unmet medical need. Therapeutic areas of concentration include HIV/AIDS; hepatitis; serious respiratory, cardiovascular, and metabolic conditions; cancer; and inflammation.

Gilead's portfolio of 15 marketed products includes various category firsts, including the only complete treatment regimens for HIV infection available in a once-daily single pill – **Atripla**, cleared for marketing in 2006; **Complera**, approved during 2011; and **Stribild**, which was approved during 2012. Additionally in 2012, **Truvada** became the first agent approved in combination with safer-sex practices to reduce the risk of HIV-1 in high-risk uninfected adults, a strategy known as pre-exposure prophylaxis (PrEP). Atripla and Truvada generate billions of dollars in annual global sales.

With annual sales exceeding $700 million, Gilead's leading hepatitis drug is **Viread**. The once-daily oral NtRTI treats chronic hepatitis B virus infection in adults with compensated and decompensated liver disease and pediatric patients 12 years and older. Initially approved by U.S. and EU regulators in 2008, Viread is also marketed for treating HIV infection in patients 2 years of age and older in combination with other antiretroviral agents.

Gilead's R&D program is at its largest capacity ever. The company has over 75 Phase II and III clinical studies evaluating compounds with the potential to become the next generation of innovative therapies for HIV; hepatitis; serious respiratory, cardiovascular and metabolic conditions; cancer; and inflammation. Through the first nine months of 2012, Gilead spent $1.32 billion on R&D compared to $826.9 million during the corresponding January-September 2011 period.

Elvitegravir is one of the first candidates in a new class of HIV drugs called integrase inhibitors. Unlike other classes of antiretroviral agents, integrase inhibitors interfere with HIV replication by blocking the virus' ability to integrate into human cells' genetic material. One of the active ingredients in Stribild, elvitegravir is also undergoing Phase III trials on its own.

Elvitegravir was licensed by Gilead from **Japan Tobacco** (JT) in March 2005. Gilead has exclusive rights to develop and commercialize elvitegravir in all countries globally except Japan, where JT retains rights. Gilead filed a New Drug Application to U.S. regulators for elvitegravir on June 27, 2012.

Cobicistat is an investigational compound being studied as a pharmacoenhancing or "boosting" agent to raise blood levels and enable once-daily dosing for certain HIV medicines, including elvitegravir. Cobicistat is being investigated as a boosting agent for other antiretrovirals, in particular, protease inhibitors. The drug candidate is in Phase III trials.

As a novel prodrug of tenofovir, the active agent in Viread, **GS-7340** has the potential to provide greater antiviral efficacy at a dose 10 times lower than Viread. GS-7340 is being studied in Phase II for treating HIV infection.

Gilead has a host of new product candidates being developed for liver disease. In its World Preview 2018 report published during June 2012, EvaluatePharma rated the industry's top 20 most valuable R&D projects. Gilead accounted for two of those top 20 pipeline projects that are anticipated to be mega-brands by 2018: GS-7977 and "Quad."

Since that report was issued, "Quad" was FDA-approved in August 2012 under the brand name Stribild. The product is a complete once-daily single-tablet regimen for HIV-1 infection for treatment-naïve adults. Stribild joins together four compounds in one daily tablet: the integrase inhibitor elvitegravir; the pharmacoenhancing agent cobicistat; and emtricitabine and tenofovir.

FDA's approval of Stribild is supported by 48-week data from two pivotal Phase III studies in which the single-tablet regimen met its primary objective of non-inferiority versus Atripla and to a regimen containing ritonavir-boosted atazanavir plus Truvada (Study 103).

EvaluatePharma analysts have projected Stribild global sales of $2.79 billion for 2018.

Anticipated to be even a larger market presence than Stribild is Gilead's **sofosbuvir**/GS-7977. Sofosbuvir is a once-per-day nucleotide analog polymerase inhibitor for HCV infection treatment. The drug candidate is being studied as part of multiple therapeutic regimens, including in combination with RBV and peg-IFN. Sofosbuvir is being evaluated as a once-daily fixed-dose combo consisting of sofosbuvir and the NS5A inhibitor **GS-5885**. For this combination product, the added goal is creating a potent, tolerable and convenient all-oral treatment for genotype 1 infected HCV patients that may eliminate the necessity for interferon and/or RBV.

In late November 2012, Gilead revealed top-line results from the Phase III POSITRON study examining a 12-week course of once-

daily sofosbuvir plus ribavirin in patients with genotype 2 or 3 chronic hepatitis C virus infection who are not candidates to take interferon. The clinical trial found that 78 percent of patients remained HCV RNA undetectable 12 weeks after completing therapy. The safety profile of sofosbuvir was similar to that evident in previous trials, and there were few treatment discontinuations because of adverse events. POSITRON is the first of three completed Phase III trials that are evaluating sofosbuvir therapy in HCV genotype 2 or 3 infected patient populations.

Positive clinical-trial results are expected to support initial regulatory submissions during mid-2013 for an all-oral therapy with sofosbuvir plus RBV among genotype 2 or 3 treatment-naïve, treatment-experienced and interferon-intolerant patients, and for sofosbuvir in combination with RBV and peg-IFN among treatment-naïve patients with HCV genotypes 1, 4, 5 and 6.

Certain industry analysts believe that Gilead appears to have a lead on its rivals in the development of a new hepatitis C drug that could compete in a potential $20 billion market. Sofosbuvir is anticipated to thrive in the marketplace due to its impressive efficacy as a single pill taken once a day compared to multi-drug combinations.

EvaluatePharma ranked the hepatitis C polymerase inhibitor sofosbuvir as its No. 1 R&D industry project as of June 2012.

"This product boasts impressive 2018 forecasts of $5.4bn, which the product will need to achieve in order to justify the $11.2bn Gilead paid for Pharmasset in order to obtain the candidate," according to the analysts in its World Preview 2018 report.

Gilead completed the acquisition of **Pharmasset** in January 2012. A clinical-stage pharma company, Pharmasset was dedicated to discovering, developing and commercializing novel drugs to treat viral infections.

BEST LATE-STAGE PIPELINE: GLAXOSMITHKLINE

As a science-led worldwide healthcare company, GlaxoSmithKline researches and develops a wide array of innovative medicines and brands. The company's three main business areas are pharmaceuticals, vaccines and consumer healthcare. According to GSK, its commercial success depends on creating innovative new products and making them accessible to as many people who need them as possible.

Research is vitally significant to the success of GlaxoSmithKline's business. The company spent £4.01 billion ($6.43 billion) in 2011 and £2.83 billion ($4.54 billion) during January-September 2012 to research to develop new medicines, vaccines and innovating consumer products. GSK is one of the few healthcare companies researching medicines and vaccines for the World Health Organization's three priority diseases – HIV/AIDS, tuberculosis and malaria. GSK's pharma business researches, develops and makes available medicines for treating an array of serious and chronic diseases. Medicines available or in development by the company include these areas: infectious diseases, cancer, epilepsy, heart disease, asthma and chronic obstructive pulmonary disease, as well as HIV/AIDS.

Phase III programs were completed for six novel medicines during the first 10 months of 2012, with worldwide regulatory filings initiated for several potential new products. "Progress in our late stage pipeline this year has been exceptional with output better than in any previous period for the company," noted GSK in its financial report based on the first three quarters of 2012.

The company held an analyst seminar in December 2012 detailing GlaxoSmithKline's late-stage pipeline. GSK says its pipeline has the potential for about 15 product launches in the next three years.

During August 2012, GSK announced U.S. and EU regulatory filings for single-agent use of the company's BRAF inhibitor **dabrafenib** and the MEK inhibitor **trametinib**. The European application requests that dabrafenib be approved for treating adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation. The U.S. submissions for dabrafenib and trametinib are for the treatment of patients with unresectable or metastatic melanoma with BRAF V600 mutations as detected by an FDA-approved test. The regulatory filing for trametinib with the EMA is expected soon.

An orally bioavailable inhibitor of the BRAF protein, dabrafenib was discovered and developed by GSK. An orally bioavailable inhibitor of the MEK protein, trametinib was discovered by Japan Tobacco and in-licensed by GlaxoSmithKline during 2006.

In vitro diagnostics leader **bioMérieux** during 2010 developed a molecular theranostic test to detect BRAF V600 (V600E and V600K) gene mutations located in several cancers, including melanoma. The French company submitted for FDA Pre-Market Approval of the test, and it is being used in the Phase III trametinib-dabrafenib combination program to identify appropriate patients.

The investigational integrase inhibitor **dolutegravir** is awaiting regulatory clearance from health authorities in the United States, European Union, and Canada. The product's application filings were announced during December 2012 by **ViiV** Healthcare.

ViiV is a worldwide specialist HIV company that was established in November 2009 by GSK and Pfizer. **Shionogi** became a 10 percent shareholder in October 2012. The aim of ViiV is to take a deeper and broader interest in HIV/AIDS than any other company and take an innovative approach to deliver effective and new HIV drugs.

Known by the product code S/GSK1349572, dolutegravir is intended for treating HIV infection in adults and adolescents. The regulatory submissions are for the treatment of HIV infection in adults and children 12 years and older.

GlaxoSmithKline's **albiglutide** is an investigational biological, injectable form of human glucagon-like peptide-1. GLP-1 acts throughout the body to help maintain normal blood-sugar levels and control appetite. Typically, GLP-1 levels increase during a meal to help the body use and control the elevation in blood sugar levels. However, GLP-1 is rapidly degraded, leading to its short duration of action. In individuals with type 2 diabetes, GLP-1 secretion in response to a meal is reduced.

Albiglutide fuses human GLP-1 to human albumin. The drug is designed to extend the action of GLP-1, and has the potential to enable weekly injections. GSK is developing a once-weekly injection of albiglutide using a fine gauge needle for reconstitution and subcutaneous administration by the patient.

The Phase III development program for albiglutide consists of eight individual trials involving 5,000 patients, known as Harmony. The program is investigating the efficacy, tolerability and safety of albiglutide as monotherapy and add-on therapy in patients with type 2 diabetes. A majority of the trials include active comparators, including a sulfonylurea, a thiazolidinedione, insulin, and a dipeptidyl peptidase four inhibitor.

In collaboration with the biopharma company **Amicus** Therapeutics, GlaxoSmithKline is developing the investigational pharmacological chaperone **migalastat** HCl for treating Fabry disease. Amicus holds commercial rights to all Fabry products in the United States and GSK has commercial rights to all of these products in the rest of the world. As a monotherapy, migalastat HCl is designed to bind to and stabilize, or "chaperone" a patient's own alpha-galactosidase A enzyme in individuals with genetic mutations amenable to this chaperone in a cell-based assay.

Oral migalastat HCl monotherapy is undergoing Phase III trials for Fabry patients with amenable mutations.

Study 011 is a placebo-controlled trial intended mainly to support an FDA submission. Study 012 is comparing open-label migalastat HCl to ERT to primarily support worldwide market clearance.

For patients receiving enzyme replacement therapy for Fabry disease, migalastat HCl in combination with that therapy may improve ERT outcomes by keeping the infused alpha-Gal A enzyme in its properly folded and active form. Migalastat HCl co-administered with ERT is in a Phase II trial (Study 013). Migalastat HCl co-formulated with **JCR** Pharmaceuticals' proprietary investigational ERT **JR-051**, a recombinant human alpha-Gal A enzyme, is undergoing preclinical development.

Through a collaboration with **Janssen** Biologics (Ireland), GlaxoSmithKline is evaluating **sirukumab** (product code CNTO 136) in Phase III development. The human anti-interleukin (IL)-6 monoclonal antibody is being developed for treating patients with moderately to severely active rheumatoid arthritis. Sirukumab targets the cytokine interleukin (IL)-6, a naturally occurring protein believed to have a role in autoimmune conditions such as RA.

GlaxoSmithKline and Janssen Biologics during December 2011 agreed to jointly develop and commercialize sirukumab for rheumatoid arthritis. Before this deal, Janssen Research & Development was developing sirukumab for rheumatoid arthritis.

GlaxoSmithKline is developing the antisense oligonucleotide **drisapersen** (also known under the product code 2402968) for the rare disease Duchenne muscular dystrophy. Recruitment into the Phase III studies was completed as of third-quarter 2012. The product came from **Prosensa**, a privately held biopharma company that concentrates on RNA-modulating therapeutics for rare diseases with high unmet need.

In 2012, GlaxoSmithKline also commenced regulatory submissions for various respiratory medicines as well as vaccines that are regarded as promising late-stage assets. For details about those products and others, please see the following two GlaxoSmithKline pipeline sections.

BEST RESPIRATORY PIPELINE: GLAXOSMITHKLINE

GlaxoSmithKline generates more sales from its respiratory portfolio than any other therapeutic category. Respiratory products produced 2011 sales of £7.3 billion ($11.71 billion), accounting for nearly one-third of all GSK Pharmaceutical sales for that year. Leading the charge with sales of £5.06 billion ($8.12 billion) was the asthma and COPD product **Advair/Seretide**, which is one of the industry's best-selling prescription pharmaceuticals ever. For the first nine months of 2012, GSK's global respiratory sales totaled £5.39 billion ($8.64 billion), with Advair/Seretide contributing £3.74 billion ($6 billion).

GSK's respiratory development portfolio includes several late-stage assets. The once-daily investigational medicine fluticasone furoate/vilanterol is awaiting U.S. and EU regulatory clearance. Vilanterol is an NME and fluticasone furoate is the active ingredient in GSK's marketed allergy medicine **Veramyst/Avamyst**.

The U.S. and EU filings were submitted during July 2012. FF/VI is awaiting approval in the European Union under the brand name **Relvar** for asthma and chronic obstructive pulmonary disease. The drug has been submitted for market clearance in the United States under the trade name **Breo**. The intended indication for Breo is for the long-term once-daily maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema and to reduce exacerbations of COPD in patients with a history of exacerbations. For asthma, GSK and **Theravance** are reviewing the strategy for an eventual FDA submission of Breo. Relvar and Breo are administered via a new dry powder inhaler called **Ellipta**.

FF is also being developed in Phase III trials by GSK as a monotherapy for treating asthma. Vilanterol on its own is undergoing Phase III studies for the treatment of chronic obstructive pulmonary disease.

Theravance is a biopharma company with a pipeline of internally discovered product candidates and strategic collaborations with pharma companies. Theravance is concentrated on the discovery, development and commercialization of small-molecule medicines across respiratory disease, bacterial infections, and CNS/pain.

GSK and Theravance announced during December 2012 the U.S. regulatory filing for UMEC/VI. The investigational once-daily LAMA/LABA combination medicine is intended for patients with COPD. UMEC/VI joins together two investigational bronchodilator molecules – the long-acting muscarinic antagonist (LAMA) GSK573719 or umeclidinium bromide (UMEC), and the long-acting beta2 agonist (LABA) vilanterol (VI). The proposed trade name for UMEC/VI in the United States is **Anoro**. The medicine is administered via the Ellipta inhaler and is intended for the long-term once-daily maintenance bronchodilator treatment of airflow obstruction in patients with COPD, including chronic bronchitis and emphysema.

The EU regulatory submission for Anoro was announced in January 2013. Filings in other countries are expected during 2013. GlaxoSmithKline also plans to commence worldwide regulatory filings for UMEC monotherapy in the Ellipta inhaler for COPD patients during 2013.

Phase III trials were under way as of October 2012 for the IL-5 antagonist **mepolizumab** as adjunctive therapy in severe uncontrolled refractory asthma. Mepolizumab is a fully humanized IgG monoclonal antibody specific for interleukin 5 (IL-5). The product is being developed for severe refractory asthma in patients who worsen despite high-dose inhaled corticosteroids or oral corticosteroids and long-acting beta-2 agonist use.

The cytokine IL-5 regulates the growth, activation and survival of eosinophils (white blood cells). IL-5 provides an essential signal

for the movement of eosinophils from the bone marrow into the lung. Mepolizumab binds to human IL-5, preventing it from binding to its receptor on the surface of eosinophils. Inhibiting IL-5 binding in this manner reduces blood, tissue and sputum eosinophil levels, which in turn reduces the amount of exacerbations.

GSK and Theravance are developing the muscarinic antagonist and beta2 agonist MABA, known by the product code **GSK961081**. The new product candidate is undergoing Phase II trials for COPD.

When inhaled into the lungs, muscarinic antagonists and beta2 agonists result in bronchodilation, but through different mechanisms of action. Each class of drug has non-bronchodilator effects that can be complementary and beneficial in patients with COPD and perhaps in individuals with severe asthma. Many patients are using inhaled muscarinic antagonists and inhaled beta2 agonists, either in two separate inhalers or through a product that joins together short-acting agents from the two drug classes.

GSK and Theravance are developing a long-acting inhaled bronchodilator that is bifunctional, thus it is one molecule with muscarinic antagonist and beta2 agonist activities. By uniting bifunctional activity and high lung selectivity, the companies plan to develop a product with greater efficacy than single mechanism bronchodilators and with equal or better tolerability. This bifunctional bronchodilator could potentially then serve as a basis for improved combination therapy via joint delivery with an inhaled corticosteroid. The medicine could deliver three complementary therapeutic effects in one product for patients with respiratory disease.

BEST VACCINE PIPELINE: GLAXOSMITHKLINE

GSK produces over 30 prescribed vaccines around the globe to prevent potentially life-threatening or crippling illnesses. These illnesses include hepatitis A, hepatitis B, diphtheria, tetanus, whooping cough, measles, mumps, rubella, polio, typhoid, influenza and bacterial meningitis. GSK's billion-dollar franchises in this area include the **Infanrix** and **Pediarix** line, as well as the company's hepatitis vaccine family. For the first nine months of 2012, GSK's vaccine sales amounted to £2.46 billion ($3.95 billion).

Based in Belgium, GSK Vaccines has 14 manufacturing sites strategically positioned worldwide. Of the 1.1 billion doses of GSK vaccines distributed during 2011, more than 80 percent were distributed in developing countries, including the least developed, low-income and middle-income countries.

A potential blockbuster vaccine in the GSK pipeline is **MAGE-A3**. The antigen-specific cancer immunotherapy is undergoing U.S. and EU Phase III trials for the adjuvant treatment of melanoma and non-small cell lung cancer. MAGE-A3 belongs to a novel class of vaccines designed to encourage a patient's own body to recognize and eliminate cancer cells by stimulating their immune system. MAGE-A3 unites tumor antigens with GSK's proprietary adjuvant system, which unites immune-stimulating compounds designed to increase antitumor immune response.

To enroll in the clinical trial, industry analysts say a patient's tumor must express MAGE-A3 as demonstrated by a molecular diagnostic test being developed by Abbott. The NSCLC study is evaluating MAGE-A3 as adjuvant therapy in 2,000-plus MAGE-A3 positive post-surgical lung cancer patients, reportedly the largest Phase III study ever performed in lung cancer.

GSK's **H5N1 adjuvanted influenza vaccine** candidate is awaiting marketing clearance from U.S. regulators. In November 2012, FDA's Vaccines and Related Biological Products Advisory Committee voted unanimously 14-0 that the safety and immunogenicity data of the vaccine supports its licensure. The vaccine is intended for the active immunization for the prevention of disease in persons 18 years of age and older who are at increased risk of exposure to the influenza A virus H5N1 subtype contained in the vaccine. The regulatory submission was announced during March 2012.

The two-component vaccine consists of a monovalent, inactivated, split A/H5N1 influenza virus antigen and the AS03 adjuvant system. The H5N1 influenza vaccine candidate is manufactured in Québec and is already marketed in Europe as **Pumarix**. The vaccine program was supported by a development contract with the Biomedical Advanced Development and Research Authority of the U.S. Department of Health and Human Services.

The malaria vaccine candidate **Mosquirix** is also known by its scientific name RTS,S, which represents its composition. RTS,S aims to trigger the immune system to combat *Plasmodium falciparum* malaria parasite when it first enters the human host's bloodstream and/or when the parasite infects liver cells. RTS,S is designed to prevent the parasite from infecting, maturing, and multiplying in the liver, after which time the parasite would re-enter the bloodstream and infect red blood cells, resulting in disease symptoms. In a Phase III efficacy study, the vaccine is administered in three doses, one month apart. A booster dose administered 18 months after the third dose is additionally being investigated in the study.

Results from a pivotal, large-scale Phase III study published online during November 2012 in the *New England Journal of Medicine* demonstrate that Mosquirix can help protect African infants against malaria. When compared to immunization with a control vaccine, infants (aged 6-12 weeks at first vaccination) vaccinated with RTS,S had one-third fewer episodes of clinical and severe malaria and similar reactions to the injection. RTS,S showed an acceptable safety and tolerability profile.

A **herpes zoster vaccine** is being developed by GSK for the prevention of shingles. The recombinant vaccine is undergoing U.S. and EU Phase III clinical development.

An EU regulatory submission was filed in September 2012 for a new indication for the pediatric pneumococcal vaccine **Synflorix**. The additional indication is for the active immunization against pneumonia caused by *Streptococcus pneumoniae* in infants and children from 6 weeks through 5 years old. Synflorix is already marketed in the European Union and 90 other countries for active immunization against invasive disease and acute otitis media caused by *S. pneumoniae* in infants and children aged 6 weeks through 5 years old. The pneumonia indication has been approved in at least 67 countries. The vaccine is not FDA-approved.

Nimenrix was cleared for marketing by the European Medicines Agency in April 2012 for active immunization against invasive meningococcal disease caused by *Neisseria meningitides* serogroups A,C, W-135 and Y. Launches were under way in the latter part of 2012 in several countries throughout Europe, including the United Kingdom, Germany and the Netherlands. The vaccine is undergoing U.S. Phase II studies for the prevention of *N. meningitidis* groups A, C, W and Y diseases.

Nimenrix is the first quadrivalent conjugate vaccine to become available in Europe for active immunization of individuals from 12 months old against invasive meningococcal disease resulting from *N. meningitidis* serogroups A, C, W -135 and Y. A highly contagious disease, *N. meningitidis* represents potentially disabling consequences including deafness, epilepsy and other neurological disorders; in severe cases the disease can be life-threatening. The highest risk of contracting *N. meningitidis* is in infants and toddlers during the first four years of their lives, with another peak in adolescents.

MOST INNOVATIVE PIPELINE: NOVARTIS

Novartis has one of the industry's deepest and most productive pipelines with about 140 projects, including many new molecular entities. According to Novartis, it creates innovative medicines and prioritizes work based on unmet medical need and strong scientific understanding of disease – not the size of the potential commercial market.

Novartis researchers are mapping complex protein signaling networks called molecular signaling pathways inside of cells. Novartis says these molecular pathways are highly controlled and interconnected signal-relay systems – similar to communication networks – and are responsible for normal cell function. When a pathway protein does not properly function, abnormal signaling and disease can occur. Novartis Institutes for BioMedical Research scientists develop small-molecule drugs or antibodies to target key nodes within pathways that, when defective, result in disease. NIBR is dedicated to discovering innovative medicines that treat disease and advance human health.

By concentrating on patients and following the science, Novartis has discovered innovative treatments for disorders varying from cancer to degenerative disease. NIBR's research areas include autoimmunity, transplantation & inflammatory diseases; cardiovascular and metabolic diseases; gastrointestinal disease; infectious diseases; musculoskeletal diseases; neuroscience; oncology; ophthalmology; and respiratory diseases.

In November 2012, Novartis provided an update touting its strong and diversified pipeline containing more than 73 new compounds. Novartis says its industry-leading pipeline will provide the basis for continued growth through 2017. The company reportedly said its pharma division could generate 14 or more new blockbusters by 2017 through pipeline projects in areas such as oncology, heart and respiratory. These promising medicines include the heart failure drugs **serelaxin** (RLX030) and **LCZ696**. Another exciting drug prospect is **AIN457** for psoriasis and multiple sclerosis. Novartis also has a comprehensive early-stage and late-stage pipeline of novel oncology compounds.

According to Novartis, since 2007 through early November 2012 the Group led the industry with 56 new approvals in the United States, Europe, Japan and China. As of Nov. 8, 2012, the Pharmaceuticals division had gained nine approvals or positive recommendations for 2012.

Novartis Pharmaceuticals has established a strong foundation for the company's continuing growth based on already-marketed products. For the 12-month period starting in November 2012, the Pharmaceuticals group anticipated data read-out on 13 pivotal studies, nine submissions and seven regulatory decisions. For the following 13 to 24 months, strong pipeline news flow is anticipated to continue with another 11 pivotal trials read-out, 11 filings and 10 regulatory decisions.

Novartis has a proven track record of bringing innovative products to market as evidenced by the recent introductions of the cancer medicine **Afinitor**, the COPD treatment **Seebri Breezhaler**, the myelofibrosis product **Jakavi**, and the Cushing's disease drug **Signifor**.

Novartis Oncology in 2012 gained regulatory clearance for six indications, including two NMEs, as of early November. Continued growth is expected for the next five years. According to Novartis, one of the major growth drivers is Afinitor. The medicine has received approval for five indications and has the potential to top $2 billion in sales for breast cancer alone by 2017. Launches of Jakavi and the planned introductions of pipeline projects such as **BKM120** for various tumors and **LDK378** in lung cancer have the potential to contribute more than $1 billion in sales by 2017.

Novartis has launched a broad-scale clinical-development program called PRISM for its leading PI3K inhibitor BKM120 across multiple indications. The drug compound is being studied as a single agent and in combination with other therapeutic agents in different breast cancer settings, as well as other indications.

Novartis started pivotal studies during December 2012 for LDK378, an ALK inhibitor that has demonstrated potent activity in patients with ALK+ non-small cell lung cancer (NSCLC) as well as activity on brain metastases. Other clinical trials are set for 2013 and regulatory submissions are anticipated to be initiated during 2014 if studies are successful.

Data demonstrate that patients receiving an infusion of serelaxin had short-term and long-term benefits. In the short term, patients treated with the drug candidate had improved heart failure symptoms including dyspnea (shortness of breath) and edema, in addition to having a shorter hospital stay. The long-term benefits led to a statistically significant 37 percent reduction in cardiovascular mortality and all-cause mortality. Fewer patients treated with RLX030 had heart failure worsening as measured on day 5 and day 14 after treatment. Based on these findings of the RELAX-AHF study, Novartis expects to initiate U.S. and EU regulatory submissions for RLX030 during early 2013.

The company is making progress on its comprehensive clinical program in respiratory to address the needs of patients with chronic obstructive pulmonary disease. **QVA149** has the potential to establish a new standard of care for patients with COPD, preventing exacerbations and demonstrating improvement in bronchodilation versus placebo and current standard of care. Across numerous clinical trials, QVA149 allows for the limited use of ICS as rescue medications as recommended by the GOLD treatment guidelines for COPD.

Positive clinical data has been established for the highly effective novel IL-17 inhibitor AIN457 across various disease areas including psoriasis, ankylosing spondylitis, rheumatoid arthritis and multiple sclerosis. In Phase II trials, AIN457 has demonstrated rapid improvement of psoriasis signs and symptoms in patients with moderate to severe psoriasis. Phase III trials in this setting continue with regulatory

submissions planned to begin during late 2013. Novartis is exploring AIN457 across multiple indications such as multiple sclerosis.

Bexsero represents an innovative and potentially successful market opportunity for Novartis. The Meningococcal Group B Vaccine is the result of 20-plus years of pioneering research. MenB has been an especially challenging target because the outer coating of the bacteria is not well recognized as an antigen by the immune system, making it particularly difficult to develop a broadly effective vaccine until recent scientific developments. Bexsero was developed using an award-winning scientific approach that consisted of decoding the genetic makeup (genome sequence) of MenB. Novartis says this innovative method provides the foundation for a new generation of vaccines that can help prevent other diseases with an important diversity of disease-causing strains.

Following the market clearance of **Menveo** during 2010, the expected approval of the groundbreaking vaccine Bexsero underscores the unique leadership position of Novartis in the worldwide fight against devastating meningococcal disease. The two vaccines together help to protect against all five main serogroups of meningococcal bacteria (A, B, C, W-135 and Y) that result in the majority of cases globally.

During November 2012, Novartis announced the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion for Bexsero for use in individuals 2 months and older. Upon regulatory clearance, Bexsero will be the first licensed broad coverage vaccine that can help protect all age groups against MenB disease, including infants, the age group at the greatest infection risk.

Bexsero is expected to be a blockbuster by 2018 according to EvaluatePharma, which ranked the vaccine at the industry's No. 9 most valuable R&D project as of June 2012. A Bernstein Research report issued in November 2012 projected that Bexsero will have 2016 sales of $390 million.

BEST DIABETES PIPELINE: NOVO NORDISK

Denmark-based Novo Nordisk is a leading force in the diabetes product arena. The worldwide healthcare company has about 90 years of innovation and leadership in diabetes care. More than 371 million individuals worldwide – including over 26 million Americans – have diabetes, and that total is projected to exceed 556 million by 2030.

According to EvaluatePharma's World Preview 2018 report published in June 2012, diabetes will be the No. 2 therapy area in worldwide Rx and OTC sales during 2018 at $58.2 billion, trailing only oncology ($104.1 billion). From 2011 to 2018, diabetes is forecasted to have one of the highest CAGRs among leading therapy areas at 9.1 percent.

Novo Nordisk markets several blockbuster diabetes brands. Containing insulin aspart, **NovoLog/NovoRapid** is the world's most widely used rapid-acting insulin for use at mealtimes. **Levemir** is a soluble, long-acting modern insulin for once-per-day use for type 1 and 2 diabetes; the product provides glucose control with a favorable weight profile. Composed of biphasic insulin aspart, **NovoLog Mix 70/30** and **NovoMix 70/30** represent another successful diabetes franchise for Novo Nordisk. Used to either initiate or intensify insulin therapy, this dual-release modern insulin covers mealtime and basal requirements. **Victoza**, composed of liraglutide, represents Novo Nordisk's fastest-growing sales generator. Victoza is the only human glucagon-like peptide-1 analog that is 97 percent similar to endogenous human GLP-1.

Novo Nordisk's next blockbuster diabetes medicine is anticipated to be insulin degludec. The company discovered and is developing insulin degludec as a once-daily new-generation basal insulin analog, with an ultra-long duration of action. The drug has a distinct slow absorption that provides a flat and stable action profile. Insulin degludec has been studied in a large-scale clinical-trial program known as BEGIN, examining its impact on glucose control, hypoglycemia and the possibility to flexibly adjust insulin degludec dosing time to meet patient needs. Insulin degludec is being branded in major markets under the trade name **Tresiba**.

Novo Nordisk is developing a combo product containing insulin degludec in a formulation with a bolus boost of insulin aspart. This represents the first soluble insulin combo of insulin degludec and the most prescribed rapid-acting insulin (NovoLog/NovoRapid), providing fasting and post-prandial glucose control. The brand name for insulin degludec/insulin aspart is **Ryzodeg**.

Tresiba and Ryzodeg were filed for FDA and EMA regulatory review in September 2011. Applications also have been submitted for regulatory clearance in Canada, Switzerland and other countries. Tresiba was approved for marketing in Japan during September 2012, and Ryzodeg was cleared in that country during December 2012. Tresiba and Ryzodeg received positive CHMP opinions in October 2012, clearing the way for approval in Europe. An FDA advisory committee during November 2012 recommended approval of the medicines despite safety questions. As a result, Novo Nordisk reportedly is expecting a first-half 2013 U.S. approval for Tresiba.

The Phase IIIa program for **IDegLira** (product code NN9068) was announced by Novo Nordisk as completed during December 2012. IDegLira is a fixed-ratio combination of Tresiba, a once-daily new-generation basal insulin analog with an ultra-long duration of action, and once-daily Victoza.

DUAL II was the second and final Phase IIIa trial with IDegLira for treating patients with type 2 diabetes. Through the 400-person study, patients previously inadequately controlled on basal insulin in combination with one or two oral anti-diabetic agents were randomized to 26 weeks of double-blinded treatment with either IDegLira or Tresiba, in addition to metformin. In agreement with regulatory requirements, the maximum dose of Tresiba in the study was fixed in each treatment arm to investigate the additional effect of the liraglutide component of the IDegLira product on glucose control.

After 26 weeks, patients randomized to the Tresiba arm – with a fixed maximum dose – achieved blood glucose control as anticipated from the findings in the Phase IIIa program BEGIN. Patients randomized to IDegLira experienced HbA1c reduction of 1.9 percent from baseline. The variation in HbA1c reduction between the treatment groups was statistically significant, and the study met its primary endpoint of achieving superiority versus stand-alone therapy with Tresiba.

Along with results from DUAL I, for which headline data were revealed during August 2012, DUAL II reconfirms the competitive profiles of Tresiba and Victoza. The studies demonstrate that patients can realize benefits from each component in the combination product. Pending marketing authorization of Tresiba, Novo Nordisk intends to submit U.S. and EU regulatory filings for IDegLira in2013.

Additionally announced by Novo Nordisk in December 2012 was the decision to begin Phase III development for **FIAsp** (product code NN1218), a faster-acting version of NovoRapid.

Phase I proof–of-concept studies for FIAsp have been finalized. In these, the pharmacokinetic and pharmacodynamic properties of insulin aspart in various different formulations have been analyzed in patients with type 1 and type 2 diabetes to identify the form with the most attractive profile with regard to speed of onset of appearance, as well as stability. The new form of insulin aspart chosen for Phase III development has a faster onset of appearance than NovoLog/NovoRapid and mimics the endogenous insulin secretory response in a non-diabetic individual more closely. This potentially allows for more flexible insulin administration in connection with meals, as well as improved post-prandial glucose control.

In the proof-of-concept studies, no apparent differences between NovoRapid and the new forms of insulin aspart were observed pertaining to adverse events and standard safety parameters. Novo Nordisk plans to begin the Phase III program called Onset – anticipated to include about 3,000 people with type 1 or type 2 diabetes – near year-end 2013.

BEST MID-STAGE/EARLY-STAGE PIPELINE: PFIZER

Pfizer is prioritizing the company's R&D efforts in fields with the greatest scientific and commercial promise: immunology and inflammation; oncology; cardiovascular and metabolic diseases; neuroscience and pain; and vaccines. The New York-based biopharma entity is carrying out major research efforts across multiple modalities, including small molecules, biologics and vaccines. Pfizer also is gearing specialized efforts toward biosimilars as well as orphan and genetic diseases to develop and deliver innovative medicines and vaccines for patients around the globe.

As of November 2012, slightly more than two-thirds of Pfizer's 78 pipeline projects – consisting of 59 NMEs, 17 new indications and two biosimilars – were in Phase I (25) or Phase II (28) clinical trials.

Pfizer is making progress with a Phase II study of the CDK 4 inhibitor **PD-0332991** in CDK4-amplified liposarcoma. There is another Phase II trial of this investigational compound exploring its potential for treating patients with estrogen-receptor positive, HER2-negative advanced breast cancer in combination with standard of care anti-estrogens.

In December 2012, Pfizer revealed randomized Phase II data that demonstrated PD-0332991 (or PD-991) in combination with letrozole significantly extended progression-free survival (PFS) versus letrozole alone in post-menopausal patients with estrogen receptor positive (ER+), human epidermal growth factor receptor 2 negative (HER2-) locally advanced or metastatic breast cancer. For patients treated with the combination of PD-991 and letrozole, median PFS was 26.1 months, a statistically significant improvement versus the median PFS in women who received letrozole alone, which was 7.5 months. Letrozole is marketed as Femara by Novartis and **Chugai** Pharmaceutical.

"These results are especially important because of the magnitude of clinical effect observed and the fact that PD-991 represents a potential first-in-class compound," noted Dr. Mace Rothenberg, senior VP of clinical development and medical affairs for Pfizer's Oncology Business Unit. "Based on these positive Phase II data, Pfizer is planning to open a randomized Phase III study of PD-991 in this patient population in 2013."

PD-991 represents an investigational, oral and selective inhibitor of the CDK 4 and 6 kinases. CDK 4 and 6 are two closely related kinases that allow tumor cell progression during phase G1 to phase S in the cell cycle. This progression is required for DNA replication and cell division. Inhibition of CDK 4 and 6 has been demonstrated to prevent the deactivation of retinoblastoma, a tumor suppressor protein, and interfere with tumor cell progression. In pre-clinical studies, the drug candidate was demonstrated to be an inhibitor of cell growth and a suppressor of DNA replication by preventing cells from entering S phase.

Besides breast cancer, PD-991 is being evaluated via Pfizer-sponsored and investigator-initiated research in other cancers. These include liposarcoma, non-small cell lung cancer, liver cancer, ovarian cancer, glioblastoma, refractory solid tumors, multiple myeloma, and mantle cell lymphoma. If approved for marketing, various industry trackers forecast annual multi-billion dollar sales for PD-991.

Pfizer has touted new pathways with new promise in the company's early-stage pipeline. Pfizer is developing **PF-04449913**, an oral inhibitor of SMO, as one of the key components of the Hedgehog signaling pathway. The Phase I trial is evaluating the effectiveness of the drug compound across multiple hematologic cancers, including CML, AML, myelodysplatic syndrome, and myelofibrosis.

Abnormal activation of the Hedgehog pathway has been linked to various human cancers. Recent data suggest that disruption of the hedgehog pathway or inhibition of its activity may provide a new strategy for treating hematologic disorders such as multiple myeloma, lymphoma, and myeloid malignancies.

PF-04856884 (also known as CVX 060), an intravenous humanized monoclonal CovX body inhibiting angiopoietin 2 (ang-2) with sunitinib, is undergoing Phase II studies. Sunitinib is the active chemical in Pfizer's blockbuster cancer drug **Sutent**.

Pharmacokinetic modeling and simulation supported dose escalation of Pfizer's **PF-03446962** in patients with solid tumors. The monoclonal antibody (mAb) against activin receptor-like kinase 1 is in Phase I development.

The biologic **PF-04950615** (additionally known as RN316) is undergoing Phase II development for hypercholesterolemia. RN-316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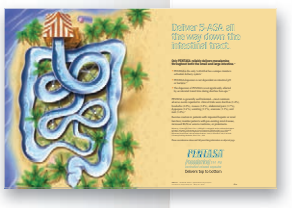

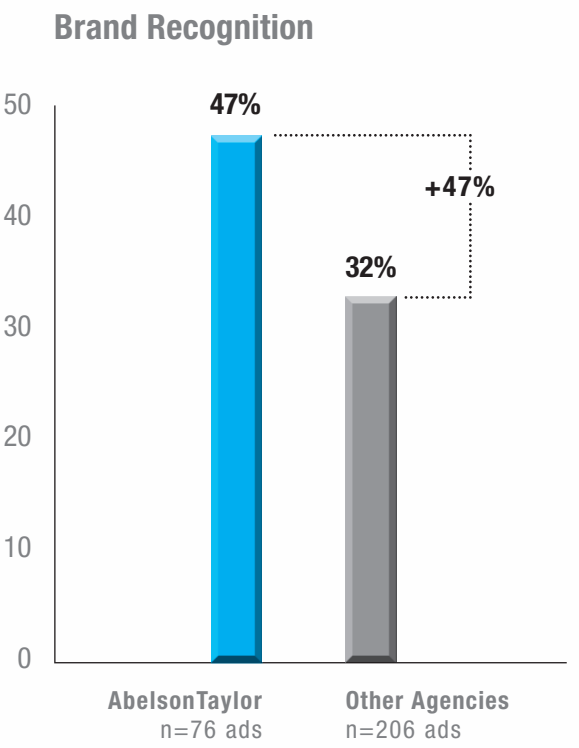

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reportedly cut bad cholesterol by 80% in clinical trials, with some patients' LDL levels so low that they did not qualify for a second injection. Some industry analysts believe a drug that can stand in the way of the PCSK9 protein that interferes with the ability of the liver to remove LDL from the blood could generate billions in annual sales.

Proprotein convertase subtilisin/kexin type 9 is a human enzyme encoded by the PCSK9 gene. Similar genes (orthologs) are located across many species. Many enzymes are inactive when they are initially synthesized, because they have a section of peptide chains that blocks their activity. Proprotein convertases remove that area to activate the enzyme. PCSK9 has medical importance because it acts in cholesterol synthesis. Medicines that block PCSK9 can reduce cholesterol, and studies are investigating whether they can improve heart-disease outcomes.

Upon completing its acquisition of San Diego-based **Excaliard** Pharmaceuticals in December 2011, with it came the Phase II drug **EXC 001** for treating excessive skin scarring. The privately owned biopharma company had concentrated on developing novel drugs for treating skin fibrosis, more commonly known as skin scarring. There is no FDA-approved treatment for excessive skin scarring.

BEST BIOTECHNOLOGY PIPELINE: ROCHE

Roche generates more product sales from biotechnology than any other company worldwide. Roche's 2011 biotech sales totaled $25.7 billion. EvaluatePharma projects that the total will reach $32.6 billion in 2018.

Roche is one of the industry's pipeline leaders with 72 NMEs as of September 2012. The company's 19 late-stage clinical trials at that time included 12 NMEs, expected to read out within an 18-month period.

Roche spent SFr.8.33 billion ($9.4 billion) on R&D in 2011. The company plans to keep its R&D budget stable by implementing continued productivity improvements as well as rigorous portfolio prioritization.

Roche acquired a majority holding in long-time biotech leader Genentech during 1990, and by 1999 had obtained all the company's shares. Then in March 2009, Genentech became a wholly owned member of the Roche Group. Established in 1976, South San Francisco-based Genentech is regarded as the founder of the modern biotechnology industry. The revamped organization of Roche and Genentech as of 2009 leverages the combined strength of both companies while maintaining the diversity of approaches essential for successful innovation.

The merger during 2002 between Nippon Roche, Roche's Japanese subsidiary, and Chugai Pharmaceutical resulted in the establishment of Japan's fifth-largest pharma entity and largest biotechnology company. Chugai functions as an independent member of the Roche Group and is listed separately on the stock exchange. Chugai is responsible for the sale of all Roche products in Japan and benefits from the Group's global sales network. Roche holds licensee rights to all Chugai products marketed outside of Japan or South Korea.

The Roche Group ensures continued research innovation by maintaining a diversity of approaches and joining together the cutting-edge research of Roche and Genentech, as well as Chugai. As part of the 2009 merger, Genentech's Research and Early Development (Phase I and Phase II) organizations were reformed as a single independent center for discovery research and early clinical development. Genentech Research and Early Development concentrates on continuing the pioneering biotech work and tradition established more than 30 years ago, and includes therapeutic antibodies, antibody-drug conjugates, and small molecules.

Genentech's R&D activities are concentrated on applying excellent science to discover and develop potential new medicines intended to represent first-in-class or best-in-class

therapeutics. The company's Research and Early Development pipeline has more than 30 NMEs undergoing active clinical development.

In parallel, Pharma Research and Early Development unites the worldwide early development and research organizations that existed within Roche, with a concentration on creating value from a deep understanding of life sciences. pRED is committed to the translation and understanding of disease biology in the clinical setting, and providing novel therapeutics to the specific patient populations in five disease categories.

Roche provides biopharmaceuticals for use in the following areas: leukemia, breast cancer, lymphoma, intestinal cancer, lung cancer, renal cancer, skin cancer, rheumatoid arthritis, transplant rejection prevention, renal anemia, hepatitis, and cystic fibrosis (mucoviscidosis).

The majority of Roche's diagnostic tests are biotech-based. Enzymes produced biotechnologically are used in many tests for blood and urine components such as cholesterol and glucose. Roche produces hundreds of enzymes and antibodies for industrial, scientific and medical diagnostic uses.

Roche's leading therapeutic area is oncology. Some of the company's most promising biotech compounds for oncology are **T-DM1**, **onartuzumab**, and **obinutuzumab**. For more details about these products, please see the Roche oncology profile following this section.

In other therapeutic areas, **aleglitazar** is being developed by Roche as a treatment to reduce major cardiovascular events (cardiovascular mortality, heart attack, or stroke) in patients who have experienced an acute coronary syndrome and have type 2 diabetes or patients with stable cardiovascular disease and type 2 diabetes/pre-diabetes. Aleglitazar is additionally being studied as a general type 2 diabetes glucose regulator.

This oral, small molecule is designed to provide balanced dual peroxisome proliferator-activated receptor (PPAR) activation. The drug compound's impact on peripheral insulin sensitivity associated with PPAR activation and dyslipidemia is being studied.

Aleglitazar is being evaluated as part of a comprehensive clinical program, including the completed Phase II trials SESTA-R, SYNCHRONY and AleNephro as well as the Phase III studies AleCardio, AlePrevent and AleGlucose. The large, long-term, event-driven Phase III outcomes trial AleCardio is under way to evaluate whether aleglitazar may reduce major cardiovascular events in patients who have experienced acute coronary syndromes and have type 2 diabetes. AlePrevent is a second cardiovascular outcomes study in patients with stable cardiovascular disease and type 2 diabetes or pre-diabetes. AleGlucose is a set of glycemic control studies to further characterise the effect of aleglitazar on glycemic control in type 2 diabetes patients.

For multiple sclerosis, Roche/Genentech is developing an innovative medicine with a mechanism of action fundamentally different than other existing therapies for the disease. MS drugs work by targeting a person's immune system, but they target fundamentally various parts. Traditionally, industry R&D has concentrated on targeting one component of the immune system – the T cells – which attack nerve fibers in the brain, resulting in lesions and ultimately MS symptoms. Ocrelizumab, on the other hand, targets the CD20 molecule located on the surface of B cells, a different component of the immune system. CD20-positive B-cells are implicated in the inflammatory and neurodegenerative processes of MS. Ocrelizumab researchers say the B cells appear to induce the T cells to attack. The Phase II study demonstrated that if one is blocked, the other may be stopped.

The humanized monoclonal antibody is undergoing Phase III studies for primary-progressive multiple sclerosis and relapsing multiple sclerosis. Regulatory filing of ocrelizumab is projected in 2015 as Phase III recruitment has been slower than expected due to the various MS studies under way.

Roche and Genentech are developing a novel humanized monoclonal antibody for severe asthma. **Lebrikizumab** is designed to specifically block the action of the interleukin-13 cytokine and reduce airway inflammation, which is a key asthma feature. The IL-13 cytokine is a signalling protein that acts as a messenger between cells that is increased in some asthma patients.

"Compared with other asthma drugs in the pipeline, lebrikizumab has progressed rapidly through clinical trials," stated Dr. Laura Runkel, associate director of Autoimmune/Inflammation for Citeline, which provides comprehensive real-time R&D intelligence to the pharma industry. "Further setting lebrikizumab apart from its competitors is the fact that Roche is the only sponsor currently employing a companion diagnostic in its asthma trials." According to Citeline, the use of a validated companion diagnostic could provide the key advantage in choosing the subset of patients most likely to benefit from IL-13 antagonism. Although companion diagnostics are rarely used in asthma studies, Citeline's Pipeline product shows that their use overall is increasing and is tracking 82 companion diagnostics intended for approval with specific medicines.

During third-quarter 2012, Roche identified the necessity to optimize the manufacturing for lebrikizumab. As a result, regulatory submission is expected to take place after 2016.

For schizophrenia, Roche and Genentech are developing the potential first-in-class drug candidate **bitopertin**. The oral, small-molecule glycine reuptake inhibitor is designed to enhance N-methyl-D-aspartate receptor activity. This is believed to be a significant pathway in psychiatric disorders, particularly schizophrenia.

A worldwide Phase III program of six trials is exploring two indications for bitopertin. The Phase III program is designed to optimize data quality by carrying out three studies for negative symptoms and three other for sub-optimally controlled symptoms in schizophrenia in parallel at the same clinical sites. A companion diagnostics assay is being developed by Roche to validate the hypothesis for an exploratory biomarker predicting response to therapy with bitopertin. Clinical data are expected to be available in late 2013.

BEST ONCOLOGY PIPELINE: ROCHE

Roche, with help from Genentech and Chugai, leads the oncology drug market behind long-established billion-dollar brands such as **Avastin**, **Herceptin**, **Rituxan/MabThera**, **Xeloda**, and **Tarceva**. According to the Roche, they represent an unprecedented five innovative cancer products that are proven to provide survival benefit in six different major tumor indications.

Roche continues to seek out new oncology compounds, and spends nearly 50 percent of its total R&D each year on oncology products.

Besides the innovative portfolio of cancer medicines, Roche is developing new diagnostic tests that will have an important effect on disease management for cancer patients in the future.

Roche's oncology pipeline contains 23 NMEs, including five undergoing late-stage development.

The company is leading the industry charge in developing antibody–drug conjugates (ADCs) that unite the specificity of antibodies with the power of chemotherapy. These ADCs may lead to improved efficacy and fewer adverse events.

Regarded as a potential market-leader successor to Herceptin when that drug loses patent protection, trastuzumab-DM1 (T-DM1) has produced positive results in clinical trials for HER2 positive breast cancer. This ADC contains the unique stable linker trastuzumab and the potent cytotoxic agent DM1. The drug candidate is designed to bind to the HER2 receptor on the surface of cancer cells and selectively kill cancer cells while minimizing cytotoxic effects on normal tissue.

T-DM1 was submitted for regulatory clearance in the European Union and United States during August 2012.

The antibody onartuzumab (RG3638) is undergoing Phase III development in combination with Tarceva for second-line and third-line non-small cell lung cancer. Clinical results from this program are anticipated for 2014. The first-in-class monoclonal monovalent antibody is designed to inhibit Met signaling in cancer cells by binding to the extracellular domain of Met, and in turn blocks HGF-mediated activation. HGF/Met signaling is activated through over expression of HGF and/or Met in tumors and via activating mutations in Met. Met signaling activation spurs tumor growth, and has been linked to tumor angiogenesis and metastatic potential.

RG3638 is also undergoing Phase II development for first-line non-squamous non-small cell lung cancer, first-line squamous non-small cell lung cancer, Avastin-naïve recurrent glioblastoma, metastatic gastric cancer, metastatic colorectal cancer, and triple-negative metastatic breast cancer. A companion diagnostic test to identify individuals with MET-positive tumors is undergoing development.

Obinutuzumab, or RG7159, is another antibody in Phase III studies, for chronic lymphocytic leukemia and non-Hodgkin's lymphoma. The drug is being developed in collaboration with Biogen Idec. Obinutuzumab is the first type II, glycoengineered, humanized anti-CD20 MAb. The drug is designed to enhance direct cell death and ADCC mechanisms when binding to CD20-positive malignant B cells. CD20 is a B-cell surface protein expressed on malignancies of B-cell precursors and mature B cells.

By virtue of its type II antibody characteristics, obinutuzumab results in higher direct cell death induction of cancer cells and lower complement recruitment versus type I anti-CD20 antibodies. Afucosylation of the Fc region of obinutuzumab (GlycoMAb technology) has led to stronger FcgRIIIa binding, which translates to enhanced ADCC. Preclinical studies show that obinutuzumab induces greater B-cell depletion in peripheral blood and in lymphoid tissue versus other available monoclonal antibodies. The drug candidate additionally mediates high antitumor activity in NHL xenograft models.

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GETTING networked

The creation of online patient registries will not only lead the way for clinical trial recruitment, but for post-marketing efforts as well.

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

As pharmaceutical companies continue to explore the social media world, it's not only marketing efforts that would benefit from interactive outreach. Clinical trial recruitment, always difficult and growing even more so, could be revolutionized by the use of online registries to gather potential participants – rather than just reaching out blindly through social media sites. And in the era of Big Data, the value of the communities created by these registries will go far beyond clinical trials, to marketing and post-marketing studies that can track side effects, use, and clinical effectiveness in the real world – information that will be invaluable for payer decisions.

Clinical trial recruitment can certainly use some kind of serious boost. According to the Center for Information & Study on Clinical Research Participation, the delays in patient recruitment for clinical trials account for an average of 4.6 months lost per trial. When calculated, this is an annual cumulative loss of 26 years, on average, for each company. Each day a drug is delayed from market, sponsors lose up to $8 million, and the average cost of clinical trials has risen to nearly 60 percent of total development costs, compared to just over 30 percent in the 1980s.

What's more, less than one third of people who come in for a screening end up completing a clinical trial. Some participants never pass the eligibility criteria, and others drop out. Overall, one out of every four patients stick with a study until its completion, and most participants drop out during Phases II and III.

Out of all of the research sites in the United States, less than one third contain 70 percent of the valuable subjects. This means 70 percent of the research sites under-perform, and between 15 percent and 20 percent never even enroll a single patient. Fifty percent of clinical research sites enroll one or no patients in their studies. In an analysis of 25,855 study volunteers in the United States, 73.2 percent of participants completed Phase I through Phase IV of clinical trials, 75.4 percent completed Phase I clinical trials, 69.7 percent completed Phase II/III clinical trials, and 93.8 percent completed Phase IV clinical trials. But studies show that enrollment rates have dropped from 75 percent in 2000 to 59 percent in 2006 and retention rates have fallen from 69 percent to 48 percent during same period.

According to a 2006 CISCRP survey, the public's perception regarding why people choose to participate in clinical trials is because they are "very sick without any other options" or they are "looking to make money." Sadly, also in this study, 34 percent of Americans said that they "do not admire" people who volunteer for clinical trials. Another study showed that less than five percent of Americans know where to find information about relevant clinical trials. On the positive side, more than 70 percent of those who have participated in clinical trials are likely to do so again.

It was with these sorts of statistics in mind that **Pfizer** announced an effort in June 2011 to let patients use social media to participate in a clinical trial. Called the "clinical trial in a box," the effort would allow patients enrolled in a trial for the overactive bladder drug **Detrol** to participate from home, using smartphones and computers, instead of having to go to the doctor's office. Patients were to be recruited through Internet ads and prospects would visit a Website that explained the trial and permit enrollment process. All materials – the blinded study drug and a mobile app for electronic patient-reported outcomes – were sent to participants at home, with blood drawn at a local clinic or during home visits.

Unfortunately, in June 2012, Pfizer made headlines again, for shutting down the effort. The company had problems recruiting patients. Craig Lipset, head of clinical innovation at Pfizer, told Pharmalot that though the company used a lot of different methods to recruit patients – Craigslist, Google searching, Facebook, online patient communities – that drove thousands of patients to the recruitment Website, actual conversion rates were low.

"That said, we didn't expect each patient who learns about this on their own and online to raise their hand and say they want to do that," Mr. Lipset said. "If you put out Google ads, you'll drive traffic but not necessarily the type of patient who's ready to participate, compared with already formed communities where patients are actively engaged. Those are lower in number, but they are an enriched group of patients."

Additionally, patients overall are still largely unaware of clinical trials and participation. Mr. Lipset said there were some success stories in Pfizer's effort, but "there are nuances we need to capture and learn from."

Although the trial in a box concept was not successful, Pfizer is still using social media channels to recruit patients for more conventional clinical trials. Other drugmakers have their own digital recruitment efforts. For example, Quintiles' Digital Patient Unit created a Website and is assisting with supplemental patient recruitment for **AstraZeneca**'s **AZD6765**, which is being developed for the treatment of major depressive disorder.

Quintiles' site, majordepressionstudy.com, asks patients, "Is your major depressive disorder a daily challenge? Have you tried medications for your depression in the past which didn't seem to help? Are you currently taking an antidepressant but still feel low, tired, and depressed? If so, you may be eligible to participate in this clinical research study." Patients can choose to complete a questionnaire to see if they would be eligible for the study, called Pursuit. The site also explains the Pursuit study, major depressive disorder, and how Quintiles will protect patient privacy.

Dave Coman, the head of Quintiles Digital Patient Unit, says the organization is capitalizing on the evolution in patient communication over the last several decades.

"We used to have as a mentality, we as an industry, would blast out information to patients, and hope they would come directly to a physician's office," Mr. Coman says. "There's very little interaction or intervention along that continuum. It was really a one-way push, and the vehicle that they pushed all their communications out through was typical mass advertising."

When hearing a typical radio spot for clinical trials, Mr. Coman, who came from the telecom industry 10 years ago and used to do direct-to-consumer marketing, said he used to ask himself, "Why in the world are they doing that?"

"I know from my past that radio is the least efficient medium to deliver a message and to get a consumer to respond," he says, adding that the pharma industry's reliance on radio spots for clinical trial recruitment fascinated him.

He acknowledges that the industry has evolved and has begun to figure out how patients are engaging and thinking, and how the industry can best interact with patients. In 2007, Quintiles started iGuard.org, now MediGuard.org. Founded by Dr. Hugo Stephenson, the site allows those who register to monitor the safety of the prescription medicines, over the counter medicines, and healthcare supplements that they are taking. Patients can leave information and "rate" the drugs they are taking, and the site provides patients with rapid alerts in the event one of their medications is the subject of a recall, or was found to have an interaction with another drug they are taking. There now are more than two million patients registered on MediGuard.

Mr. Coman says when it first started, MediGuard was seen as "a pure experiment, to see if you could speak with patients in a different manner, and try to create a community, more than a social network of patients looking for all the same type of information."

"I would say it's more of a two-way, we're providing information, and they're providing a little information back," he says. "We post data, we provide a service, and 95 percent, give or take a percentage point, of the patients that we have in that community are pretty explicit in saying that they'd be willing to take part in health research."

In 2009, Quintiles created a second patient community, clinicalresearch.com, which allows patients to search registries of clinical trials, get e-mail notifications about new clinical trials in their area, read health news, and watch videos, among other things. About 250,000 patients are registered in that community. Unlike the patients enrolled in MediGuard, the patients of clinicalresearch.com are actively seeking to get involved in clinical trials.

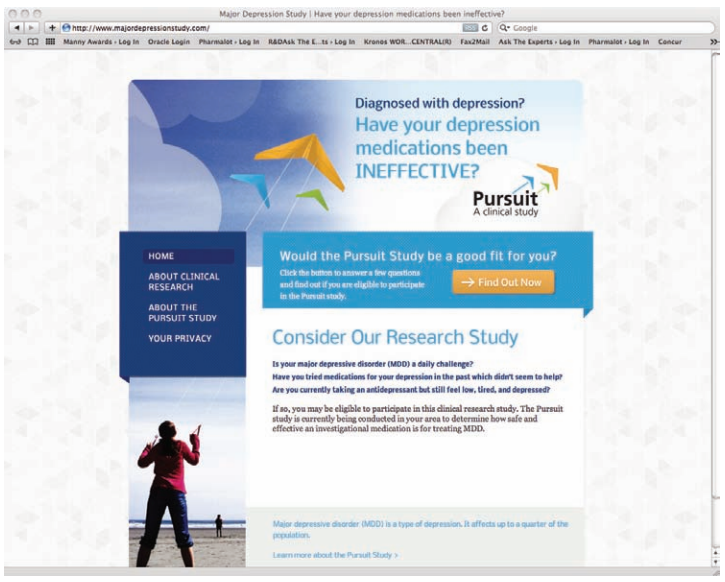
Quintiles created its Digital Patient Unit in January last year, formed around the concept of how the company can best mobilize patients directly into clinical research, observational studies, and disease management programs. Mr. Coman says the driving idea is patient engagement, not patient recruitment.

'It's about how you interact with patients in a manner in which they get a real, clear benefit, and the sponsor gets a really clear benefit," he says. "I often say here that the Digital Patient Unit is often like the eHarmony of healthcare, but the reality of it, the things that we do are very similar. We're marrying a pharma sponsor to a patient – those patients are really actively engaged in trying to resolve their health questions or health issues. And the pharmaceutical industry is even more needy, in terms of trying to find patients to participate in clinical research or to find information they need for observational studies to improve the economic value of a drug or to manage safety surveillance studies they have, or even engage with those patients in adherence or product adoption in the commercial side of the life cycle."

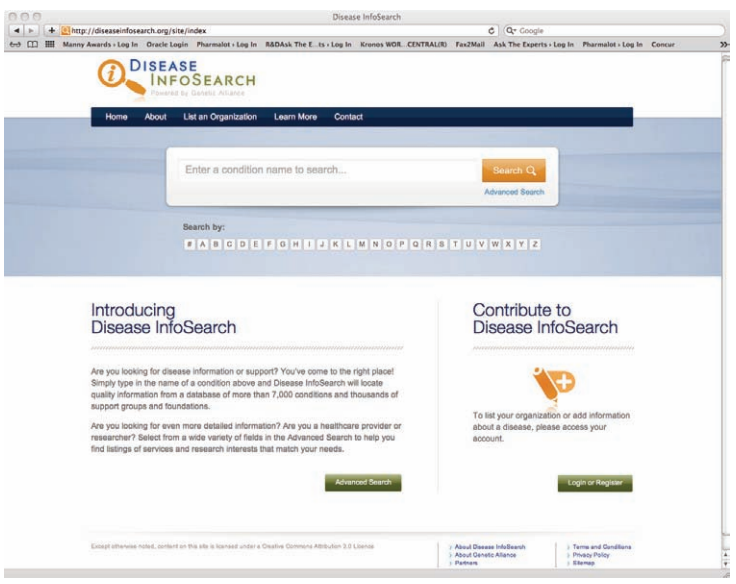
Pharma companies have to start engaging with patients in all areas that they can, because patients are far more involved with their health than ever before.

"This is the age of the digital patient," Mr. Coman says. "We have to match the demand with the supply – and that is to help those patients find studies and the opportunities that can help them improve their own health and the health of others than have those same conditions."

Since 2007, Quintiles has engaged with more than three million patients through online means, Mr. Coman says. "We've tried and failed, and tried and failed, and tried and succeeded," he says.



Quintiles' Digital Patient Unit created this recruitment Website for AstraZeneca. The site is for supplemental recruitment for a study of AstraZeneca's depression drug AZD6765.



The Genetics Alliance created this patient registry as part of its entry for the Collaborate/Active Innovation Challenge sponsored by Sanofi.

"And in that process, we've discovered how best to interact with a patient in a manner that's going to drive the appropriate behavior."

And according to Mr. Coman, recruiting patients digitally, rather than through traditional outreach, is more economical and effective. For the money spent on traditional outreach to get one patient into a clinical trial, Quintiles can spend on digital outreach to get 100 patients.

In addition to lowered costs comes greater speed. Recently, Quintiles had to recruit 500 patients into a trial that was studying patient behavior relative to patient outcomes. Setting up the recruitment in a traditional manner and getting the first patient in would have taken six months, with the recruitment process taking another six months to complete. "We were able to recruit the first patient in literally six minutes," Mr. Coman says. "The completion of the recruitment process was literally six business days."

By setting up communities of patients, through registries or other means, Quintiles can set up long-term relationships with patients that can extend through clinical trials and beyond. Patients can be notified throughout the clinical trial about drug successes and failures, and Quintiles does not have to duplicate its efforts to find patients for post-marketing initiatives.

"From a commercial perspective, if you are trying to accelerate your adoption curve, you've got a patient community who have already been through the process, who are going to be the first adopters, your early adopters, and they're also going to be your advocates upon launch as well," Mr. Coman says. "So it's how do you start leveraging those patient relationships in all aspects of the product life cycle."

Innovating for patient needs

Not every pharmaceutical company wants to get directly involved in building long-term patient registries, because of the effort and maintenance involved. **Sanofi** has found a way to actively support others in building these registries. In December, the company awarded $300,000 to a consortium of advocacy groups to build a diseases registry in its 2012 Collaborate/Activate Innovation Challenge.

Registries for All Diseases is a collaboration between more than a thousand disease advocacy organizations, including Genetic Alliance, CFIDS Association of America, National Psoriasis Foundation, and the Inflammatory Breast Cancer Research Foundation. These groups have come together to create a platform for individuals to store and share their medical data and biological samples.

Registries for All Diseases will comprise three parts: A gamified survey to engage people in sharing clinical information, through Disease InfoSearch (diseaseinfosearch.org); a virtual research network, asking individuals to respond to a couple of hundred clinical questions to characterize them for potential research; and a detailed questionnaire created by a disease advocacy organization with the opportunity to bank biological samples.

According to Sharon Terry, president and CEO of Genetic Alliance, Registries for All Diseases will allow individuals to participate in their health, and gives disease advocacy organizations a valuable tool in the quest for therapies. Registries for All Diseases is expected to accelerate translational research by linking clinical information and samples in a registry that allows recontact in a trusted environment. "Because Registries for All Diseases breaks down the silos between diseases, it allows for advanced research into comorbidities stretching across seemingly unrelated diseases," she says. "Finally and most importantly, sharing data broadly will transform the competitive paradigm. This will provide an opportunity for any interested party to apply his or her skills to the problems at hand – think about a math and engineering high school student, or retired database analyst – sunshine on the data will cause an explosion in new discoveries."

Edward Greissing, senior VP and U.S. head of corporate affairs, global services, and Partners for Patient Health for Sanofi, says the innovation challenge and the company's patient initiatives are part of an effort to "leapfrog the current landscape and get out there and do things that are more important to the future of the patient and patient needs."

By understanding what patients want and need, this shapes the company's research model, and allows more collaboration with the R&D team, Mr. Greissing says.

As Registries for All Diseases moves forward, it will provide access to information for the patients and understanding. The effort initially looked at creating registries for 1,000 diseases, but as time went on, Mr. Greissing says the consortium decided to target 13,000 diseases.

Mr. Greissing stresses that though the Innovation Challenge and Registries for All Diseases will have a beneficial impact on Sanofi, "We didn't [start the challenge] for Sanofi. We did it for the learnings that would come and the partnerships and the collaboration that would develop with these groups. We had 280 groups submitting 128 applications."

The challenge is a way of bringing ideas together, and the enthusiastic response speaks to the desire of these groups to collaborate with a pharma company. What's more, everyone seems to be aware of the same problems, Mr. Greissing says. "You would be surprised in conversations with them, how many themes start popping up, you hear it from one group and you hear it from another, and they've never been in touch with each other," he says.

Mr. Greissing hopes the challenge will set a new example in the pharma industry of how companies and patient groups can work together to truly solve patient needs, as well as change the way patient groups look at the industry. *(For statstics on how pharma executives view online patient recruiting, see page 24).*

MEDADNEWS

By Joshua Slatko joshua.slatko@ubm.com

The patient journey: An evolved approach to treatment flow modeling

By Yesim Ilkin and Rohit Sood

The treatment flow model, also known as the buying process, is one of the foundational elements of pharmaceutical marketing strategy. Marketers develop treatment flow algorithms to better understand the patient-physician interaction for their product. Once developed, these models can reveal the leakage and leverage points that can help inform strategies and tactics to maximize the uptake of a drug.

Several gaps exist in the traditional physician-centric approach to treatment flow modeling, however, which has limited the strategic usefulness of the tool. The increasing influence of new and existing stakeholders, coupled with the challenges of directing limited resources to the right areas to shape the market, are driving this need for an evolved approach to treatment flow modeling that focuses on the true journey a patient takes through the healthcare system. The journey approach to treatment flow modeling can provide actionable insights, resulting in more insightful, better-informed strategic decisions for marketing pharmaceutical products. This approach diverges from the traditional method in four key ways that make the practice a far more effective tool.

Map all stakeholders

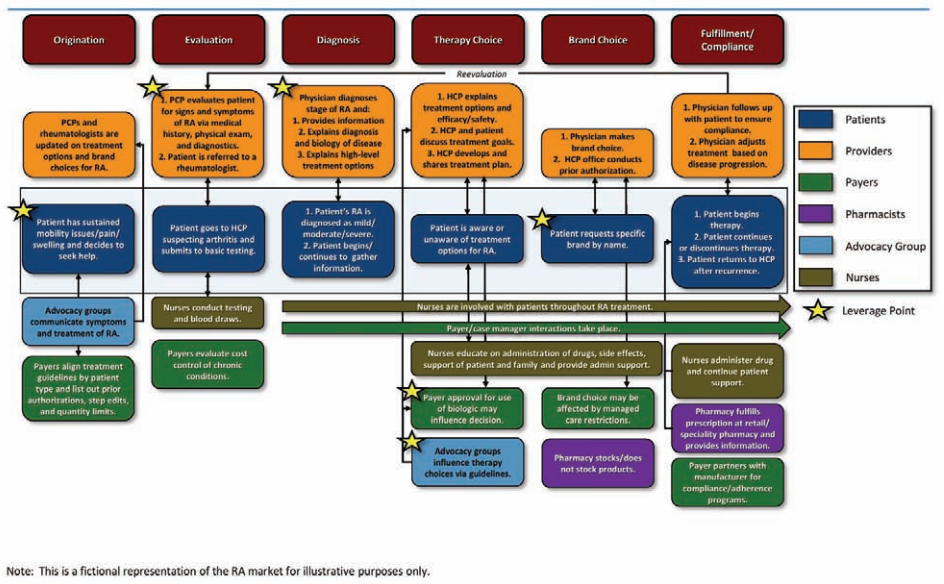
At a high level, the traditional treatment flow model is designed to capture the flow of a patient population through the healthcare system from origination through evaluation, diagnosis, therapy, brand choice, fulfillment, and compliance. It may begin with a patient displaying symptoms of a particular condition, spurring a visit to her primary care physician. If the primary care physician determines the condition warrants further investigation, the patient may be referred to a specialist. The treatment flow model then summarizes the course of various treatment options, through first-line therapy, second-line therapy, and so on. Next, the patient's compliance and persistence is outlined with her assigned course of therapy, followed by product fulfillment, with payers playing an increasing role in most therapeutic areas.

Traditional treatment flow models tend to be more physician-centric, failing to take into account all of the key stakeholders affecting a brand, including payers and other non-traditional stakeholders such as advocacy groups, nurses, hospitals, pharmacists, and office managers. In addition, the interactions between these key stakeholders are usually not represented by traditional treatment flow models.

In the evolved approach to treatment flow models, marketers consider the full range of stakeholder interactions and how those interactions may evolve over time. This is only made possible by considering alternative research approaches, such as ethnographic studies, in which observers enter the office setting to watch firsthand the interactions patients have with physicians, nurses, and other office personnel. A trained ethnographer observes underlying attitudes, thoughts, and feelings of key stakeholders. Although often considered expensive, this can provide powerful insight to help marketers uncover unmet needs, as well as drivers of and barriers to product adoption.

Understanding how patients interact with the full range of stakeholders is important, but it is also necessary to understand how these key stakeholders inte ract with each other. For example, advocacy groups and payers have increasing influence on the prescribing decisions of doctors. Sometimes the extent of the influence is overlooked. By mapping these relationships, marketers can now place these new stakeholders on their radars and develop strategies to potentially influence behaviors over time.

Figure A. Illustrative Patient Journey Example Based on Rheumatoid Arthritis (RA)



Note: This is a fictional representation of the RA market for illustrative purposes only.

Quantify the patient journey

After identifying key stakeholders and mapping out the patient journey, it's important to gauge the impact various stakeholders have and to translate their impact into tangible numbers. Treatment flow models are often qualitative, broadly indicating, for example, whether patients went to a primary care physician versus a radiologist. Too often, these traditional models will not reveal what number of patients visited one type of healthcare provider over another. They lack the quantification that may enable more advanced analysis.

Instead, primary and secondary research should be used to quantify the patient journey. If the data is simply not readily available, resources should be invested to conduct the appropriate research to gain the most complete information possible. Chart audit data, for example, can provide powerful insights on the distribution of the patient flow. This enables deeper insight into the movement of patients through the healthcare system at a manageable cost and helps the marketer prioritize where the marketing team should focus its efforts to make the biggest impact in the marketplace.

Quantifiable data from the treatment flow will show marketers where to direct dollars in order to drive product utilization. Knowing where the most impactful leverage points are in the treatment flow allows marketers to prioritize their strategies and tactics in ways that maximize return on investment.

Take a futuristic view

Traditionally, treatment flow models offer a static representation of the marketplace, providing a snapshot that captures the market landscape in one moment in time.

Marketers should consider developing an evolving treatment flow that captures key trends over time and models the expected impact of future events and scenarios in the marketplace. In tandem and as necessary, marketers should develop alternative models that look ahead and predict what the patient journey will evolve to once their product launches. Meanwhile market disruptors, such as the launch of competing products, changes in payer attitudes, or the implementation of healthcare reform provisions, should also be considered in the treatment flow. This will help to shape product development from a clinical perspective and develop appropriate counter-strategies.

Ideally, the treatment flow is mapped out for the first time before Phase II of commercial development. Marketers should review and refine the patient journey as the product transitions from Phase III and launch, and reflect any additional changes in the marketplace, such as policy changes or guideline revisions.

MOST-RECOGNIZED BRANDS

ANTIVIRALS

The most-recognized antiviral brand in North America is **Valtrex**. The brand was most recognized by 11.9 percent of physicians in a survey conducted by **Brand Institute** Inc. in third-quarter 2012. Valtrex, comprising valacyclovir, is marketed by **GlaxoSmithKline** (gsk.com). The drug was first approved by FDA in June 1995 as a treatment for shingles and has since received additional indications for the treatment of genital herpes, cold sores, and the treatment of chickenpox in pediatric patients two years old to 18 years old.

Zovirax is the second most-recognized antiviral brand in North America. About 11.3 percent of physicians recognize this brand the most. Comprising acyclovir, Zovirax is also marketed by GlaxoSmithKline. The drug was first approved by FDA in March 1982 and has received indications for the treatment of initial and recurrent mucosal and cutaneous herpes simplex in immunocompromised patients, chickenpox, herpes simplex encephalitis, genital herpes, neonatal herpes infection, shingles, and cold sores.

The third most-recognized antiviral brand in North America is **Tamiflu**. About 8.2 percent of physicians recognize this brand the most. Tamiflu, comprising oseltamivir, is marketed by **Genentech** Inc. (gene.com), a subsidiary of **Roche** (roche.com). The product was first approved by FDA in October 1999 to treat uncomplicated acute illness due to influenza infection in adults who have been symptomatic for no more than two days. In November 2000, Tamiflu was approved for use by adolescents 13 years and older; the following month, a liquid suspension for children 1 year and older was also approved. The product's most recent approval by FDA was for infants two weeks of age or older, in December 2012.

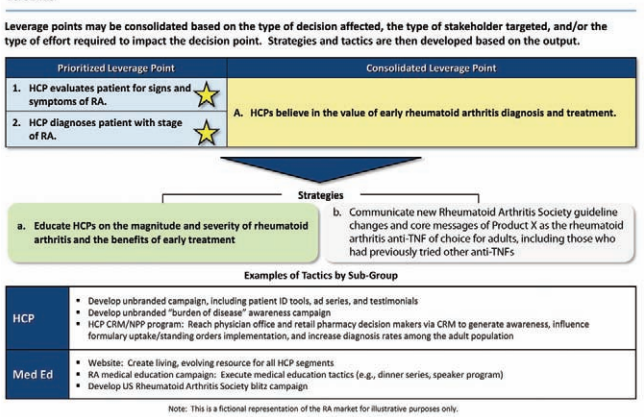
The most-recognized antiviral brand in Europe is Zovirax. This brand was most recognized by 15.1 percent of physicians.

Tamiflu is the second most-recognized antiviral brand in Europe. About 8.1 percent of physicians recognize this brand the most.

The third most-recognized antiviral brand in Europe is Valtrex. About 5.5 percent of physicians recognize this brand the most.

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

Figure B. Consolidation of Key Leverage Points and Translation to Strategy and Tactics



Make it a strategic tool

Marketers do not always leverage treatment flow models as the strong strategic tools they can be. The patient journey model should be used as a standardized framework for the development of strategies and tactics based on key stakeholder-prioritized behavioral objectives.

While ultimately the patient journey development framework will be unique for each product, typical development usually begins with mapping the patient engagement process. This usually takes into account trends in drug usage, trends in managed care, promotional activity, trends in patient and prescription data, and launch analyses. From this secondary research, a hypothetical patient journey can be mapped out that includes the key stakeholders affecting brand uptake. Depending on the stability of the brand's future market scenario, key trends and competitive events may be modelled to reflect changes and their respective affects over time. This makes the development of strategies and counter strategies easier to identify. Customized primary market research is implemented along the way to validate and quantify the treatment flow, including techniques such as interviews, ethnographic research, and Web-based surveys.

With the patient journey established, the evolved approach to treatment flow modeling goes one step further, using the findings to refine the commercial strategy of the brand. During this phase, the brand team identifies key leverage points on the patient journey map. Appropriate value propositions are subsequently developed for the respective customer groups.

Figure A shows a fictional example based on rheumatoid arthritis (RA). The stars in the figure represent leverage points that should ideally be validated by a cross-functional team, including Marketing, Clinical, and Managed Care functions. As seen in Figure B, these leverage points may be consolidated based on the type of decision affected, the type of stakeholder targeted, and/or the type of effort required to affect the decision point. High-impact leverage points are now converted into behavioral objectives, which outline the desired target behaviors that stakeholders exhibit in favor of the brand. Based on these prioritized behavioral objectives, it is then possible to develop an actionable and realistic strategic and tactical plan designed to encourage these behaviors.

Yesim Ilkin is an engagement manager with Campbell Alliance. Rohit Sood is a VP with Campbell Alliance.

FACTS & FIGURES

While nearly **two thirds** of Americans believe Medicare needs to undergo some form of change, respondents were not in agreement on the nature of the reform, according to the Truven Health Analytics Health Poll.

The survey, which asked respondents about their attitudes regarding the Medicare system, found that **65 percent** of Americans believe changes need to be made. That figure consisted of **71 percent** of Republicans and **58 percent** of Democrats. The highest rate (**80 percent**) of respondents who said they would favor changes to the Medicare system was among those who make over **$100,000** per year.

When asked if Medicare would benefit by encouraging competition within the program, half of respondents (**50 percent**) said they believe that would be the case. **Sixty nine percent** of Republicans and **31 percent** of Democrats said changes to encourage competition were necessary.

A proposed voucher plan was not well received overall. When a voucher plan similar to the one Congressman Paul Ryan proposed prior to the Presidential election was described for respondents, just **35 percent** agreed it would be the right way to reform Medicare. Slightly over half of Republicans (**52 percent**) and one-in-five Democrats (**19 percent**) agreed with Medicare being turned into a voucher program.

"The first step in any change process is to realize that change is needed," says Raymond Fabius, M.D., chief medical officer at Truven Health Analytics (truvenhealth.com). "With two-thirds of the public agreeing on the need for Medicare reform, the nation can now focus on solutions."

Sales of cancer pain therapies will increase to **$5.2 billion** in 2021 in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan, according to projections by Decision Resources. Over the next decade, several premium-priced agents are expected to enter the market, taking significant patient share from low-cost drugs and spurring growth. Decision Resources analysts believe that further growth will be restricted by the enduring presence of generic opioids, which will continue to play a major role in cancer pain treatment, and by the onset of generic erosion in other drug classes, most notably the bisphosphonates.

Based on convincing results from numerous Phase III clinical trials in bone metastases and bone loss due to ablation therapy in prostate cancer patients, Decision Resources forecasts that denosumab (Amgen/GlaxoSmithKline/Daiichi Sankyo's Xgeva/Ranmark) will gain blockbuster status in the cancer pain market by 2016. Denosumab is expected to derive the majority of its market share from the rapidly-eroding bisphosphonate class.

Decision Resources analysts also believe that one of the greatest commercial opportunities in cancer pain is for effective products that lack the gastrointestinal and central nervous system side effects of opioid analgesics.

"Experts we interviewed are skeptical that the goal of greatly improved safety and tolerability will be achieved in the next ten years," says Decision Resources (decisionresources.com) analyst Natalie Taylor, Ph.D. "This is because the majority of development activity has focused on reformulations of existing opioids."

By Joshua Slatko joshua.slatko@ubm.com

FDA really will issue social media rules

By Brian Reid

Two years ago, FDA watchers were atwitter: the agency had announced it would, in less than four months' time, issue long-awaited guidelines on how companies could use social media to promote their products and educate the public. Speculation was rampant about how the FDA would deal with a world of "likes" and 140-character Twitter missives.

The deadline came and went, though the agency told reporters that the new rules were among its "highest priorities." But that high priority didn't get tackled in 2011, and – with a new year looming – it looks like won't be tackled in 2012, either. As a consequence, marketers have largely given up on the FDA. Companies have either decided to forgo social media altogether or move ahead with a play-it-safe strategy unlikely to raise the hackles of the agency.

But the wait for guidance may be coming to an end, thanks to a little-noticed provision in the FDA reform bill passed last summer. In the legislation, the agency is directed to come up with social media rules by the summer of 2014 or face congressional scorn. The date you can circle on your calendar is July 9, 2014.

This opens up three possibilities, any of which would bring some clarity to those wishing to use Twitter, Facebook or any one of the dozens of other platforms available.

The first possibility is that the FDA develops a giant, comprehensive guidance document that drops sometime before the deadline, capturing the agency's thinking on everything from online video to how you shoehorn risk information into a tweet. It won't be a Rosetta Stone, but an effort to create a comprehensive site of rules would provide the green light to many companies nervous about operating without explicit guidelines.

The second possibility is that the agency simply blows the deadline and gets hauled before Congress. And then we'll all get to watch as the FDA's thinking gets probed — successfully or otherwise — by our elected representatives. And that will be illuminating, one way or another.

But it's the third possibility that is the most likely and the most interesting: the FDA spends the next 18 months rolling out small rule changes that fold in new communication methods into all manner of FDA rules, integrating rather than segregating social media. This may have already begun; the FDA published guidelines on off-label promotion almost a year ago that explicitly speaks about social media. But that document, rather than the first of many, remains the only FDA guidance to use the words "Twitter" or "YouTube." That's likely to change.

That doesn't mean that current practices will change radically. New guidance documents may only codify existing rules, impairing companies from providing much in the way of branded information. But having rules will only encourage more experimentation.

And that change will be welcome. In the next month, Google estimates that Americans will type "cholesterol" into the search bar more than a million times. A quarter-million searches for "statin" will be served. And 165,000 searches will explicitly ask "how to lower cholesterol." And few of those searches will bring consumers to the social properties of the companies that have invested billions in understanding heart disease.

That's not to say that the pharma industry should be the only voice trying to provide information on social media. But it probably makes sense to make sure they're not the only voice excluded from doing so.

Brian Reid is a director at the integrated communications agency WCG.

Strategic use of social media in patient recruitment

With a billion people, or one in every seven on the planet, already using Facebook, it is no wonder that clinical development professionals are increasingly dipping their toes in the social media waters for patient or subject recruitment needs. Those who respond to the online study stimuli are certainly interested and motivated; but social media channels do not yet make up a large percentage of the industry's patient recruitment strategies. According to a recent report by Industry Standard Research, though, that is about to change, and change quickly.

"With sixty-two percent of world-wide population somehow engaged in social media, there's no surprise pharma is eager to take advantage of the pool of potential subjects for their clinical trials," says Kevin Olson, CEO of ISR (isrreports.com). "Patient recruitment professionals we spoke to feel the use of social media will grow drastically between now and 2015."

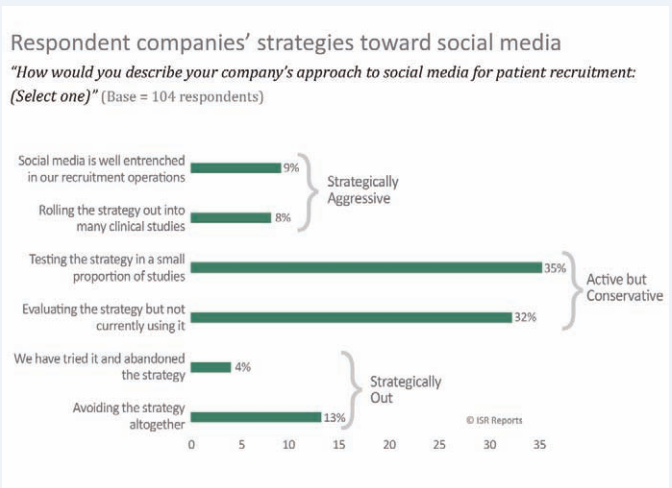
Social media tools are becoming increasingly smart in their ability to target users with appropriate content. But ISR's researchers found two main issues working against the growth of social media use in recruitment. The first is regulatory ambiguity. Recruitment professionals are, perhaps understandably, being cautious in their approach to social media because they don't want the rug pulled out from under them by regulatory bodies who later issue guidance for its use. Of respondents in ISR's survey, 66 percent percent said their organization does not have policies in place regarding the use of social media for patient recruitment.

The second main issue are anecdotes of underperformance. ISR's data show that drug development professionals are skeptical of the effectiveness of social media in recruitment. Several tell stories of over-promising and under-delivering. Most commonly, this comes in the form of a severe drop-off rate in the number recruited through web-based channels that express interest in the study and ultimately convert into a randomized subject. Partly to blame for this underperformance is a "lack of internal expertise to execute on strategy" – the organizational barrier most commonly mentioned by patient recruitment professionals. To deal with these issues, ISR's recommendation is to give these channels some time. Companies should develop a body of knowledge by testing strategies in a portion of studies; understand the strengths and limitations of these tools; learn to speak the language of social media users; and share best practices. The opportunity, ISR's team says, is too enticing to discard.

According to ISR's research, present use of social media in recruitment is mixed. Seventeen percent of respondent companies to ISR's survey are either "avoiding" social media or have "abandoned" it after having tried it, while another 17 percent report their companies are quite aggressive, describing social media as "well entrenched" or that their company is "rolling the strategy out into many clinical trials." Much more commonly, though, 67 percent of respondents report their companies are either "evaluating" or "testing" the strategy.

ISR's report, "Social media: Best practices and strategic use in patient recruitment," is based on data compiled from a survey of 104 patient recruitment professionals. The report profiles the "ideal trial" for recruitment via social media; quantifies pharma's use of social media and other Web-based channels; and discusses barriers to adoption, the use of and satisfaction with third-party service providers, and industry best practices.

(For the reasons why pharma companies need to engage in social media for patient recruiting, please see page 20)



According to ISR's survey, the use of social media for patient recruitment has been mixed so far.

FACTS & FIGURES

More than six in 10 (**62 percent**) of primary care physicians use an iPhone or iPod Touch as their primary mobile device platform, according to an October 2012 survey by Epocrates. Another **20 percent** use an Android device, while **4 percent** use tablets and **3 percent** use a Blackberry.

More than **one in four** PCPs use a tablet in their practice. Of these, **39 percent** use the tablet as a supplement to other devices, while **27 percent** use it equally with other devices and **19 percent** use it as the primary device with other devices as supplements. Another **13 percent** rarely use their tablet, and **3 percent** use a tablet only, with no other device as a supplement.

Of the tablets being used by PCPs, nearly four in five, or **79 percent**, are Apple iPads. Another **9 percent** use Android OS, **5 percent** use Windows OS, and **7 percent** use some other OS. **22 percent** of respondents to the ePocrates survey plan to purchase the iPad Mini.

One in four PCPs recommend an app to patients at least once a week. Categories of apps recommended to patients include patient education (**72 percent**), lifestyle change tools (**68 percent**), chronic disease management (**32 percent**), prescription drug info (**23 percent**), medical adherence (**22 percent**), and EHR patient portals (**17 percent**).

Four in 10 (**40 percent**) pf physicians who recommend apps to patients learn about those apps from a friend or colleague. Another **38 percent** recommend apps they use themselves, and **37 percent** find apps to recommend in an app store, while **34 percent** find apps with an Internet search engine and **20 percent** find them at a conference or tradeshow.

More than three in four (**76 percent**) of PCPs still use the good old telephone as their primary method of communication with patients. Another **10 percent** use patient portals as their primary communication method, **9 percent** use direct mail, and **5 percent** use email. About **1 percent** each use SMS messages and video chat.

As for communications with each other, **46 percent** of PCPs still use the telephone as their primary method of communication with colleagues, while **22 percent** use email as their primary method, **15 percent** use an EHR system, and **11 percent** use SMS. Another **4 percent** use secure messaging, and **2 percent** use direct mail. None of the respondents to the ePocrates survey listed video chat as their primary method of communication with colleagues.

Source: "Social Media: Best Practices and Strategic Use in Patient Recruitment," Industry Standard Research (isrreports.com).

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Within Reach

www.PharmaLive.com

AdAgencyUpdate

By Joshua Slatko joshua.slatko@ubm.com

Publicis launches Health Media unit

Publicis Healthcare Communications Group has announced the creation of Publicis Health Media, a new offering which aims to fuse media into a specialized health and wellness practice. PHM, its leaders say, will be a new business unit within PHCG that will address the marketplace's ever-changing media landscape by helping pharma, health, and wellness clients to connect with their audiences with relevant, engaging experiences.

The distinction of this offering, network executives believe, is the integration of media at all agencies within PHCG. Not only is this model new for PHCG, network leaders say it is unique for the healthcare category because it unites media and creative thinking while delivering time and cost efficiencies for clients. PHCG can now help its clients navigate the entire paid-owned and earned media ecosystem through brokering partnerships with global publishers for the co-creation and syndication of content across platforms.

Matt McNally has been named president, Publicis Health Media, and will lead the new business unit for PHCG. He will be responsible for media strategy, planning, buying, content distribution, and search across all PHCG agency brands worldwide, including Digitas Health, Saatchi & Saatchi Health, and Publicis Life Brands. Mr. McNally launched and led the media divisions of Digitas Health and Razorfish Health since 2004. His career spans more than 15 years; he has partnered with world-class brands in the pharmaceutical, OTC, medical device, managed care, and wellness spaces. Mr. McNally helped launch the media practice at Insight Interactive Group, and led health media at one of the first digital agencies in the United States

"PHCG is the only network capable of delivering a fully integrated, strategic media and planning offering in the health and wellness space, giving us a strong advantage over our competitors," says Nick Colucci, president and CEO of Publicis Healthcare Communications Group. "We are thrilled to have Matt head the introduction of Publicis Health Media. Matt is a well-known leader in media and has introduced some of the most innovative programs in the sector today. He truly has the vision to take this model to the world stage."

According to Mr. McNally, the market demands a media company that is dedicated to the health and wellness industry. The sector has been changing dramatically with consumers, physicians, and providers seeking information, support, and treatments from a variety of sources and across media platforms. Health and wellness requires a unique skillset; there is a fundamental difference between searching for "the best Italian restaurant in New York," and "what chemo agent is best for my mother." Because of this, clients need partners who understand today's health consumer and can help create engaging experiences, not the latest ad campaign.

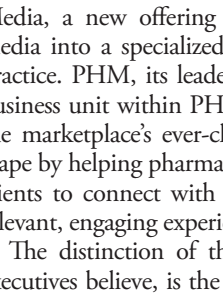
"We created this integrated offering to provide all of our clients with unique thinking that blurs the line between content and context, while meeting each client's needs through tailored service by the local agency teams who best know and understand their markets and their clients," Mr. McNally says. "Many health and wellness brands want a global partner to deliver innovative cross-channel media thinking. Because PHM is derived from the integrated media offerings at Digitas Health and Razorfish Healthware, we have the experience to think about and deliver solutions across a holistic media ecosystem – paid, earned owned, digital, and traditional. Most importantly, PHM will help clients abandon common practices of selling what they hope to push into the market and focus on building their brands and businesses by helping reach their consumers in meaningful and engaging ways."

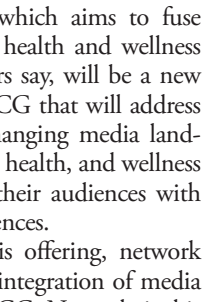
"We created this integrated offering to provide all of our clients with unique thinking that blurs the line between content and context, while meeting each client's needs through tailored service by the local agency teams who best know and understand their markets and their clients," says Matt McNally, president of the new Publicis Health Media.

AGENCY PEOPLE ON THE MOVE

■ AbelsonTaylor

Eric Densmore and **Mark Finn** are promoted to VP, AbelsonTaylor (abelsontaylor.com). Mr. Densmore and Mr. Finn were both account directors. **Amando Navar** is promoted to copywriter. Mr. Navar was an associate copywriter. **Cassandra Searls** is promoted from clinical research associate to associate copywriter. **Meredith Matthews** is named medical proofreader. Ms. Matthews joins AbelsonTaylor from the American Medical Association in Chicago, where she was media relations officer. **Zofia Gwarnicki** becomes clinical research associate. Ms. Gwarnicki recently received her Masters of Biotechnology from the Robert R. McCormick School of Engineering at Northwestern University.





■ Cadient Group

Stacey Davis is named creative director, copy, Cadient Group (cadient.com). Ms Davis has worked as a freelance creative director, copywriter and marketing consultant for the past decade. **Linda Bailey** becomes senior copywriter. Ms. Bailey joins the agency from InVentiv Health Communications, where she was lead writer for a new pediatric vaccine.

■ Cambridge BioMarketing

Maureen Franco is promoted to partner and CEO, Cambridge BioMarketing (cambridgebmg.com). Ms. Franco takes over from founder and former CEO and creative officer **Steve West**. Mr. West becomes chairman of the agency, while **Mike Hodgson**, a ten year veteran of the agency, is appointed chief creative officer.

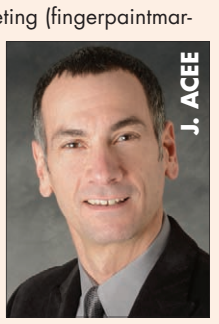
Prior to joining Cambridge BioMarketing, Ms. Franco spent 12 years at Genzyme,where she held a number of executive leadership roles in commercial development, product marketing, global brand management, and product promotions.

■ Evoke Interaction

Heather Coyle becomes executive VP, HCP marketing, Evoke Interaction (evokeinteraction.com). Ms. Coyle has 20 years of global healthcare communications experience, with a leadership background in pharmaceutical sales, HCP, DTC, and DTP marketing, digital strategy, payor strategy, medical education, and publication planning. **Brian Whalen**, Ph.D., will lead all of Evoke's medical and scientific activity. Dr. Whalen has been translating his experience in biomedical research at Harvard and Columbia Universities to pharmaceutical industry promotion, where he has focused on peer-to-peer medical education and advertising for the past seven years.

■ FingerPaint Marketing

Julie Anne Lewis and **Joe Acee** have joined FingerPaint Marketing (fingerpaintmarketing.com). Ms. Lewis most recently worked as a senior copywriter at AbelsonTaylor. Mr. Acee has worked at a number of agencies, including Publicis/ARC Worldwide, Designframe NYC, and Palio.



Ogilvy rebrands wellness, behavioral groups

Ogilvy CommonHealth Worldwide, the health behavior experts of Ogilvy & Mather, has announced that Ogilvy CommonHealth Consumer Care and Ogilvy CommonHealth Insights & Analytics will be rebranded as Ogilvy CommonHealth Wellness Marketing and Ogilvy CommonHealth Behavioral Insights, respectively.

Both groups were relaunched on Jan. 1, with the intention of having the new names better reflect the services that each group offers clients. Ogilvy CommonHealth Wellness Marketing will continue to serve as a full service consumer agency with an added focus on both health and wellness. Its name change further highlights the group's increased focus on helping brands become an integral part of consumers' and patients' lives for healthier living, particularly as they find themselves more and more responsible for managing their own health and well-being. Ogilvy CommonHealth Behavioral Insights' focus is on observational research, linguistic and ethnographic, relating to health and healthcare behaviors. The name change is also intended to further differentiate the group from the Ogilvy Healthworld Marketing Analytics & Consulting team in the New York office, whose name reflects its expertise in back-end quantitative business analytics.

Ogilvy CommonHealth Worldwide (ogilvychww.com) is a WPP company. The organization houses and maintains individual Ogilvy CommonHealth and Ogilvy Healthworld brand identities within the marketplace. Brad Davidson is the general manager of Ogilvy CommonHealth Behavioral Insights, and Neil Contess is the president of Ogilvy CommonHealth Wellness Marketing.

"This decision to rebrand these two groups is a result of our ongoing determination to provide clarity and focus in all our business efforts," says Matt Giegerich, chairman and CEO of Ogilvy CommonHealth Worldwide. "We believe this better reflects the service offerings at each unit."

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PeopleontheMove

By Joshua Slatko joshua.slatko@ubm.com

Endo announces CEO transition

David Holveck will retire in 2013 after five years as Endo's CEO.

Endo Health Solutions Inc. has announced that **David P. Holveck**, 67, the company's president and CEO, will retire in 2013. Mr. Holveck will continue to serve in his present positions until the earlier of his successor being in place or the May 2013 annual meeting of Endo shareholders. Mr. Holveck will also leave the board at that time.

Endo's board is conducting a search for the company's next CEO and will consider both external and internal candidates with the assistance of Korn/Ferry, an executive search company.

"I have had the opportunity to work with many talented and dedicated colleagues at Endo, and I am proud of all that we have accomplished together over the past five years," Mr. Holveck says. "I believe Endo is well positioned for the next chapter of its success, and I will do all I can to contribute to a smooth leadership transition."

Before joining Endo in April 2008, Mr. Holveck was president of Johnson & Johnson Development Corporation and VP, corporate development of Johnson & Johnson since 2004. He joined Johnson & Johnson as a company group chairman in 1999, following the acquisition of Centocor Inc., a biotechnology company, by Johnson & Johnson. Mr. Holveck was CEO of Centocor Inc. at the time of the acquisition. He joined Centocor in 1983 and progressed through various executive positions. In 1992, he assumed the role of president and chief operating officer and later that year was named president and CEO. Before joining Centocor, he had held positions at General Electric Co., Corning Glass Works, and Abbott Laboratories. Mr. Holveck is a member of the board of trustees for The Fund for West Chester University, as well as the board of directors of the Pharmaceutical Research & Manufacturers of America (PhRMA), the University City Science Center, and the Kimmel Center.

"Dave Holveck has done an excellent job in his five years as CEO," says Roger Kimmel, chairman of the board, Endo Health Solutions (endo.com). "Endo has made significant progress in a number of important areas during his tenure, including diversifying the business, reducing our dependence on Lidoderm, and laying the foundation for future growth, including by building a robust R&D pipeline. My fellow directors and I appreciate his creative vision and his early recognition of the changing healthcare landscape. As we transition to new leadership, the board is sharply focused on achieving Endo's full potential for the benefit of our shareholders and on the execution and continued integration of our four main businesses. We are moving quickly and have already begun a comprehensive search for our next CEO."

BIOPHARMA

■ **Hans Christian Rohde** is appointed chief commercial officer, uniQure B.V. Mr. Rohde joins the company from Basilea Pharmaceutica, where from 2007 he was chief commercial officer. uniQure develops human gene based therapies; the company's product Glybera, a gene therapy for the treatment of lipoprotein lipase deficiency, has been approved in the European Union, and is the first approved gene therapy in the Western world.

■ **Jonathan P. Mow** is named chief business officer, PhaseBio Pharmaceuticals Inc. Before joining PhaseBio, Mr. Mow was VP, business development for Amylin Pharmaceuticals. PhaseBio (phasebio.com) is a clinical stage biopharmaceutical company developing novel drugs to treat diabetes, metabolic, and cardiovascular disease.

■ **Daniel J. O'Connor** becomes senior VP, chief legal and business development officer, Advaxis Inc. Mr. O'Connor has 15 years of executive, legal, and regulatory experience in the biopharmaceutical industry with ImClone Systems, PharmaNet, and Bracco Diagnostics. Advaxis (advaxis.com) is a clinical-stage biotechnology company developing the next generation of immunotherapies for cancer and infectious diseases.

■ **Brian Wiley** is named VP of business development, NewLink Genetics Corp. Mr Wiley has had management responsibilities at Celgene Corp., Gloucester Pharmaceuticals, Millennium Pharmaceuticals, and Aventis Pharmaceuticals. NewLink (linkp.com) is a biopharmaceutical company focused on discovering, developing, and commercializing novel immunotherapeutic products to improve treatment options for cancer patients.

SPECIALTY

■ **Gil Ben-Menachem**, Ph.D., is named CEO, OphthaliX Inc. Dr. Ben-Menachem joins OphthaliX from Teva Pharmaceutical Industries Ltd, where he had served since 2008 as director of business development at the Global Branded Products division. OphthaliX (ophthalix.com) is an advanced clinical stage biopharmaceutical company focused on developing therapeutic products for the treatment of ophthalmic disorders.

■ **Randy Milby** is promoted to CEO, CorMedix Inc. Mr. Milby previously served as chief operating officer. **Richard M. Cohen** will serve as chief financial officer and will continue as executive chairman and director of CorMedix. Mr. Cohen was previously interim chief financial officer and interim CEO. **Antony E. Pfaffle**, M.D., a director on the CorMedix board, joins the executive team as acting chief scientific officer. **Mark Klausner**, M.D., current chief medical officer, will depart CorMedix effective February 28, 2012 upon the expiration of his employment agreement with the company. CorMedix (cormedix.com) is a pharmaceutical company that seeks to in-license, develop, and commercialize therapeutic products for the prevention and treatment of cardiac and renal dysfunction, also known as cardiorenal disease.

■ **Mark Iwicki** is named president, CEO, and a member of the board of directors, Blend Therapeutics Inc. Mr. Iwicki most recently served as CEO of Sunovion Pharmaceuticals and chief commercial officer of Sepracor. Blend Therapeutics (blendtx.com) is a biopharmaceutical company discovering new classes of medicines that have unique modes of action to result in drugs with differentiated therapeutic properties.

■ **Alison Lawton** is appointed chief operating officer, OvaScience. In conjunction with this appointment, the company's current chief operating officer, **Christopher Bleck**, will assume the role of chief commercial officer, leading sales and marketing. Ms. Lawton joins OvaScience from Sanofi Biosurgery (formerly Genzyme Biosurgery), where she was senior VP and general manager. OvaScience (ovascience.com) is a life sciences company focused on the discovery, development, and commercialization of new treatments for infertility.

■ **Greg Madison** becomes executive VP and chief commercial officer, AMAG Pharmaceuticals Inc. Mr. Madison joins AMAG from Genzyme Corp., where he spent the past 12 years in various commercial roles in the renal division, most recently as the division's VP and general manager. AMAG (amagpharma.com) is a specialty pharmaceutical company that manufactures and markets Feraheme (ferumoxytol) Injection for Intravenous use in the United States.

■ **Jason Levin** is named chief business officer, Sorbent Therapeutics Inc. Before joining Sorbent, Mr. Levin was chief business officer at BrainCells Inc. Sorbent (sorbent.com) is a private biopharmaceutical company developing therapies for patients requiring targeted cation and fluid removal from the body.

■ **Bryan M. Reasons** is appointed senior VP and chief financial officer, Impax Laboratories Inc. Mr. Reasons joined Impax in January 2012 as VP, finance, and has served as acting chief financial officer since June 2012. Impax (impaxlabs.com) is a technology-based specialty pharmaceutical company applying its formulation expertise and drug delivery technology to the development of controlled-release and specialty generics in addition to the development of branded products.

■ **Kristine M. Ball** becomes senior VP and chief financial officer, Relypsa Inc. Most recently, Ms. Ball was senior VP and chief financial officer of KAI Pharmaceuticals Inc. Relypsa (relypsa.com) is a late clinical stage pharmaceutical company discovering and developing novel non-absorbed polymeric drugs for important applications in cardiovascular and renal diseases.

■ **Fred M. Powell** is appointed chief financial officer, Celator Pharmaceuticals. Mr. Powell joins Celator from OraPharma Inc., where he was also chief financial officer. Celator (celatorpharma.com) is a privately held pharmaceutical company developing new and more effective therapies to treat cancer.

■ **Laizer D. Kornwasser** is named to Valeant Pharmaceuticals International Inc.'s executive management team and will assume the role of executive VP/company group chairman, where he will be responsible for the company's operations in Canada, U.S. Neurology, and various other U.S. functions including managed care and distribution, effective Feb. 1, 2013. Mr. Kornwasser was a senior executive at Medco Health before its acquisition by Express Scripts. Valeant (valeant.com) is a multinational specialty pharmaceutical company that develops, manufactures, and markets a broad range of pharmaceutical products primarily in the areas of neurology, dermatology, and branded generics.

■ **Joel Schaedler** is named VP of market access and **Daniel Martin** becomes VP of marketing, A.P. Pharma Inc. Mr. Schaedler was most recently senior VP of business development at P4 Healthcare. Mr. Martin was most recently the head of U.S. marketing at Dendreon. A.P. Pharma (appharma.com) is a specialty pharmaceutical company developing products using its proprietary Biochronomer polymer-based drug delivery platform.

SERVICE SUPPLIERS

■ **Siva Narayanan** is appointed senior VP, Ipsos Healthcare, charged with leading the company's evidence generation, value and access portfolio. Mr. Narayanan was previous a senior VP at TNS, leading the global treatment performance optimization/HEOR business unit. Ipsos (ipsos.com) is an independent market research company controlled and managed by research professionals.

■ **Daniel Malloy** becomes senior VP, QuantiaMD. Mr. Malloy was a VP at IMS Health within the IMS Payer Solutions business in the United States. In addition, current QuantiaMD president **Mike Coyne** has been appointed CEO, and the company's founder and previous CEO, **Eric Schultz**, has been named executive chairman. QuantiaMD is a free online community where practicing physicians can share practical medicine. ■ MEDADNEWS

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THELASTWORD

Looking for a new job? Stimulus spending won't help – but innovation will!

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

If the U.S. Treasury had a dollar for every time "jobs" were mentioned in the November election, I'd be less worried about the deficit. Yet for all the focus on jobs, it's remarkable how little sense it all made. It's simple: when the economy shrinks, as it periodically does, jobs are lost. They're the jobs employers find easiest to shed – positions marginalized by new technology, new competitors, or even new fashions. The illusion is that when the economy recovers, the jobs will come back, like obedient sheep. Well, some will; others won't. You'll never see newspaper "Want" ads for typists again. You may not see as many newspapers or magazines in print form either.

In the last election, we heard two schools of thought (I won't bother to identify the parties). One side insisted that if you lower taxes for "job creators," they will suddenly start hiring. To do what? Fill obsolete positions? Make a company noncompetitive again? Give me a break. The other side wanted to emulate the 1930's New Deal and pump money into public works. Hire people with borrowed money to fill potholes. Great!

Jobs are created in response to innovations that open up opportunities that didn't exist before. These breakthroughs often come from upstarts and dreamers who don't need to be coddled or funded. Can you imagine Gates, Page, Jobs, or Bezos, or Zuckerberg waiting for taxes to drop before starting their multibillion dollar businesses? Can you picture them burning the midnight oil applying for stimulus grants? No, they're visionaries who blasted through the status quo to create new enterprises of a kind and on levels previously unseen. And that's where the jobs by the thousands came from. Of course, we can't all be innovators on this scale, but we can take a clue from their vision and actions.

Have you heard this riddle? Which way does a dead fish swim? Wherever the current takes it! If your company is always reacting to events and trends and never embarking on new courses, then it's time to think about moving your tail (fins).

In my Leadership Forum class at Fordham University Graduate School of Business Administration, we have an innovation exercise in which the MBAs divide into teams and develop a full strategic plan for a new innovative product or service. After several rounds of evaluation, the most promising ideas are referred to a panel which offers advice, guidance, and perhaps even seed money. One recent proposal was for a smartphone "app" that allows drivers to locate and reserve a spot in a parking garage on the way into Manhattan close to their destination. (Just not while you're actually driving!)

Innovation doesn't need to be taught, but encouraged. Remaining open to new ideas is essential – especially in business. I'll wage the now-infamous sum of $10,000 that someone within the Polaroid organization proposed expanding into digital photography, and I'll bet another 10 grand that he or she got a pat on the head (or a kick in the butt) and was told that big thinking was a job for the C-suite elite.

I'm not saying that we all need to be innovators. Some of the most successful business leaders I know are those who have learned how to encourage ideas and nurture those with the most promise. If a dream ends up as a dud, then simply move on – without blame or finger pointing. Can you think of a new business that didn't look like a gamble at the start?

If you hear (or worse, find yourself thinking) "we can't do it that way…we tried it before and it didn't work" or "let me play devil's advocate," think of a mackerel, belly up and headed out to sea. It's not too late.

Turn over, head upstream, and take charge. And as you move forward, you'll be helping create new opportunities (and jobs) for others in your wake. And that's something awesome! (to quote my granddaughter). ■ MEDADNEWS

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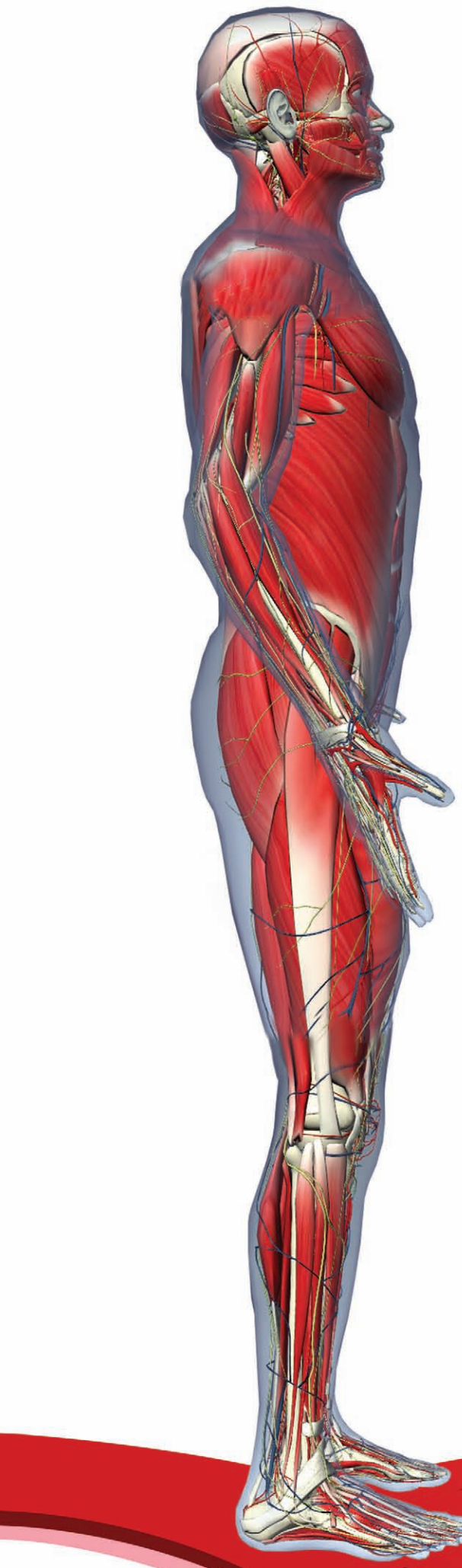

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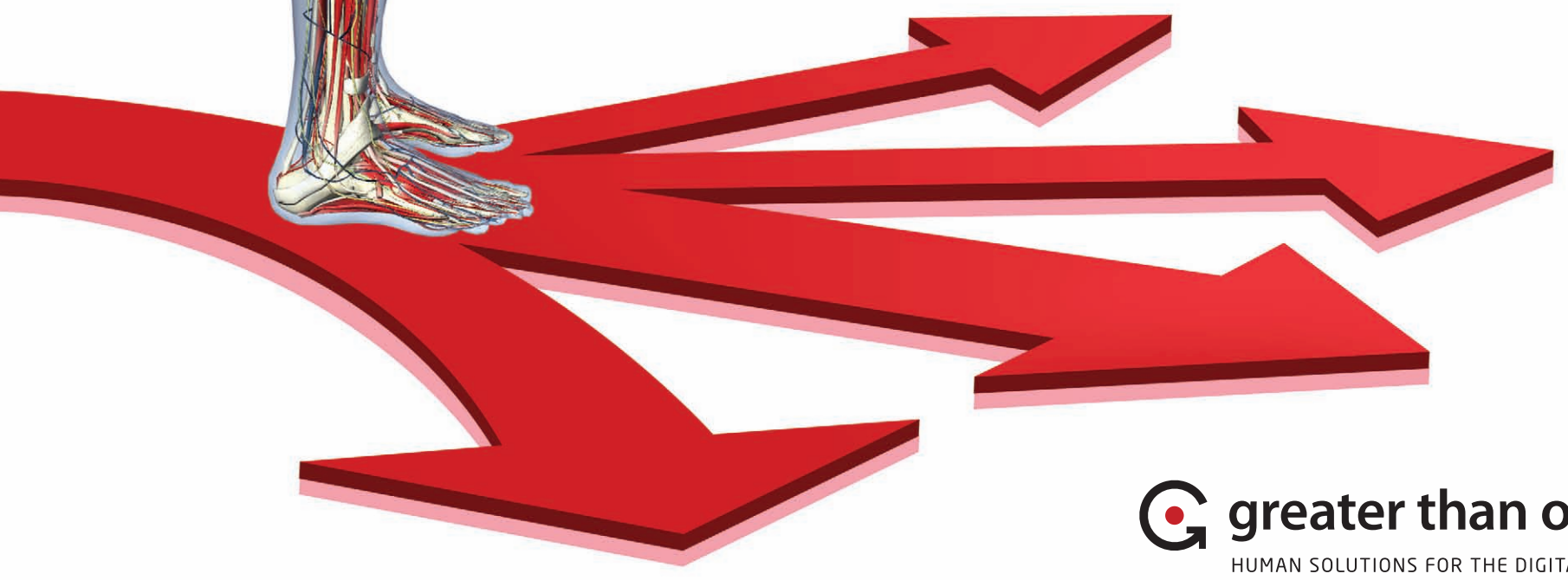

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