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Agency



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Dominic Viola, management supervisor, ICC Lowe Trio: As the ACA mandates, we're going to see an increasing need for physician success metrics.

continued on page 8

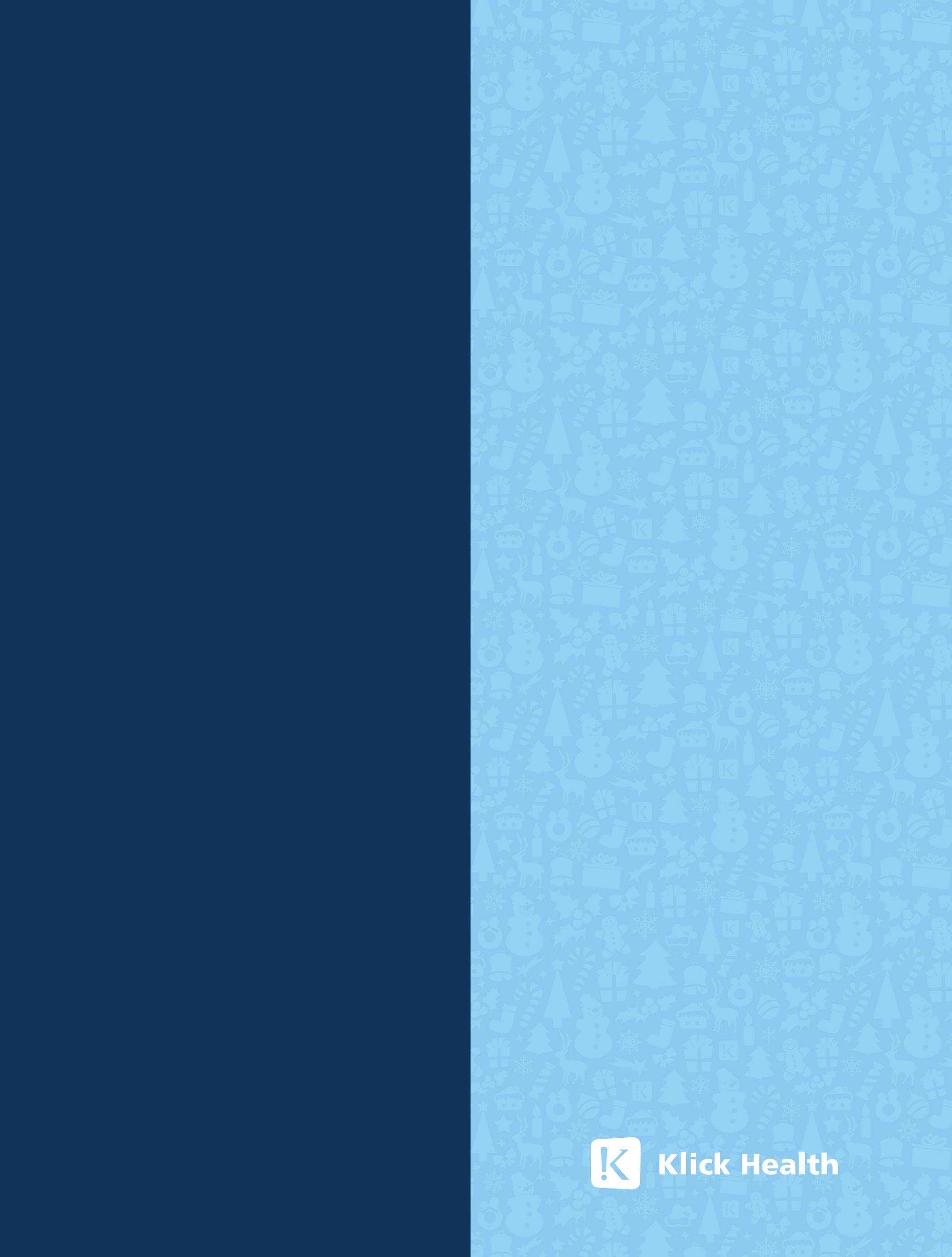
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Quote: The #mHealth App Market is Primarily Useless (For Now) http://ow.ly/27tjxy #hcsmeu #pharm #epharm

Think about breadth in your career; seize the opportunity to get out of your comfort zone and grow. #HBALead #leadership





Klick Health

IN THIS ISSUE:

14 DTC

DTC messages are going beyond the brand to engage with patients on the topics of health and wellness.

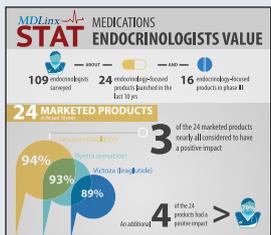
16 MANAGED MARKETS

Faced with the appearance of new financial decisionmakers, increasing pricing pressure, and the growing demand for outcomes data, marketers attempting to communicate with payers of all shapes and sizes must adjust their thinking or fall behind.



18 DIABETES

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Healthcare Agency Roundtable

For the 10th year, the leaders of selected Manny Award-winning and nominated communications agencies respond to key industry-related questions from Med Ad News.

By Joshua Slatko joshua.slatko@ubm.com

Med Ad News: How do you see next year's ACA rollout impacting the way you do business? What will marketing agencies have to do better or differently under ACA in order to continue to thrive?



Jay Carter

Jay Carter, senior VP, director of strategy services, Abelson Taylor: The biggest changes that ACA is driving are the effects upon our client's physician customers. The requirements for EHR have driven many practices to either consolidate into larger groups or sell themselves outright to regional hospital healthcare providers. It's been said that fully one-third of the oncologists in the United States have become employees of such groups since ACA was enacted. That presents changes in the way that specialty products are purchased and distributed, and we're very focused upon this change.



Jon Sawyer

Jon Sawyer, president and chief operating officer, closerlook: In large part, the ACA is going to mean more patients for physicians and more patients on product for pharma but with increased scrutiny on cost. Pharma can play an important role in helping physicians manage that increased load with more effective and efficient communication and programs that keep patients informed about their conditions, compliant with their therapies and embracing a plan for disease management "beyond the pill" for better long-term outcomes. Agencies can be good partners to pharma by helping industry understand their physicians and patients better so that these programs and their associated communication have as much impact as possible. The belief that the solution to our marketing challenges lies in shiny new tactics must end; investment in strategic programs that enrich the relationships between physicians, payers, pharma and patients in the interest of better outcomes is the answer to what ails our marketing efforts.



Ed Mitzen

Ed Mitzen, partner, Fingerprint: As a small business owner, we will continue to provide health insurance for our staff. We are expecting that it will cost us more as small businesses bear the brunt of subsidizing the newly covered individuals who didn't have insurance before. Our clients may reduce their marketing spend to cover the "hit" the firms will take in rising healthcare costs. Obviously, rising healthcare costs is nothing new to any of us. ACA is going to increase pressure to reduce marketing budgets, as companies look for ways

to recoup the increase in healthcare spend. Marketing agencies need to be able to find ways to have their clients' dollars go further. Nothing new.



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continued on page 8

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HEALTH EXPERIENCE

By **Christiane Truelove** chris.truelove@ubm.com

Resolutions for 2014

Hopefully as you are reading this, you are enjoying the holiday season and getting ready for 2014. It's been a chaotic, uneven 2013, and my wish is to see it over with as soon as possible and make a fresh start.

Not all of 2013 has been entirely bad; midway through the year, I managed to get myself re-enrolled at the local gym and between watching what I ate and exercise, have lost almost 30 pounds since the beginning of July. This time I am determined to not lose heart and to continue beyond that. It is interesting, however, to see how many targeted weight-loss ads I've been encountering across the Internet, especially on Facebook. Consumer marketers are working some sophisticated algorithms to bring my attention to cereal, workout gear, and amazing "tips" from Dr. Oz to lose body fat.

Nowhere, however, have I found any nonbranded wellness love from pharma. But that may be changing, as pharma is following the trend to direct wellness advertising to consumers (see story on page 14). The pharmaceutical industry is starting to wake up to the possibilities of using wellness topics to establish their brands in the hearts and minds of consumers. Perhaps 2014 will be a turnaround year in that regard.

Also looking ahead to 2014, executives from agencies that won or were nominated for Agency of the Year and various other Manny Awards have given their opinions on which trends are affecting them and their clients (see cover story). The impact of the Affordable Care Act, agency consolidation, and mobile marketing are among the topics of consideration. Overall, executives seem to be hopeful that the year ahead will treat the industry better than the year behind, but they know change is always around the next corner.

In the area of diabetes, we hopefully can look forward to the progress of Novo Nordisk's IDegLira and Tresiba as well as Sanofi's Lyxumia among others in eventually reaching the U.S. marketplace (please see story on page 18).

Another thing to look forward to in 2014? Cegedim Relationship Management will be launching its own social network for physicians, Docnet, in the United States in the first quarter of the year (see story on page 24).

In other things to look forward to in the new year, perhaps we'll see more economic recovery; sweeping changes in the way healthcare is administered in the United States; and less political bickering and no government shutdowns. Heck, if you have to make wishes for the new year, make them big, I say.

Personally, in 2014, I want to do more traveling; talk with more people; take up playing the guitar again; create a groundhog-proof garden; become more adept at social media technology; laugh more; and spend more time with family and friends.

Things I would like to do less of in 2014: stress out over things I can't change and can't affect; worry in general; see friends and loved ones hospitalized on major and minor holidays; and see far fewer groundhogs in my back yard.

Here's wishing that all of your wishes come true in 2014.



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all of your wishes
come true in 2014.

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@99stickers: Drug Companies and Social Media: Awareness/Good vs. Marketing Lies/Bad - <http://bit.ly/1ak5Zl7> #pharma #drug #ehealth

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inside



ON THE COVER

HEALTHCARE AGENCY ROUNDTABLE

For the 10th year, the leaders of selected Manny Award-winning and nominated communications agencies respond to key industry-related questions from *Med Ad News*.



INSIDE

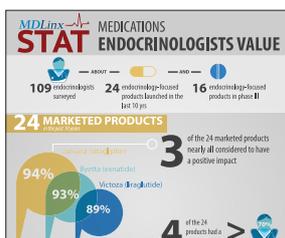
14 DTC • WELL IS THE WORD

DTC messages are going beyond the brand to engage with patients on the topics of health and wellness.



16 MANAGED MARKETS • SHIFTING SANDS

Faced with the appearance of new financial decisionmakers, increasing pricing pressure, and the growing demand for outcomes data, marketers attempting to communicate with payers of all shapes and sizes must adjust their thinking or fall behind.



18 DIABETES • REACHING EPIC PROPORTIONS

One in 10 of the global population will have diabetes by 2035 based on the latest statistics.

DEPARTMENTS

22 SALES AND MARKETING

As provider organizations mature toward implementation of accountable care organizations (ACOs), manufacturers of biopharmaceutical products will need to stay abreast of changes, set the stage for innovative partnership, and take advantage of emerging opportunities.

24 INTERACTIVE AND DIGITAL MARKETING

Cegedim Relationship Management is casting its lot in the online doctor social community category in the United States with its own offering, Docnet.

25 AD AGENCY UPDATE

The dynamics in the exam room are changing rapidly and mobile is having a profound impact on how patients treat their conditions and the overall doctor-patient-caregiver relationship, according to a new study of mobile usage in healthcare undertaken by Digitas Health.

27 PEOPLE ON THE MOVE

Bristol-Myers Squibb has announced a series of related changes within its senior management team. To support its ongoing success as a BioPharma leader, the company is evolving its business model, creating a global integrated commercial organization and expanding the scope of its finance organization.

28 THE LAST WORD • BE CREDIBLE – OR BE COOKED

Sander Flaum offers a few tips to maintain or repair credibility in the age of social media.

A man with short brown hair and a grey button-down shirt is holding a white sign in front of his face. He is looking directly at the camera with a slight smile. He is wearing a silver metal watch on his left wrist. The background features large, black, 3D letters spelling out "DRAFT" on the left and "FCB" on the right. The sign he is holding has the following handwritten text:

Stood for 5 hours in
a monsoon
just to flash my campaign
T-shirt on
The Today Show.

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DRAFTFCB HEALTHCARE

ABOVE AND WAY BEYOND

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@SAMMIELW:

Fastest growing age group on #twitter 55-64 yrs olds and other surprising #SoMe stats [http://www.fastcompany.com/3021749/work-smart/10-surprising-social-media-statistics-that-will-make-you-rethink-your-social-stra ...](http://www.fastcompany.com/3021749/work-smart/10-surprising-social-media-statistics-that-will-make-you-rethink-your-social-stra...) #socialmedia

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WHAT'S IN PRINT

HEALTHCARE AGENCY ROUNDTABLE

Top agency leaders discuss HealthCare.gov, the future of mobile and social, and other important digital questions.

[Go to the cover](#)

WELL IS THE WORD

The expansion of potential media for DTC communications from the traditional TV spot and print ad to digital and mobile has allowed pharma marketers to craft unbranded messages that go beyond benefits and risks.

[Go to page 14](#)

CEGEDIM LAUNCHES SOCIAL SITE FOR DOCS

Cegedim Relationship Management is casting its lot in the online doctor social community category in the United States with its own offering, Docnet.

[Go to page 24](#)

MOBILE USAGE TRANSFORMING DOC/PATIENT RELATIONS

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[Go to page 25](#)

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Dominic Viola

We're already seeing the beginnings of the shift in healthcare provider compensation from fee-for-service to pay-for-performance. We're continuing to see the evolution of what's considered "effective" and "successful" care become increasingly quantified with hard metrics.

Another important way the ACA will apply to the evolution of pharma is ensuring value beyond the drug: Insurance companies and accountable care organizations will continue to influence how and which drugs are prescribed. So a drug itself is becoming just one key part of the overall brand value: the full value also resides in the bundle of services the drug company offers to patients and doctors, including behavior modification tools and techniques, patient and professional education, counseling, and training, to name a few. All these additional measures of success – and more – will need to be factored into brand promises and will drive competitive advantages and brand differentiation.



Wendy Blackburn

Wendy Blackburn, executive VP, Intouch Solutions: It's true that more insured patients in the system means more potential customers for pharmaceutical products. Looking deeper into the pool, many of these newly insured represent younger generations. And we cannot overlook the tech-savvy of these digital natives and the expectations they have for companies seeking to connect with them.

That, in turn, places a premium on agencies that offer much more than just basic competence in digital media. Agencies that already know how to communicate two-way, in real-time and responsively will quickly replace others who tend to communicate one-way and build brochure-ware Websites.

We'll be looking at an even more fractionated landscape and a redefinition of pharma's "customer." Brands must learn to speak to managed care organizations; to understand what an ACO is and who the decision makers in ACOs will be. They must talk to pharmacists, hospital systems, government agencies, and consumer watch groups. And brands must understand the diverse needs and definitions of value that each of these influencers hold.



Leerom Segal

Leerom Segal, president and CEO, Klick Health: This is a sea change in the market and we need to respond by providing more of the information that patients demand: formulary and access issues. Yes, we still need efficacy and safety information, but the one thing missing from patient information, access, is what they crave. Insurance and payment has always been an issue in the background of every physician/patient conversation, but it's now the dominant agenda item. According to the PwC report Customer experience in the pharmaceutical sector: Getting closer to the patient, patients are paying a greater share of the costs, 250 percent more in fact. This increased "skin in the game" means that patients are beginning to shop for medical treatments in much the same way that they shop for other important "big purchase" items and cost has become the dominant concern. In fact, 89 percent indicate that insurance coverage is the number one issue, with physician recommendations number two at 74 percent.



Kim Wishnow-Per

Kim Wishnow-Per, president, McCann Managed Markets: The next round of ACA rollouts in 2014 has an impact on our business in several ways. McCann Managed Markets considers the managed markets landscape to determine a medication's value and place in the market. We work with our clients as their guide, by sharing our access intelligence to develop tools they need to shift the marketplace.

The ACA has created new market dynamics, and our clients must carefully consider these as part of their brand planning for 2014. These include essential health benefits (EHB) for pharmaceutical drugs mandated by the ACA for the newly formed Marketplace plans in each state; Medicaid expansion and hospital 340B drug pricing programs; evaluation of opportunities with organized customers, such as Accountable Care Organizations (ACOs) and Integrated Delivery Networks (IDNs); and Medicare and Medicaid electronic health records (EHR) incentive programs – meaningful use requirements.

We educate our clients on the evolving payer landscape and develop strategic and tactical plans to consider how components of the ACA might or might not affect their brands.

Marketing agencies need to understand how the local market payer dynamic affects the prescribing habits of healthcare professionals. It is no longer enough to deliver just a clinical message to the HCP. Providers also need to be confident their patients can afford the drugs they prescribe. Therefore, we must now include a customized local market "cost and coverage" message along with the clinical message. This messaging must be easy for the sales representative to deliver and for the HCP to understand.

This is no small task; the marketplace is becoming even more fragmented with the implementation of the new state Marketplace plans, ACOs, and the evolving benefit designs being deployed by insurers in response to the ACA. It is essential for marketing agencies to understand how these payer market dynamics affect local markets and develop relevant messaging to instill confidence in HCP prescribing.

Med Ad News: The ACA enrollment website launch is a popular topic in the news of late. What do you think went wrong, and how would your agency have handled it differently?



Kyle Barich

Kyle Barich, president, CDM New York: Of course it's easy to pass judgment in hindsight, but no agency would be proud of the HealthCare.gov rollout to date. If we were awarded that assignment and were able to manage through the likely inflexible contracting process, we would have put a lot of effort behind uncovering the user design and experience needs. And we certainly would have built in a more comprehensive testing plan that allowed adequate time for QC and user acceptance testing prior to launch. Perhaps a state-by-state phased approach could have been explored, because if it isn't cooked, it shouldn't be served. Once the site was launched, we would have developed broad and compelling drivers to get people to the site. Finally, if things didn't go as planned, we would face harsh reality with some good old-fashioned truth-telling conversations with everyone involved.

Jon Sawyer: Politics aside, websites can be very complicated and demand particular conditions under which their development can be successful. The several disparate entities involved in the creation of HealthCare.gov seemed to erode those necessary conditions for success. The bottom line is, regardless of the scope or the high profile nature of any technical endeavor, there needs to be enough time allocated for quality assurance in the beginning and quality control throughout the effort or problems are almost certainly guaranteed.

Ed Mitzen: It would be incredibly arrogant of me to think that our agency could produce a website that is on this order of magnitude. And we are an incredibly talented digital shop. I would like to think that more time would have been allocated to testing and QA control. The massive integration project between HealthCare.gov and all of the various insurance carriers (all with different back-end technology) is not something that can be executed without an equally colossal QA/QC procedure.



Christine Armstrong

Christine Armstrong, senior VP, managing director brand experience, Giant: What happened to HealthCare.gov is not an uncommon problem. It stems from three main pitfalls we face often as an agency that provides digital services. 1) A convoluted procurement process for an unprecedented project requiring many vendors to partner together without one "lead" agency. While it's not uncommon to encounter collaboration with three to five vendors on complex projects, 55 agencies contributed to (the failure of) the development of HealthCare.gov. 2) Poor program planning. The website was designed as a single launch with a finite beginning and end. No good agency approaches site development in that way anymore. Sites are more than just a single project; they are more like living beings that need to be monitored, nurtured, and evolved. Phased goals needed to be developed and designed with room for user feedback and iteration. 3) Poor communication protocols. The government did not have the right in-house technical "quarterback" to lead the team and call the shots.

Additionally, communication and transparency protocols needed to be established to avoid "coding in a vacuum" with no

one taking accountability for how their piece fit into the greater whole of the site.

At Giant, we hold both agency and client accountable for the milestones and validation points along the way. There are many check-ins that allow for more small, iterative success and communication that builds confidence between all parties. This approach allows for greater management of expectations, discussion of risk, and ability to respond quickly to requests or change without causing alarm, effecting scope and timelines. We avoid the "big reveals" which tend to over promise and under deliver.

Dan Renick: While there appear to be numerous technical glitches involved with the website fiasco, the underlying issue is more about how the administration wanted consumers to be presented with information – or rather, how they didn't want them to be presented with information, specifically the cost of coverage without subsidies included. So instead of consumers simply being able to browse available plans and associated "retail" prices, those exploring coverage first had to provide complete application information, after which plan options and prices were returned less the subsidy amount for those qualifying. While there is some merit to this approach from the standpoint of trying not to discourage those who will be subsidized by not displaying the full price up front, it adds tremendous burden to the system and converts what many thought would be a "shopping" experience to an "application" experience, and to date that has not worked well. The primary thing to do differently is explain the process right up front so that consumer expectations more closely align to what the actual experience will be.



Sophy Regelous

Sophy Regelous, chief digital officer, ICC Lowe Trio: When developing any type of digital environment, the creation of user-case scenarios is a critical step in the discovery and design phase ... especially when lots of users are expected to visit the site.

When working towards hard deadlines of high profile sites, it is often difficult to manage and meet all expectations. There is a tendency to rush through or skip steps in a standard software development life cycle plan, however taking time to follow the correct process almost always results in shorter development and QA cycles, leading to more successful launches. User case scenarios and a functional prototype tested by sample users can head off any usability issues, resolving them prior to code being started.

In addition, based on the ongoing progress and tracking of projects, when it becomes clear that the appropriate amount of time for load balance and thorough QA testing is not possible, it is worth creating a plan B failsafe, to roll out as soon as a site starts reporting issues. For example, a redirect URL with an advising page that the site is experiencing heavy traffic or a sign-up form to receive a time to return when they can be guaranteed service, may have been appropriate.

David Windhausen, executive VP, Intouch Solutions: To me, it sounds as though they approached the project all wrong. They approached it like other big development efforts in the past: spend an eternity documenting requirements in a vacuum; build, build, build; and then test late. You end up delivering something that doesn't meet the customer's needs.



David Windhausen

A better approach would have been an iterative one – one that included real-end users – those that would be signing up for insurance. Then the cycle becomes launch, test with users, plan, launch again, etc.

It also feels there were way too many "cooks in the kitchen." A lean approach would have been much better than the approach they took. It seems as though they had an inordinate amount of time and budget. (I wish we had that kind of time and budget for some of our projects!) Think of all the time and resources consumed by just trying to keep all of the parties on the same page. This was brought out a bit in the hearings with all of the back and forth finger pointing between agencies involved.

The final thought was because they approached this project in a very traditional waterfall manner, they didn't begin testing until way late in the cycle. That led to an inevitable timeline crunch and the bad decision to launch when the site wasn't working.

Leerom Segal: We have a view of what went wrong on HealthCare.gov (see our blog), and from our perspective, this is another example of bigger is not better. The code base has been estimated

at an obscene 500 million lines of code. Anything that big is just poorly designed, usually because there are too many, not too few, people on the project. A smaller team of highly skilled individuals will always create a better product than a huge team of moderately skilled people.

Med Ad News: From where we sit, it appears that the general trend of consolidation in marketing services procurement – i.e., clients demanding more services at lower cost and the big guys merging or buying themselves bigger in order to meet that demand – appears to be accelerating. What is your response to that point of view?

Jay Carter: When consolidations happen, it's big news, whether the announcement comes from a victorious agency network or a happy procurement group. It's not so big a story when the pendulum swings the other way, and nobody shouts about it. In 2013, our agency was approached by two different large pharma organizations who were contemplating elimination of their network consolidation efforts due to diminution in services. One resulted in a new business win. At the same time, we partnered with a very large agency network for a client consolidation, because our relationships aided in the network's chances of a win. Net/net, I think that there's going to continue to be change in the way that agency services are acquired, all along the continuum from single agency network to a different agency for each brand in a portfolio. All of those options offer opportunities for the independent agency.

Kyle Barich: Indeed many of our larger clients have already consolidated their marketing services at the holding company level while others are carefully observing before joining the trend. At the same time however, several are in the process of unraveling their earlier consolidation efforts. That being said, consolidation has taken hold in our industry and is having an influence on the ways agencies behave and are structured. For it to work on the agency side, the holding company offering has to be authentic, with not too many moving parts, and where everyone in the mix ultimately benefits by participating. On the client side, we are finding that this requires a huge degree of behavioral and structural change as well. We, and our partners in procurement, are seeing that consolidation is not the right answer for every situation. The manufacturer's organization needs to have patience and be committed – senior management, global marketers, and local units around the world. There needs to be some level of stability; if clients restructure several times in a year, it is unlikely that the necessary cultural and behavioral changes will happen. Otherwise the consolidation pendulum can easily swing away from these models. The industry is searching for a perfect and cost-effective answer to the complexities of modern communication and consolidation can help. But only if all parties involved are willing to take on the necessary organizational change.

Jon Sawyer: Certainly it's a macro event facing our industry, and we don't blame clients for wanting value for the investment they make in procuring services. However, we believe that great efficiencies can be gained through partnership and honesty with the smaller independent firms as well, and that the conglomerates don't have an exclusive lock on delivering greater efficiency, strategy and creativity or – at the end of the day – lower cost. Profoundly good work is the result of great working relationships between client and agency based in trust. Both parties need to feel like they are in that partnership willingly and only as long as they can do great work together. When it comes down to

the actual people doing the work, these large roll-ups often put agencies and clients together that are unwanted bedfellows. This often doesn't lead to the best output or the most cost-effective approach.

Ed Mitzen: Both large pharma and large advertising conglomerates are in a tough spot. They can't save their way to prosperity, and they are creating a huge talent drain. More senior staff are bolting (voluntarily or involuntarily) to smaller firms where they can do great work and avoid all the corporate bureaucracy.

Adam Gelling: Sponsors commoditizing the strategic and creative product through heavy-handed procurement is extremely short sighted and ignores the forest through the trees. Switching or excluding agencies over a nominal discount in hourly rates discounts the investment a brand makes in a true marketing partner and ignores true performance metrics such as total time and cost of project and overall brand performance. Our model to put senior staff on the front lines of client business to ultimately reduce client budgets and accelerate brand performance gets lost in a straight procurement rate comparison model. We believe in the role of procurement and appreciate their support and guidance, but encourage them to re-evaluate their success metrics or else risk lagging behind their competitors who have a holistic view of their marketing objectives and partners.

Dan Renick: It depends on where you sit. If you are a leader in a highly specialized space like payer marketing, focused on access and reimbursement needs in a complex market, consolidation may be viewed as a positive since it will drive even less differentiation among the giants. While a lower blended rate for consolidated services appears attractive on the surface, not receiving the necessary strategic support and related exceptional execution to secure profitable formulary access will cost far more than any procurement exercise will ever save. Marketing support is like any other area of purchasing – you get what you pay for.



Joe Daley

Joe Daley, president, GSW: Pharmaceutical marketing and commercial organizations are under significant pressure to bring forward the level of innovation that has been the cornerstone of R&D – and to do so with ever increasing efficiency and productivity. Leaning into this dynamic requires our bringing together ever broader complementary, non-duplicative skill sets and knowledge that allows us to complete a tight, focused partnership team with our clients; a simple, single team that works in a connected fashion across all customer segments driving a high value, consistent, impact brand experience. In my opinion, it's going to be difficult to address this environment without accelerated evolution and change that includes combining resources in more aggressive ways, including mergers.



Renee Wills

Renee Wills, president, ICC Lowe Trio: Agencies that are consolidating to achieve cost efficiencies and round out their capabilities must keep this in mind: Bigger isn't necessarily better. While change is accelerating across the industry, it's important to think carefully about what mergers can promise, and what they can't.

The fact is, all shops are making moves to better position themselves to handle current and future client demands: as procurement wants greater efficiencies, and brand directors want to leverage new and emerging technologies, some shops have consolidated. For example, a few traditional, full-service shops have merged with specialty digital agencies. Some that started out as digital shops are now part of bigger entities.

Searching for efficiencies through large-scale consolidations seems to make sense – on the surface – but when clients are seeking bigger and better ideas and more creative solutions, those ends may be better achieved in other ways, for example, through resource sharing and inter-agency collaboration.

The danger with consolidation is that there are so many variables affecting the outcome, the agencies' joint specialties could get "lost in the sauce." Agencies also need to make sure our work product doesn't become a commodity. After all, we don't make widgets.

In our business, the currency is still great ideas: there will always be tremendous value for agencies that come up with novel ideas that connect brands with target audiences, and drive the preference for and selection of those brands. Delivering those great ideas is still predicated on agency talent, philosophy, and culture.



Faruk Capan

Faruk Capan, CEO, Intouch Solutions: As an independent firm, this is something we watch closely. We have seen the trend wax and wane for the 15 years we've been in business, with mixed results both ways. The mega-merger of Omnicom and Publicis has again put this procurement trend back into the spotlight.

The reality for us is, we have continued to grow 30 percent or more year over year, and that growth is coming from both existing and new clients. Over time, clients find the consolidated services or "preferred network" model doesn't always meet their needs. And they discover they aren't saving any money after all, because those contracted networks aren't incentivized whatsoever to be efficient. So clients find ways around it. That's where some of our most recent growth has come from – from clients looking for innovative ideas and specialized digital consulting that they are just not getting from their arranged-marriage agencies.

Leerom Segal: The issue of cost is a red herring. It's not about cost, it's about efficiency, efficacy, and quality. If you make the right decisions based on the right information, then create the right artifacts, and place them in the right places, you can have the effects on the market that you need. If you don't, then no amount of money will save you, it will just be wasted. Right message, to right person, at the right time might sound like old news, but it's more important than ever and it ultimate comes down to a predictable and consistent execution capability.

Kim Wishnow-Per: Will the consolidation trend continue? Yes. Will it accelerate? I think so. For our clients, the trend is less about "more for less" and more about "better more efficiently." The ability to get best-in-class resources under one umbrella is one that intuitively makes sense. Connected experts in each core discipline is a powerful tool for today's marketers. Our clients have broken down their internal walls and agency networks have followed suit. This approach sets up fertile ground for better thinking, but does so in a way where organizations can realize cost savings through team efficiencies. Bigger networks don't necessarily translate to

bigger teams. They foster connectivity allowing for more focused teams providing better overall solutions.

Med Ad News: What are clients asking for today in the mobile marketing front? The social media front? What will they be asking for next year? What do you think are the keys to successful mobile and social strategies for pharma brands?

Kyle Barich: Most of our senior clients grew up in a world of controlling the message, reach and frequency, share of voice, and outbound marketing. And then most everything changed. For brands to be recognized and relevant in a digital world, they have to engage in social media. So we started with social listening, whether passive or active (research). Then we helped some braver clients launch corporate Twitter accounts and YouTube channels. But the magic two-way conversation about our brands or disease content across social media channels remains elusive for the most part. While the ideas reside in most tactical plans, so many barriers and fears remain. As policies evolve and we find "safer" and more compliant ways of engaging with HCPs and patients, we will decrease our sense of risk and increase our collective sophistication in healthcare social marketing.

What will they be asking for in 2014? Mobile Apps, Social Gaming, Responsive Web Design, Virtual Conference Support, In-app Branded Experiences, and continued improvement of the iPad personal selling experience top the list. Clients want more seamless integration of digital into their broader plans. They want better and more cost effective ways to develop and deliver digital marketing globally. Relationship marketing is enjoying a renaissance with immense improvements in data collection and analysis. Clients are pushing us to better leverage interactive visualization of data, to explore content marketing strategies, to customize and personalize content to drive relevance and engagement, and to integrate more deeply with our digital media partners. Frankly, it's exhausting but exhilarating.

Jon Sawyer: Look, mobile and social are just channels. They're certainly remarkable in that they are almost ubiquitous today, but ultimately they are just channels. Our clients are asking for sound counsel on when and where to leverage mobile and social and are no longer feverishly clamoring to get on the bandwagon just because they're there. Fundamentally good strategy calls for digital content to be at least mobile friendly and even better enabled to serve a mobility-driven purpose. Social has far-reaching, important implications for patient connectivity – perhaps less so for HCPs, but pharma is just beginning to understand the respectful and appropriate role it can play in social. We believe next year mobile and social will evolve and be contextualized into broader strategies and be less of a stand-alone focus of attention.

Erin Keefe, senior VP, group director, digital strategy, and Michael Pruskowski, VP, group director of strategic planning, Draftfcb Healthcare: One mobile question we're being asked more frequently and from a broader array of our clients is what should my brand's iPad 2.0 or next generation strategy be? It's an exciting question to hear because it signals an increased demand for more than just front-end only focused iPad-based applications, especially when it comes to the rep-based sales tool. Both reps' and physicians' expectations for the iPad continue to rise. They tell us they're looking for the "Amazon.com-like experience." They want iPad experiences that offer more customization, utility, and convenience. So the task at hand for



Erin Keefe



Michael Pruskowski

the next generation of pharma's iPad applications is how to best leverage both the front- and back-end technology. This means the continuance of strong creative and story-telling along with a steady increase in more data-enabled marketing capabilities including better collection and use of customer intelligence; more targeted and personalized content; more closed loop and relationship-oriented marketing. The end goal is an experience that leaves the physician and rep more satisfied while improving the marketing performance of iPad-based marketing efforts.

Another mobile question we hear from clients, especially those in organizations where there's been a clear mandate to prioritize mobile, is how can I get access to mobile innovation while not breaking the bank? We believe the answer is collaboration, funding and creating new partnerships with third-party technology companies. With the implementation of the HITECH Act of 2013, there is an increasingly larger world of technologies accessible to every developer as well as Pharma. This will fuel a surge in technology entrepreneurship and innovation within and outside of Pharma. We believe for our clients and ourselves that more efficient access to these technologies and energetic partners will expand pharmaceutical companies' mobile offerings and lower the opportunity costs related to innovation.

Regarding social, there is an interesting evolution of ask here. For our clients, especially on the DTC side, the question is no longer focused on how can I do social in the current regulatory environment, but where, when and with what messages that will align with a broader integrated marketing strategy? Two-way, pharma sponsored social has been proven in the unbranded space. Gated/moderated is happening in branded. In 2014, we expect these trends to continue along with greater social media marketing experimentation and activity.

Ed Mitzen: Clients continue to look for innovative disease awareness programs that can be implemented through mobile and social. While FDA ambiguity continues to be a concern, companies seem to be more open to different ways to reach their potential customers. Responsive-design sites are the standard now as well, as are well-thought out landing pages. It's been encouraging to see clients' understanding of mobile and social increasing, and they are open to us teaching them best practices.



Jonathan Peischl

Jonathan Peischl, senior VP, director of innovation and digital marketing, Giant: Mobile breaks out into three key areas: tablet detailing, point-of-care access, and patient/consumer/caregiver information access. On the tablet, specifically the iPad, each of our clients is moving in that direction; some have gone so far as to nearly eliminate paper from the sales call, while others offer the sales force the choice. Regardless of the mix, the convenience of a single point of access for all brand and disease education messaging, as well as program promotion and enrollment, has won over sales organizations.

Meanwhile, access to rich customer insights via engagement metrics has won over marketing and business analytics. Once tablet detailing is off the ground and embraced by the sales organization, the hunger for new content and fresh features keep our teams busy day and night.

Point of care access to drug and disease information is alive and well. Physician adoption of mobile is off the charts, and HCPs have a wealth of resources they rely on every day in their practice. The opportunity for pharma is significant, from the simple step of mobile brand site optimization to HCP toolkits offering features that may not be found on some of the third party sites and apps that are commonly used. Additionally, with HCP adoption of tablets we see great opportunity for patient education tools that can be used in the practice, ultimately replacing the printed HCP-to-patient education pieces.

For patients, consumers, and caregivers, the need is there. Consumers expect to be able to find what they need in mobile-optimized form, whether it be banking, travel, dining, etc. Why shouldn't our industry address the need as well? This is the greatest area of opportunity for our industry. Apps are nice for chronic conditions, but consider the waiting room or exam room scenario where a patient is faced with a diagnosis or prescription that they immediately need to know more about. The iPhone comes out, and the search begins. We must be there for them.

Social remains somewhat of a one-off area for pharma. It's important that we listen and use the information we hear to make smart decisions, and participate or drive the conversation only when the need is clear. Transparency is essential in social media, so anything less than a genuine interest in helping a community will result in failure. We need to be present, but we cannot be leaders in the conversation, it's simply not in keeping with the nature of the media.



Leigh Householder

Leigh Householder, chief innovation officer, GSW: Multi-screen marketing is a critical new skill set our clients are focusing on this year. Specifically creating the right experience for every context that involves a screen. Depending on the audience, that could mean snackable, scannable content a physician can browse on his tablet during morning coffee, a debate-ending video that a daughter can pull up on her smartphone to show her mother, or even a smart retraining tool that delivers a different experience when he's looking at the screen vs. when he's driving to a meeting.

On the social front, video is huge this year. It earns more attention in social than any other type of media plus it already earns 50 percent of mobile traffic. In healthcare, video can play a key role in motivating people. Disease makes people feel isolated and alone. Video lets us bring them inspiration from people who are dealing with the same decisions, the same therapies, the same disease, in documentaries and storytelling that are authentic and peer-driven.

Dan Renick: A significant key to success in these areas will simply be understanding the rules and regulations as they are generated and applied, and then being as creative as possible within that framework. We have seen that each of these areas presents novel creative challenges, and one-size-fits-all solutions have been shown not to work well. Right now, clients are actively trying to figure out the right balance – too much investment in high-growth areas like mobile and social media at the expense of more established methods runs the risks of losing touch

with traditionalists, while too little suggests an overly conservative approach that is out of touch with the realities of today's digitally connected world.



Andrew Thorn

Andrew Thorn, digital strategist, ICC Lowe Trio: The principles of "mobile-first" design have worked their way into the fabric of professional marketing, which is a great thing.

Our clients are increasingly more interested in evolving their Web-based content so it can respond to immediate customer-centric needs – in their location, in context, and in more conversational language. Pharma companies can no longer "re-apply" Web content for mobile media: We all need to think "mobile first," not simply adapt one to the other.

While many of the most enticing aspects of mobile marketing (location-based services, augmented reality, experiential design, social immediacy) remain untapped in the professional landscape, there is an ever-growing number of professionals who use mobile platforms to satisfy their need for information, so the potential in this channel is huge.

Social media continues to be another difficult nut to crack in the professional side of pharma, for well-documented reasons. The increasing awareness of the role social networks play within the Customer Life Cycle is inspiring us to work even harder to find manageable ways to leverage these channels.

According to a 2013 report by Wildfire, the No. 1 way a customer discovers a new brand/product/service is by seeing ads on social networks. That's almost double the rate of online ads. Moreover, search engines (40 percent) barely edge out social networks (37 percent) as a platform for researching brands/products/services.

Vital to successful mobile and social strategies for 2014 is exploiting analytics to help pinpoint the best way to connect the right messages with the right professionals. Equally important, however, are customizing experiences for different platforms and developing content strategies that truly reflect how professionals consume information within these channels.

Wendy Blackburn: With FDA issuing final guidance, much of the uncertainty around mobile medical apps has evaporated. Now we can determine with some level of clarity if FDA would consider a certain mobile app as a medical device, and plan accordingly. We have heard a collective sigh of relief, and innovation is opening up again.

Meanwhile, social has become mainstream, even without guidance. Slowly but steadily, we are seeing interest in long-term engagement programs vs. one-off campaigns, which is good for everyone. We're seeing clients hire full-time in-house social media staff. And we continue to see an uptick in utilization of our social media products that help pharma companies engage in a compliant manner.

Pharma companies are seeing that social media is here to stay, they are getting more comfortable with it and they are finding ways to engage.

Leerom Segal: Mobile is no longer a separate issue, it is just the current reality. If your site does not display well on mobile then you are late to the party. Doctors and patients do not care about your MRL process, they care about information that is clear and readable on the device they are using. So, mobile is no longer an afterthought; it

needs to be a consideration in everything we do.

Social on the other hand is still in regulatory purgatory. There are a lot of experiments being tried, but there are still a lot of questions. I don't expect the FDA guidance scheduled for 2014 to really change much for the industry except it may provide those moving slowly, permission to experiment.



Eric Pilkington

Eric Pilkington, executive VP, digital strategy, North America, McCann Health: 2013 was certainly an important year for pharma, as their embrace of digital came front and center. 2013 was a remarkable year for McCann Health too,

as we perhaps began working with our client to better leverage digital as THE CHANNEL by which to establish and extend relationships with critical customers and organizational stakeholders. Based on this demand, I think that there are five critical trends to follow as we move into 2014.

1. Increased personalization/customization of ad messages

While dynamic ads have been around for some time in other verticals like retail, we see them as becoming more prevalent in the pharma space. Ads will be customized based on users' behaviors observed both on advertiser-owned properties as well as publisher sites. Dynamic ads enable pharma advertisers to create multiple creative variations using a single ad template, which increases marketing performance.

2. Mobile becomes a basic

The year of the smartphone has come and gone in other industries, but 2014 is poised to be the year of mobile in Pharma. And as more and more people move away from the desktop towards mobile devices, mobile advertising (search and display) will become a standard element in digital media plans.

3. Pharma gets social

Pharma companies have struggled to harness the power of social media given the concern with adverse events (AEs) being reported in online forums or networks. For this reason, they have adapted their approaches to find ways to engage in social in a low-risk way; for example, adding voting mechanisms or social sharing features to websites.

4. Online video as a replacement, or to companion DTC advertising

TV advertising continues to be a mainstay in the pharma marketer's toolkit. However, with the extra airtime required to add in the mandatory safety language, pharma advertisers take a hit on TV media buying – unable to buy the shorter, cheaper spots. Unless you have a blockbuster product, cost can be prohibitive. With the rise of online video advertising and connected TV, more and more advertisers are running their commercial spots in the online space. Our clients are beginning to take advantage of the additional targeting available with online video that is not usually available with traditional DTC buys.

5. Pharma finally embraces mHealth/Digital Health

Consumers are managing their weight, improving exercise routines, modulating stress levels, and tracking their behavior through a host of smartphone applications, wireless devices, and wearable technologies. Many of our clients today are beginning to look at how they can best leverage this trend – how apps and technologies can extend better service and support to patients and physicians alike, while leveraging the cohort of data to better understand customer behavior and trends and more individualized levels.

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Med Ad News: With digital moving to the center of most brand marketing plans, it seems that the good old-fashioned journal ad or physician print piece may be going the way of the dinosaurs. What is the proper place of print in a modern brand marketing strategy, and what are clients seeking – or not seeking – in this area?

Jay Carter: *Ad Age* says that in 2012 one-third of agency revenues came from digital services. Our agency was a few percentage points higher than this, but certainly at least 60 percent of revenue came from other sources. Journal ads remain, in our estimation, vitally important. Physicians still read them, and journal media remains one of the most cost-effective ways to deliver frequency to physician audiences. This allows pharma to more effectively “brand the sales call” and remind physicians of their most recent persuasive sales call by a rep. Print remains an important component for patient education as well ... we need to be mindful that an enormous portion of the medicine consumed in the United States is among patients who are less likely to go to the Internet (though they almost universally have it available).

Kyle Barich: Paper is not dead. Rather print is evolving to be part of a holistic multi-channel experience. Print can serve as a reminder, a driver, or a connector. We just released a print leave-behind with a tag that launches an immersive augmented reality experience to help explain a complex mechanism of action. We are developing journal ads that are repurposed on iPad journal apps that link to engaging and relevant video. Print can act as a physical door to a digital world.

Jon Sawyer: We believe that all channels including print will eventually settle into their proper place with their proper intent and purpose to help customers along their continuum of adoption. Certainly print is challenged because it provides little feedback or opportunity for learning, but we all read or interact with something physical and tangible from time to time for different reasons under different circumstances. The objective is to determine when and where print is appropriate. However, the stampede to digital hasn't necessarily revolutionized the impact beyond print. Most interactive sales aids deployed today on tablets or laptops are simply digital versions of paper-based sales aids, and many don't provide much tracking of feedback or comprehension beyond the event that a sales call took place. This will need to improve dramatically to realize the vision of true CLM or CLP, in which case the day of the paper sales aid may truly be over. But the industry is not there, yet.

Ed Mitzen: There is still a place for “traditional” media, as long as it is integrated with the larger objective. The percent mix is really dependent on the target audience and product profile. We have a client now that has a product for a very socially awkward sexual issue, and patient anonymity is a big concern when self-diagnosing. In this case, more than 90 percent of our efforts are online. It really varies by marketing challenge.

Jonathan Peischl: We've seen data that shows that tablet detailing is not the end-all, be-all and that the combination of a tablet-enabled discussion and a print leave behind is more successful when it comes to message retention. Print media is another issue altogether. We know that physicians continue to rely on medical publications for information, but more and more that information is consumed via a tablet like the iPad or a laptop (sometimes even a small format device like a mobile phone). That said, we see variances

by disease state and specialty, so it's important to take a close look at media consumption habits before you rule out print advertising as an effective tool in our industry. Overall, our clients are simply seeking our guidance on where they should invest their marketing dollars.



Bruce Rooke

Bruce Rooke, chief creativity officer, GSW:

There is no place left for an old-fashioned print ad. There is, however, a place for a new-fashioned print ad; one that can drive readers, through both the content of the message and OCR/AR technologies, to a fuller, more interactive experience. The old-fashioned print ad expected readers to get every single bit of information necessary to make a brand decision right then and there (as if it were the only brand communication there was,) which was unrealistic anyway, and perpetuated by equally unrealistic executional research methodologies.

But think about it. There are print magazines and newspapers that continue to thrive, way beyond the expiration dates of pundits, due to the content and rewarding experience they create. The same can go for print ads. Clients would be smart to ask themselves two questions: “What could being in print do for my brand?” (Could you own the book, now that your competition is running away?), and “What would make that print ad a compelling, engaging experience?” (versus the usual, how do we fit all of this stuff on the page with our branding colors?)

Dan Renick: We are definitely seeing an accelerating trend for journals to offer digital (ie, ebook) as well as print editions. Either way, digital or print, the publishing houses will continue to compete on the metric that matters most to advertisers – readership. The digital space presents unparalleled opportunities for our clients to create customized engagements with their customers, and a more efficient way of controlling frequently updated content such as label changes, access changes, and updated value propositions. But print can do things that digital can't – sometimes a tangible piece that ends up on a decision-maker's desk for a few weeks could be what gets the message through. For advertisers, the question is therefore not one of print or digital, but print and digital, both providing the opportunity to cater to customers' disparate preferences. It does not matter how you deliver a weak message, so focusing on creating the strongest value propositions unique to specific customer segments is the most important thing we do.



Catherine Jones

Catherine Jones, management supervisor, ICC Lowe Trio:

More than ever, our clients are seeking the most effective ways to engage with their audiences. We still have to find ways to make better connections between those brands and their audiences, and build a trusted relationship between them. That starts with a strategy that takes into account all the channels in which we will be engaging with that audience. In the healthcare space, while there's often a lack of success metrics in some of the newer channels, the metrics remain solid in print.

Journal advertising and print media should always be a part of your brand's communication strategy. The metrics are solid, and according to Manhattan Research, physicians still rely on printed journals 93 percent of the time, versus

89 percent of the time with online journals.

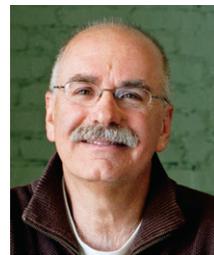
Plus, in the digital realm, it's easy for professionals to be distracted and miss the message, whereas in print, there are fewer distractions. In both print and journal advertising, strong calls-to-action and tracking mechanisms help confirm the ad's effectiveness. Using print to gain brand awareness and support digital activation will remain a key part of any effective communications plan.

David Windhausen: Traditional offline media outlets continue to merge with digital. For instance, with the emergence of smart TV technologies, TV advertisements can now be targeted via the same predictive analytics models that we are using through other channels. In addition these ads are bridging the gap between the offline and the online through interactive and second-screen technology experiences that drive greater engagement outside of the ad. The same is true for print. Print in pharma is still a big avenue for gaining awareness, especially when it comes to healthcare professionals who still consume a large amount of their content through normal print channels. The challenge for digital marketers is to find the opportunities to cross over to interactive engagement. Opportunities like interactive embedded ads within the digital version of a traditional journal are just the first step.

Leerom Segal: Reports of the death of printed journals have been greatly exaggerated. Print is important and will always be an important on-ramp to digital programs. Once there, the basics of HCP communication haven't changed for 20 years.

Med Ad News: What other trends and changes have you observed in your clients' respective promotional mixes?

Jon Sawyer: We are seeing a wholesale trend toward data-driven marketing and relationship marketing programs that meticulously track behavior, engagement and results. All tactics are tied to individuals, with the ultimate goal of substantially increasing the level of insight and understanding of customers. This is leading to highly customizable and effective campaigns that not only communicate more effectively but deliver a meaningful value proposition to physicians and patients. This is affecting the marketing mix in that all tactics are being assessed as to their ability to contribute to the relationship marketing effort, namely 1) Does the tactic reach a specific known target? 2) Does the tactic capture behavior and attitudes that may be attributed to an individual target? and 3) Does the tactic provide an opportunity to leverage that interaction into another that is part of the coordinated mix? We're seeing that tactics that don't meet the above criteria are being rapidly deprioritized if not discontinued.



Mike Sperling

Mike Sperling, principal, Giant: With the Sunshine Act, ACA, and greater competition we're seeing a shift towards greater sales rep responsibility and the need for programs that enable them to solidify their customer relationships, to differentiate themselves from the competition and for them to feel comfortable with a changing healthcare marketplace. The leaders in the pharmaceutical/biotechnology space recognize the importance of educating and explaining to the sales force why they are doing what they are doing. How this gets communicated in a motivational way is all about what agencies do – deliver sound strategy and communicate it in

an exciting and impactful manner.

Leigh Householder: One big trend we're seeing with our clients is a big shift in the promotional mix from primarily rep-delivered messages to an innovative, and uniquely personal set of not-in-person marketing strategies. Peers are huge players in this new mix. Data-driven marketing is, too.

Dan Renick: The main trend we have seen is towards using iPads for customer interactions instead of traditional printed pieces. Yet many underestimate the training needs for their customer-facing teams in taking the greatest advantage of this medium. Digital interactivity allows for unparalleled gathering of customer insights, which ultimately leads to the growing role of health outcomes. This includes field support personnel and allows for incorporation of endpoints relevant to payers earlier in clinical development programs, though that has not been consistent and is easier said than done. The enactment of the aggregate spend reporting regulations in the Sunshine Act has an increasingly significant impact on the development and dissemination of educational materials, though it remains to be seen how strictly the pharma and biotech companies will interpret the requirements.

Sandra Szlachtiachyn, account planner, ICC

Lowé Trio: Despite the “fumble” of the Obamacare launch, healthcare professionals are bracing for an unprecedented wave of new patients and policies to pour into their offices next year, fueling tremendous opportunities for health care marketers. In response to these evolving physician needs, health care marketing will continue to shift toward a more service-oriented mix, and away from a purely product-selling role.

The channels and tactics through which our messages are being delivered will increasingly include value beyond the drug – bringing brands more in line with preventive medicine and patient-centric healthcare.

Further, there's a growing trend in professional communications to better leverage the value of PAs/NAs, as well as implementing strategies that enlist the help of pharmacists in driving drug adherence. As these trends continue, we can also expect to see a growing service offering within pharmacies – from MinuteClinics to virtual doctor visits conducted via Webcams.

As physician prescribing behavior and treatment locations continue to evolve, health care marketers are going to have to deliver more targeted content – in both message and channel selection.

Faruk Capan: Big data is coming of age, and clients are showing interest in new ways it can be used. Our programs are becoming more and more sophisticated with the use of data, including customer profiling, personalization, customization, predictive modeling, real-time responsiveness, and program optimization. The possibilities are exciting and endless, but we also must stay mindful of privacy concerns.

Leerom Segal: The biggest shift in thinking is towards digital first programs with every element of the increasingly complex ecosystem being better instrumented for personalization and systematic optimizations. At Klick Health, we've also been investing heavily in building deeper capabilities in both clinical recruitment and managed markets. ■ MEDADNEWS

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Well is the word

DTC messages are going beyond the brand to engage with patients on the topics of health and wellness.

By **Christiane Truelove** chris.truelove@ubm.com

The role of traditional DTC – highly branded messages in television and print – continues to shrink as marketing is evolving into a multichannel spectrum. A new trend is unbranded messages to consumers and patients about health and wellness in a variety of digital mediums, and for pharma, the challenge is being able to claim that space in a way that eventually connects back to the brand in a meaningful fashion.

Industry thought leaders have been noticing this health and wellness trend among their clients. Alexandra von Plato, president and chief creative officer of Publicis Healthcare Group, says a number of factors are shaping this trend.

“We’re seeing really an alignment of incentives take shape where payers and providers and patients all recognize that getting the patient to take care of themselves and helping the patient make better healthy choices is good for business,” she says. “We’re seeing people connect with sources of content and information that help them make better decisions and we’re seeing brands trying to build brand awareness and loyalty and preference around being the source of information and inspiration, not just of the solution itself, in terms of the drug.”

Bill Drummy, president of Heartbeat Ideas, says a number of macro factors are driving this trend. “One of them is the fact that with the Affordable Care Act now being implemented, and all the incentives in the Affordable Care Act to move from a pay-for-performance model to more of an outcomes-based model, everyone really is incented now to look at the overall wellness of a patient, and not simply look at particular therapeutic regimen to accomplish only this specific goal with no harm being done and there’s some efficacy. It’s actually about, ‘Am I making the patient better and at a lower cost than an alternative.’”

Paul O’Neill, president of Ogilvy CommonHealth Wellness Marketing, is also seeing the wellness trend play out, but sees the main driver being the way consumers are becoming more independent about how they seek healthcare.

“We as healthcare consumers, all of us, are captains of our

own destiny at this point much more than we’ve ever been, and I think marketers have smartly said that if I try driving you into making a branded request around the HCP, that’s not enough; more and more it’s about educating healthcare consumers as their own self-advocates in driving their own care, to understand the context of health and wellness and also potentially their disease and to engage them within that context,” he says. “The brand is completely part of that, part of the solution. But to really have a broader view of the disease and their role in managing the disease or maintaining health and wellness is recognizing that they’re more in charge than they’ve ever been, so we should be talking to them a little differently or engaging with them in a different way.”

According to von Plato, this evolution is a positive trend as healthcare reform and adherence become more important. “We see that the wellness component of a brand story, the behavior medication, the lifestyle management, the helping people through the long tail of chronic illnesses not just acquiring the patient and getting them on drugs, but keeping them on drugs, and keeping them healthy on drugs and proving that the combination of the drug therapy and lifestyle modifications, actually are successful and beneficial to the patient. All of that is causing brands to examine their strategy and invest a little bit more in wellness messages and wellness content.”

Drummy says the trend in wellness messaging is being driven by the efforts to make everything more patient-centric. “I have a problem with the whole phrase DTC as direct to consumer. First of all, referring to someone as a consumer of healthcare is an odd way to be putting it, to be honest with you. I don’t think people consume healthcare services in the same way you consume Cheetos. You probably should not, and there is probably a negative correlation between the two. So, calling someone a consumer of healthcare is wrong probably, at the get-go. So talking about it as patients is a much better idea. They’re

people looking to improve wellness, make their lives better, and there’s lots of ways to do that, not just narrowly looking at the therapy itself, but everything around the therapy.”

Another driver of non-branded wellness messages to consumers and patients is the move by pharma and healthcare to move “beyond the pill.”

The phrase itself is overused, Drummy says, “But it is really about delivering services beyond the therapy itself in a meaningful way for all the people involved in the patient’s wellness – the doctor, the patient him or herself, the caregiver, all those folks have a role in that. And increasingly, there’s also a role for the people who are, quote on quote, more the financial decision makers.

“And increasingly, we’re seeing how important it is to make the pharmacoeconomic argument as well as the safety-efficacy argument, so that people understand that if you take this particular therapy you will actually be reducing overall costs to the healthcare system, if this particular therapy can be proven through its clinical trials, do what we do to reduce bad outcomes, reduce rehospitalization, for example, reduce the number of days somebody spends in the hospital, that sort of thing, if you can show a correlation there, you can actually then make a case that not only is it a safe and efficacious therapy, but it is one that is less costly to the overall healthcare system. And increasingly, that’s where we have to be going.”

The medium for the message

It has become quite clear that the expansion of the medium for DTC – beyond just general television spots and print ads into digital and mobile – has allowed pharma to craft unbranded messages that go beyond the messages of benefit and risk.

“Everything we’re doing now [at Digitas Health] is multichannel; almost every ad campaign has some kind of a back story or some kind of content offer that has to do with the condition,” von Plato says. “Our clients are looking to provide things that are of shareable value, that have some kind of a service component to them that’s across the board. We have very few clients that only want an advertising campaign. They might want something that would include and add strategy, but the larger strategy is a multichannel brand strategy that has content and media partnerships and apps and a social strategy, all designed to engage a customer in a conversation that a patient would want to have. So you have to figure out what patients are interested in almost back the brand positioning into that.

“It is a little bit of a different way of working than the traditional approach, which is you figure out what your label can say and then develop messages to make that relevant to consumers,” according to von Plato. “We are actually looking at what consumers or patients are looking for or need, and how do we use that to inform the brand platform and the ultimate technical plan, which includes many different kinds of channels and approaches.”

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Like See All

Cushingconnections.com, created by Heartbeat Digital, is an unbranded campaign for Corcept Therapeutics, the marketer of Korlym, a glucocorticoid receptor antagonist that is indicated to control hyperglycemia associated with Cushing's syndrome. The site's app and other functions encourage conversations about wellness between patient and physician.

O'Neill maintains that traditional direct-to-consumer messages will not go away, but they are going to continue to be far less dominant.

"It still has its role in the mix in terms of broad and rapid awareness as a primary driver of its value, but as we get into wellness messaging and ask for a mindset shift among the healthcare consumer, there's a depth of information that must be conveyed and a higher level of engagement, beyond just driving a branded request into the HCP," he says. "So I think that will drive even further this movement towards more media channels that provide a greater and deeper engagement."

Von Plato points out that traditional DTC can be effective for specific brands. "If you have a big indication like cholesterol was, there's a reason to use mass media," she says. "You have a pretty educated audience, and you can simplify your message and use mass media strategically."

With pipelines yielding products with more niche indications, however, traditional DTC will not be cost effective for these brands.

"But that being said, all brands need to engage with the customer on their terms and the customer, and the patient, and the consumer is using multiple channels and multiple points of reference to form an opinion and make a decision, and gain confidence and decide to act," von Plato says. "Nobody relies solely on television anymore because they recognize that even though it might give them the reach it has to work with other channels, primarily other digital channels and other sources of content."

Cegedim Strategic Data shows that DTC spending dropped 22 percent in 2012, to \$3.10 billion.

According to Nielsen data, the industry spent \$3.47 billion on direct-to-consumer advertising during 2012, 12 percent less than in 2011. Breaking down the spend, Nielsen reported that \$2.17 billion was spent on television in 2012, a drop of 11 percent compared with the previous year. Magazine spending dipped 16 percent to \$1.01 billion. Newspaper advertising spending dropped 21 percent to \$192.3 million. Radio advertising spending had the biggest decline, 34 percent to \$23.1 million. Spending on outdoor advertising rose 61 percent to \$3 million.

Also per Nielsen, the industry in 2012 spent \$68.4 million on Internet and digital advertising (excluding Myspace.com, Realtor.com, Yahoo! Mail and YouTube), with the 2011 figure not reported.

Citing Nielsen statistics, Richard Meyer, blogger at World of DTC Marketing, reported in April that DTC Internet media spending went down 33 percent in 2012. He had heard from agency contacts that pharma was actually increasing its spend, but from pharma people that all budgets, including that for Web, were being cut.

"Given that pharma cannot fully leverage search marketing because of the requirement for fair balance, I could see pharma reducing their spending, especially on drugs that have high awareness," he says. "That leaves actual site development, mobile marketing, and CRM programs. With the consolidation of interactive agencies and pharma's insistence that they use only approved vendors, I could see how the costs of actually building a product Website could increase. ... So we are left with overall declining DTC budgets and less money being spent on internet media. This could mean that more money is being shifted into digital marketing at the expense

of TV, but again, even though the Nielsen numbers show that the web media is taking a bigger hit than TV, that does not include a lot of online marketing initiatives."

Spending on traditional direct-to-consumer marketing will continue to decline in 2013, Meyer says. According to Meyer, spending will be down in most categories as drug makers are forced to cut back because of changes in the Affordable Care Act and the continued loss of some big-name drugs coming off patent. He predicts that spending on digital marketing will increase but not in terms of media, as more dollars will be spent to develop and test digital marketing to healthcare professionals and consumers, but that will not translate into more online media spending.

"The biggest decline in Internet spending, I believe, will be in paid search and marketers will rely more on organic search," he says. "TV is great for building awareness but with more and more consumers multi-tasking and time shifting TV watching, DTC marketers are going to look for other ways to build awareness. In addition, research has shown that more and more consumers are 'tuning out' when it comes to DTC TV ads."

Additionally, newspapers and magazine will continue to decline and dollars will be shifted more to targeted health magazines, he says.

With the precipitous drop of traditional DTC marketing and the switch to digital, it is no surprise that the style of the messages is changing, Drummy says.

"In digital, it's really been an interesting and effective approach to talk about condition state and not necessarily always lead with brand, because in digital, you want to create an engagement of value, a long-term relationship with folks who have a particular condition, and you move into the branded conversation when it's appropriate," he says. "But very often it's not the very first thing you do, because in many cases there's no awareness of what the issue is, so you need to target the right people and give them a message about the particular condition, and then move from condition to brand and it's a multistep process, which is really easy to accomplish, really effectively in that realm. It's a little more difficult to accomplish that in the television realm or in the print realm, but it's a very effective approach in digital."

Unbranded initiatives are increasingly taking center stage, von Plato says.

"I do see more unbranded initiatives I think in the last year than I have seen in previous years," she says. "Some clients are looking now, whereas a couple of years ago they would have said, 'We would never do unbranded,' they're finding a way to use unbranded to connect with their audiences, maybe different segments of their audiences, and start a conversation with a different group of people."

Companies are using digital media to be able to more effectively segment their audience and talk to different cohorts, especially undiagnosed people. "We're seeing this sound more like a wellness conversation because obviously you're not talking with people who are overly symptomatic, or they haven't been diagnosed, you have to find a way to start the conversation or try to get them interested, and it usually starts with something that has to do with wellness or lifestyle," von Plato says.

Part of that digital expansion is the use of mobile, according to Drummy. "With mobility being a bigger and bigger part of how healthcare information is being consumed, and how we are able to add value to the rela-

tionship between the physician and the patient, we see that as a huge area of growth for pharmaceutical companies and other healthcare providers," he says. "And also it shows a different way of approaching the question of how do we help and are we really only about advertising, or are about something broader."

Traditional forms of advertising are limiting, Drummy says, and he believes communications with consumers and patients should be about creating value, in terms of providing information or utility that will help a patient and a physician come to the right medical conclusion. "We're not practicing medicine of course, but we are trying to enable better outcomes through a conversation between a healthcare provider and a patient," he says.

As a result of this philosophy, a lot of the work Heartbeat Digital has been doing in the app space has been about facilitating the dialog, making it easier for the right patient to walk into the doctor's office with the right questions and to prepare the doctor for the right conversation with the right patient. "These things are really heavily enabled by the digital revolution and those apps and mobile solutions that are most effective are ones that actually make that possible in a more valuable way," Drummy says.

Shifting the viewpoint

Although some clients have enthusiastically adopted the nonbranded, health and wellness approach in their messaging, it is still far from universal in the industry.

"In pharma, there is a tendency among marketers to do what they've always done because they've always done it," Drummy says.

Because television has been traditionally the most prominent way to get messages to a consumer audience, many marketers are reluctant to lessen their reliance on it.

"In many cases it makes sense, but in many other cases, it really doesn't make sense or let's say, to put it this way, it's not the only thing that makes sense," Drummy says. "I think we've gotten a little too comfortable with doing things that way, and it sometimes works really well, but in many cases, it's not the most effective or efficient way of reaching the target audience."

Digital programs can target down to the ZIP code level or the behavioral level, making them more inherently efficient. And when marketers say digital does not have the reach of broadcast TV, Drummy has challenged that. "I've said I don't think that's true any longer, with the networks that are out there now, we can get tremendous reach comparable to TV reach," he says. "There's a lot of ways you do things with much better targeting in the digital realm, and then much more effective TV-like creative to get attention."

"So by combining things such as the superior targeting with the high-impact, television-like creative, you can really get some tremendous results. We have a campaign in market right now for one of our clients that is doing extremely well, because we combine multidimensional targeting – geotargeting, behavioral targeting, along with high-impact creative."

Heartbeat has had a lot of success with wellness and health messages in direct-to-patient digital for another of its clients, Corcept Therapeutics. For Corcept, Heartbeat designed Cushingconnection.com, a digital campaign for patients with Cushing's disease. Corcept markets Korlym, a glucocor-

ticoid receptor antagonist that is indicated to control hyperglycemia associated with Cushing's syndrome.

Heartbeat helped develop a solution for patients to know whether their Cushing's disease was returning after surgery. An app helps these patients track their symptoms, and they can use the information gathered by the app to have a conversation with their doctor. Besides the app, the Website also contains links to a Facebook page and a way for patients to share their stories.

"It's been very successful in identifying and being an aid to patients who really are trying to understand what is the exact state of their disease and what other types of therapeutic options they may want to consider," Drummy says. "So it's all unbranded, which is what we were saying in the earlier part of the conversation. But it's really focusing on how can we add value to the conversation between the patient and the doctor."

According to von Plato, if pharma marketers don't start shifting the message to health and wellness issues, other markets will claim that message.

"I'm seeing non-pharma brands all over wellness," she says. "I'm seeing McDonald's all over wellness, I'm seeing insurance companies all over wellness, I'm seeing K-Mart and Walmart and everybody is getting into this."

The Affordable Care Act with its incentive-aligned issues is driving many industries and companies to become part of the solution, even if they were part of the problem, von Plato says.

"The danger in that for pharma is that the skillful storytelling and marketeering that goes on in other categories, they'll claim health and wellness right out from under the pharmaceutical industry, which has every right and reason to be a beacon for promoting health and wellness," she says.

O'Neill indicates the success Nike has had with its fitness devices and apps. "If you think about the Nike Fuel or Nike One or some of these other programs, they've created a role for the brand itself both in the context of fitness, in what the word fitness means to people," he says. "This device becomes part of a much bigger or ongoing relationship than just a brand purchase or anything like that. It's how integrated into their care system, the opportunity within healthcare, and some of the consumer products that have succeeded."

Von Plato points to a "beautiful" campaign done for Special K cereal. "It's about numbers and women, how we're taught to measure everything like our weight, our body fat, our calories, our bra size, and it's another take on real beauty. But it's such a beautiful, emotional women's health ad and at the end of it, it's from Special K. And Special K, I bet the lifetime value of a customer to Special K is \$50. I mean, how many boxes of Special K can a person eat?"

"And the lifetime value of a customer for someone who's being treated for diabetes, hypertension, depression, is tens and tens of thousands of dollars," according to von Plato. "But this territory of wellness and well-being and taking care of ourselves and the virtue of health over wealth, the value system that says being healthy is important, it's important as being wealthy, it's important as being employed, it's important as being successful ... but I think as other things in our world change, we're going to have to evaluate our own ability to take care of ourselves and these other marketers are going to get in and take it right out from under us."

■ MEDADNEWS

Shifting sands

Faced with the appearance of new financial decisionmakers, increasing pricing pressure, and the growing demand for outcomes data, marketers attempting to communicate with payers of all shapes and sizes must adjust their thinking or fall behind.

by Larry Blandford



Larry Blandford

To say our healthcare system is evolving is an understatement. How our healthcare is delivered and consumed is rapidly transforming – and the driving force is the quest to achieve greater value through reducing costs while improving quality of care. These shifts will impact how various stakeholders view pharmaceuticals in the overall value equation. The process for determining product access, what information is used to inform decisions, and which entity within the healthcare system makes the final decisions are all expected to alter as a result.

The traditional decision-makers – health plans and pharmacy benefit managers (PBMs) – remain the top influencers of product access. These entities are also on the front lines of driving value on behalf of their customers, the purchasers of healthcare, including employers and government programs. However, health plans and PBMs are not alone in feeling this pressure. Providers, who have traditionally operated on an individual patient-based service reimbursement model that encouraged higher volume, are being pushed to manage populations of patients and take some accountability of risk for outcomes, both clinical and financial.

We at Hobart expect and are starting to see that providers who have organized themselves around these factors exhibit some of the traits of traditional payers – assessing treatments based on clinical and financial impact across their population and managing toward quality metrics for specific subsets of patients. Given the relative inexperience of most providers in managing populations and risk, health plans and PBMs are in some cases becoming the data and analytics engines supporting these provider entities. For each of these stakeholders, quality performance is approaching the same significance as cost of care due to financial incentives, particularly in Medicare, where participants have the opportunity to make up or exceed reimbursement cuts with high-quality performance.

This drive for value and outcomes has led to much talk about incorporating outcome-relevant endpoints as early as possible in the initial development of pharmaceutical clinical trials. While it will not replace post-market, real world evidence, companies that incorporate both quality metric and value-based endpoints into their clinical trial programs will have a distinct advantage regardless of who is making the access decisions.



Pricing pressures continue to increase

While the relevance of quality has risen drastically, there remains a tremendous amount of pressure on pricing. With continued growth in healthcare costs, broad pricing pressures remain strong. An example of this is the tremendous growth of generics. Today, around eighty percent of prescriptions covered by payers are generic drugs. Many see this trend to be the end of the small molecule heyday in the industry – new entrants in these mature and crowded categories will have to clearly demonstrate value to justify higher unit costs.

To combat this, the pharmaceutical industry is increasing its focus on specialty pharmaceuticals and branded biotech products that treat smaller patient populations. The average monthly cost of specialty therapeutics is nearly 10 times that of small molecule drugs – and much like traditional drugs 10 years ago, specialty pharmaceuticals are most always covered. However, given payers' experiences in managing small molecule therapies and the addition of multiple therapies with similar efficacy, they have begun to apply the same techniques to specialty therapies as well. As new specialty products are approved and introduced into existing classes, payers will leverage preferred positioning for cost savings. This is becoming evident in the multiple sclerosis

category with the entry of the orals and, potentially, a new generic. Reviewing the major PBMs' annual trend reports, each touts both the growth of specialty pharmaceuticals as well as their skills in managing the costs of these products. Clearly they see this area as an opportunity to demonstrate their ability to generate value, which will position health plans and PBMs as critical influencers of product access.

An evolution in industry strategies

Another result of the pricing pressures has been to raise the cost-sharing component of pharmaceuticals for patients. The explosion in copay card or cost-share offset programs underlies the latest strategy manufacturers have taken to counter these escalating out-of-pocket payments patients have for medications. As Hobart analysts have previously projected, payers are expanding their actions to counter this mechanism out of concern that cost share offsets blunt their utilization management efforts.

To prevent this, payers are in some cases flatly denying any coverage for products where they see little value. Two years ago, CVS Caremark's implementation of formulary exclusions made national headlines and caused significant angst among their clients as well as pharmaceutical companies. Not to be outdone, Express Scripts recently announced similar formulary exclusions for the upcoming commercial plan year, including specialty-class drugs for multiple sclerosis. While each PBM primarily noted their responsibility to identify ways to help their clients with managing costs, the actions were also at least partially attributable to the extensive cost offsetting initiatives by the manufacturers. While cost-share offset programs continue to be important in many cases, continued aggressiveness by formulary decision-makers will thwart the impact for some patients.

As the landscape of those taking on risk for managing patient populations changes, pharma must also evolve how it both engages with customers and delivers value. Marketers

Market Trends

Payers will continue to look for new ways to reduce costs and improve quality. Some cost-containing trends to expect:

- Preferred placement and protocols or pathways for certain conditions that will influence product utilization
- Continued plan consolidation, especially in the Medicare arena where those unable to improve quality will likely not survive
- Growing provider risk, including some global capitation beyond that seen in mature markets like California and Florida
- Patients exerting more decision-making on product selection due to growth in personal cost sharing through both copays and higher deductibles

must invest in the development of a value proposition and customize how they apply it for specific payer types. It is not good enough to differentiate Medicare versus commercial benefits; it is critical to demonstrate how their target Medicare population breaks down into MA-PD and Part D-only plans and what portion of their population receives subsidies based on low-income status. This requires a precise value proposition based on payer sub-segmentation. We still see a number of brand teams rely on the prescriber field sales aid for payer interactions. This really undermines the payer relationships as they generally have the pivotal trial information already and it illustrates a lack of understanding or priority of the payer's needs.

In addition to accounting for payer nuances, successful manufacturers will be leveraging outcome endpoints relevant to specific payer types. That means, in the case of integrated health systems, bringing forward data elements such as hospital readmission and patient satisfaction metrics, while focusing on net pharmacy cost and drug utilization impact for Part D plans. Time with decision-makers is limited so if marketers don't bring forward relevant messaging from the start, the opportunity to positively influence access considerations may be missed.

With the reimbursement system evolving to value-based purchasing (VBP), payer decision-makers will further scrutinize the value of pharmaceuticals based on their impact on costs and quality measures. Health economics and outcomes activities have experienced tremendous growth over the last several years that is expected to further accelerate. The government is fueling the focus on outcomes with the launch of several VBP initiatives, including penalties for hospital readmissions within thirty days, accountable care organizations and bundled payments.

In addition, the creation of the Patient-Centered Outcomes Research Institute (PCORI) as part of the healthcare reform law is specifically charged with creating and executing the research agenda designed to inform the marketplace of the most effective therapies. Funding for outcomes research jumped significantly in the first year of PCORI. In addition to funding more actual outcomes studies, a significant proportion of the funding went to the development of outcomes research methodologies and training programs designed to create a whole new set of outcomes researchers.

Pharma must be wary that these shifts will not have an overnight impact, nor be consistently applicable across varied customers. Each payer will evolve their own direction and momentum toward change depending on their business drivers, whether geographic, client-specific, population-based, or any number of other factors. Unit cost and total cost of therapy will remain major drivers for payer decisions on product access. Ultimately, focusing on these expected shifts cannot come at the cost of today's reality. Marketers can not lose sight of unit and net cost as remaining the primary focus for nearly all organizations managing patient populations today. Yet, they must prepare for where these customers will be in two to five years, and include important relevant endpoints into studies now to be best positioned. In addition, planning on how to engage potential new product access decision-makers, such as accountable care organizations, should not come at the expense of neglecting the current dominance of health plans and PBMs in this role.

The approach to these shifts by pharma-

ceutical payer marketing and brand teams requires greater depth of knowledge about different payer lines of business and what specific value their products bring to each. For the field teams, resources should identify the most relevant populations for the product. They should include specific value messages that apply to each payer type, and tools that support the value proposition in that situation.

Marketers additionally cannot underestimate the need for training the field on all available resources. In addition to routinely having multiple products to address with payers, account teams are often pressed off their agenda by the payer's needs or their initial lack of interest. Simply sending an e-

mail or noting on a conference call the availability of a new resource is not enough to achieve the consistency of message delivery necessary.

Since payers often make coverage decisions within a few months of product launch, it is critical to have your payer value messages prepared in parallel with the clinical story and available at launch. A best practice Hobart recommends to clients is having payer resources ready to go with the first weeks of product availability. This allows the account teams to deliver payer-specific product value propositions to their customers that complement the information they will seek separately through their own searches or from a product dossier.

The healthcare industry evolution will certainly cause changes in who influences product access and how they will make their decisions. The good news is that value is at a premium and evaluation across total healthcare costs provides the opportunity for pharmaceuticals to break away from a product price focus they have so desperately sought to overturn. Ultimately, focusing on generating evidence that demonstrates value should best position pharma, regardless of who makes the final product access decisions. ■ MEDADNEWS

Larry Blandford, PharmD, is a Managing Partner at Hobart Innovation, a Hobart Group Holdings company.

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Reaching epic proportions

One in 10 of the global population will have diabetes by 2035 based on the latest statistics.

By Andrew Humphreys andrew.humphreys@ubm.com

From 2012 through 2035, the number of people with diabetes is forecasted to rise from 382 million to 592 million. According to the International Diabetes Federation (IDF), the amount of individuals with type 2 diabetes has grown in every country. Diabetes is the No. 7 cause of death as well as a leading cause of kidney failure, non-traumatic lower-limb amputation and new cases of blindness in the United States. During 2013, an estimated 5.1 million individuals will have died from diabetes-related complications. Additionally, there are roughly 175 million undiagnosed cases of diabetes. Per the most-recent version of the IDF's Diabetes Atlas, \$548 billion was spent on the disease during 2013.

According to a 2013 report from PhRMA, there are more than 450 medicines in clinical development for leading chronic diseases affecting seniors. Diabetes accounts for 140-plus of that product total, well ahead of the other leading categories: arthritis, Alzheimer's, heart disease, COPD and depression.

Anti-diabetes products are expected to be the No. 2 therapy area (after oncology) in terms of global prescription and OTC sales in 2018 at more than \$60 billion after totaling \$36.3 billion in 2012, per an EvaluatePharma June 2013 report. According to the analysis, the 2018 diabetes market will be paced by **Januvia** and **Janumet** (combined \$9.28 billion), **Lantus** (\$8.12 billion), **NovoRapid** (\$4.94 billion), **Victoza** (\$4.07 billion), and **Levemir** (\$2.52 billion).

The dipeptidyl peptidase-4 inhibitors Januvia and Janumet are marketed by **Merck**. DPP-4 inhibitors represent a class of prescription drugs that improve blood sugar control in patients with type 2 diabetes by enhancing a natural body system known as incretin, which helps to regulate glucose by affecting the beta cells and alpha cells in the pancreas. Januvia (sitagliptin phosphate) was launched in the United States during October 2006. Janumet, which combines Januvia with metformin hydrochloride in one tablet for treating type 2 diabetes, won U.S. approval on March 30, 2007. FDA in February 2012 granted clearance to once-daily **Janumet XR**, which combines sitagliptin and extended-release metformin.

For the first nine months of 2013, Merck reported worldwide sales of \$2.88 billion for Januvia (down 2 percent year-over-year) and \$1.33 billion for Janumet (up 10 percent). The main compound patent for sitagliptin is scheduled to expire in the United States in 2022, and the product's salt patent is protected in the United States until 2026.

Sanofi's once-a-day Lantus (insulin glargine) is one of the top-selling prescription medicines globally. Marketed in more than 120 countries, Lantus is the best-selling insulin brand in terms of sales and units worldwide. A long-acting analog of human insulin, the drug offers improved pharmacokinetic and pharmacodynamic profile. Lantus is the most studied basal insulin with more than a decade of clinical evidence in diabetes treatment and a well-established safety profile. The medicine can be administered subcutaneously via syringes or specific pens.

Lantus generated global sales of €4.2 billion (\$5.4 billion) during the first three quarters of 2013, up 20 percent. The product's sales are projected to peak at €5.79 billion (\$7.44 billion) during 2014, according to Sanford C. Bernstein analysts. Lantus' compound patent is due to expire in the United States during August 2014, and in most of Western Europe as well as Japan in November 2014. A six-month pediatric exclusivity extension was granted in the United States (February 2015) and European Union (May 2015).

NovoLog/NovoRapid is the world's most widely used rapid-acting insulin for use at mealtimes, according to its marketer **Novo Nordisk**. For patients with type 2 diabetes who have uncontrolled blood-glucose levels while on a basal insulin, intensification with the medicine helps patients attain and maintain treatment goals.

NovoLog/NovoRapid exceeded \$2 billion in yearly sales in each of 2010, 2011 and 2012, and already attained that mark as of the first nine months of 2013 at DKr12.39 billion (\$2.14 billion). Containing insulin aspart, NovoRapid was launched in the European Union during 1999 and NovoLog debuted in the U.S. arena during September 2001. NovoLog's U.S. compound patent expires in 2014 and the formulation patent is protected until 2017. The compound patent has expired in Germany, France, the United Kingdom, China and Japan.

The human glucagon-like peptide-1 (GLP-1) analog **Victoza** has an amino acid sequence 97% similar to endogenous human GLP-1. Like natural GLP-1, **Victoza** (liraglutide) acts by stimulating the beta cells to release insulin and suppressing glucagon secretion from the alpha cells only when blood sugar levels are high. Due to this glucose-dependent mechanism of action, the drug is associated with a low rate of hypoglycemia. **Victoza** also reduces body weight and body fat mass via mechanisms involving reduced appetite and lowered food intake. The medicine debuted in the European Union during 2009 and is marketed in 60-plus countries. **Victoza** gained regulatory clearance in the United States and Japan in January 2010 for adults with type 2 diabetes.

Victoza generated sales of DKr5.99 billion (\$1.03 billion) during 2011 and DKr9.5 billion (\$1.64 billion) in 2012. For the first nine months of 2013, the product's sales amounted to DKr8.4 billion (\$1.45 billion), with sales up 28 percent in local currencies and 24 percent in Danish kroner. According to Novo Nordisk, **Victoza** holds the worldwide market share leadership in the GLP-1 segment with a 70 percent value market share as of October 2013 versus 66 percent during 2012.

Levemir was first approved by EU health authorities in June 2004, and the diabetes medicine made its U.S. debut during March 2006. Available for once-daily use for people with type 1 and 2 diabetes, **Levemir** provides glucose control with a favorable weight profile. Following its FDA clearance during 2012 for use in children ages 2-5 years, **Levemir** became the modern long-acting basal insulin offering treatment to the broadest range of U.S. and EU patients.

Levemir sales reached DKr7.68 billion (\$1.33 billion) during 2011 and DKr9.79 billion (\$1.69 billion) for 2012. The product attained sales of DKr8.4 billion (\$1.45 billion) for the first three quarters of 2013, increasing 22 percent in local currencies and 18 percent in Danish kroner.

Pipeline prospects

Novo Nordisk in May 2013 filed for EU regulatory clearance of a new medicine that would

further bolster the company's market-leading diabetes arsenal. **IDegLira** was submitted for approval to the European Medicines Agency for the treatment of people with type 2 diabetes. The combination product consists of the once-daily new-generation basal insulin analog **Tresiba** (insulin degludec) and once-a-day **Victoza** with an ultra-long duration of action.

Results from an EU Phase III randomized controlled trial showed that **IDegLira** significantly improves glycemic control in patients with type 2 diabetes mellitus compared with either drug alone. The fixed-ratio combination therapy, which was administered to patients inadequately controlled on the oral agents metformin and pioglitazone, was also demonstrated to have a low risk for hypoglycemia, weight gain, and gastrointestinal side effects. Pioglitazone is the active chemical in **Actos**, the former annual multi-billion sales generator marketed by **Takeda Pharmaceutical and Lilly**.

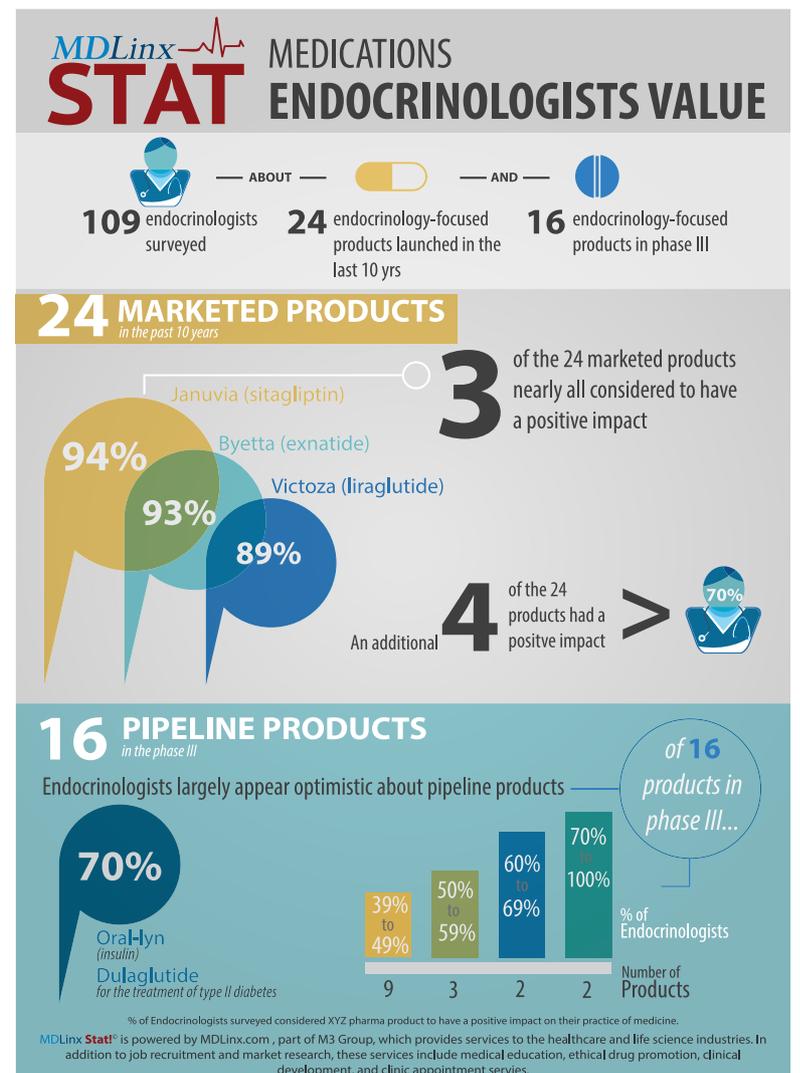
Tresiba is cleared for marketing in Europe and Japan. During February 2013, FDA said large-scale cardiovascular studies would be necessary before insulin degludec can be approved in the United States.

"**Tresiba** is an ultra-long-acting insulin with a duration of action beyond that of **Lantus**, the most popular once-daily insulin from Sanofi," comments Frost & Sullivan Life Sciences Senior Industry Analyst Debbie Toscano. "The combination of this next-gen insulin with liraglutide has shown clinical data superior to any diabetes product, and stands an excellent chance of reaching blockbuster status, leveraging the well-known highly effective therapeutic approach of insulin and GLP-1 therapy."

Another anticipated pipeline prospect taking longer than expected to reach the U.S. marketplace is **Lyxumia** (lixisenatide). During September 2013, Sanofi decided to withdraw **Lyxumia's** New Drug Application to FDA. That decision followed dialog with FDA regarding its proposed process for the review of interim data. Sanofi believes that potential public disclosure of early interim data, even with safeguards, could potentially compromise the integrity of the continuing ELIXA study. Sanofi's decision was not related to safety issues or deficiencies in the New Drug Application for **Lyxumia**.

The ELIXA study, which started during 2010, continues as planned and is fully enrolled. Complete results are expected to be available 15 months after the NDA withdrawal announcement. Sanofi expect to refile the NDA for **lyxisenatide** with U.S. regulators during 2015 following completion of the ELIXA cardiovascular outcomes study.

Some industry experts contend that **Lyxumia's** delayed potential U.S. market entry could ultimately help the new drug



compound's eventual market success with the accompaniment of more robust study data. "This trial is very important to Sanofi, not only because of the tough FDA regulations, but also because one of the main opportunities in the type 2 diabetes market is the development of a drug that addresses not only glycemic control but also cardiovascular complications," comments Valentina Gburcik, Ph.D., an analyst for GlobalData.

Lixisenatide represents a new-generation version of the blockbuster brand Lantus. Lixisenatide is the first once-daily prandial GLP-1 receptor agonist for treating adults with type 2 diabetes mellitus. The medicine was accepted for marketing review by FDA and was granted clearance by the European Commission under the trade name Lyxumia in February 2013. Lixisenatide, which is in-licensed from Zealand Pharma, has been additionally approved for marketing in Australia, Japan, Brazil and Mexico for type 2 diabetes.

The initial U.S. NDA for lixisenatide was based on results from the GetGoal clinical program. Through this program lixisenatide demonstrated significant reductions in HbA1c, a pronounced post-prandial glucose-lowering effect, and a beneficial effect on body weight in adult type 2 diabetics. GetGoal results showed that the product had a favorable safety and tolerability profile in most patients, and a limited risk of hypoglycemia.

Industry forecasters have projected lixisenatide global revenue of nearly 500 million euros in 2018. A late-stage clinical study of lixisenatide combined with Lantus remains on schedule to start during first-half 2014. Lantus is set to lose U.S. patent protection during 2015.

Fasiglifam represents the industry's first G protein-coupled receptor (GPR-40) agonist to reach late-stage clinical development. Fasiglifam is a novel, highly selective agonist of GPR-40, one of the G protein-coupled receptors expressed in pancreatic islet cells. The oral drug has the potential to be a safe and effective treatment for type 2 diabetes by selectively improving glucose-dependent insulin secretion with a low risk of inducing hypoglycemia and pancreatic exhaustion, unlike sulfonylurea or glinides.

The novel glucose dependent insulin secretagogue was discovered and is being developed by Takeda. The new molecular entity is undergoing Phase III trials in the United States, Europe, and Japan. GlobalData analysts say fasiglifam has the potential to be a compelling therapeutic option and will likely be investigated for use in combination therapy, given its unique mechanism of action.

A Phase III clinical will evaluate the efficacy and safety of fasiglifam in combination with Januvia. According to GlobalData analysis, this combination holds great potential due to each drug's respective distinct mechanism of action, oral route of administration and good safety profile.

Another potential blockbuster opportunity in the diabetes pipeline is **NewMet**, a delayed-release formulation of generic metformin. As the gold standard oral diabetes therapeutic, metformin is the foundational treatment for Type 2 diabetes. San Diego-based **Elcelyx** Therapeutics is developing the pharma product candidate NewMet for use by type 2 diabetes patients who have difficulty tolerating generic metformin or are contraindicated for its use.

NewMet offers best-in-class glucose control by reducing metformin's gastro-intestinal side effects in a once-daily, low-dose tablet that does not require titration for initiation of treatment. Results from a randomized, 240-patient, multicenter U.S. Phase IIb clinical trial confirmed previous studies demonstrating that NewMet reduced fasting plasma glucose to a similar ex-

tent as generic metformin, but at plasma exposure levels previously shown to be as much as 65 percent lower than comparable doses of generic metformin.

According to Elcelyx, the company has not changed the way metformin works, but instead has discovered how metformin works and leverages this understanding to develop an improved product. Rather than acting via circulation, Elcelyx proposes that metformin works at the lower bowel to activate signals resulting in glucose regulation. NewMet targets the lower bowel, maintaining metformin's glucose effect, but significantly reducing bioavailability, thus minimizing systemic exposure.

This improved safety and tolerability profile makes NewMet appropriate for individuals re-

quiring the glucose control of metformin with reduced gastrointestinal side effects or the need for titration. Renally impaired patients contraindicated for metformin use may benefit from the product's much lower exposure. Because NewMet can deliver a maximally effective dose of metformin, it is regarded as an ideal candidate for fixed-dose combos (FDC) with other oral anti-diabetes agents. Elcelyx says NewMet offers the potential to be the only metformin/DPP4i FDC with a full effective metformin dose in a once-daily formulation not needing titration.

"Elcelyx is developing their gut-targeted formulation of metformin based on their discovery of metformin's mechanism of action in the gut," Toscano states. "This new formulation promises

to exert comparable efficacy with a much smaller dose and greatly improved tolerability since it stays in the gut and does not get absorbed systemically. Since this is a well-known drug that has been used and trusted for decades, it is highly likely to see strong uptake, but this will probably be highly dependent on a strong marketing campaign and we are anticipating a partnership with a large pharma to see it through."

The biotech company **Adocia** announced in November 2013 the start of a Phase I/II study for a combination product consisting of the long-acting insulin glargine and the fast-acting insulin lispro. As mentioned previously, insulin glargine is the active ingredient in Lantus, the gold standard of long-acting insulin. Insulin lispro is the main chemical in **Humalog**, which is



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SELECT DIABETES PRESCRIPTION MEDICINES IN LATE-STAGE DEVELOPMENT

Product Status	Product	Chemical	Intended Indication	Countries	Developers
Awaiting approval	Afrezza	Insulin human [rDNA origin]	Afrezza is intended for the treatment of type 1 diabetes and type 2 diabetes.	United States	MannKind
Awaiting approval	Alogliptin	Alogliptin	Alogliptin is intended for the treatment of diabetes mellitus.	Taiwan, Indonesia	Takeda Pharmaceutical
Awaiting approval	ASP1941	Ipragliflozin	ASP1941 is intended for the treatment of type 2 diabetes.	Japan	Astellas Pharma
Awaiting approval	CSG452	Tofogliflozin hydrate	CSG452 is intended for the treatment of type 2 diabetes.	Japan	Chugai Pharmaceutical and Kowa
Awaiting approval	Empagliflozin	Empagliflozin	Empagliflozin is intended for the treatment of type 2 diabetes mellitus in adults.	United States, European Union	Eli Lilly and Boehringer Ingelheim
Awaiting approval	Eperzan	Albiglutide	Eperzan is intended for the treatment of type 2 diabetes.	United States, European Union	GlaxoSmithKline
Awaiting approval	Forxiga	Dapagliflozin	Forxiga is intended for the treatment of adults with type 2 diabetes.	United States, Japan and China	Bristol-Myers Squibb and AstraZeneca
Awaiting approval	Forxiga	Dapagliflozin	Forxiga, as add on to DPP-4, is intended for the treatment of diabetes.	European Union	Bristol-Myers Squibb and AstraZeneca
Awaiting approval	Forxiga	Dapagliflozin	Forxiga, as add on to insulin and metformin, is intended for the treatment of diabetes.	European Union	Bristol-Myers Squibb and AstraZeneca
Awaiting approval	Forxiga/ Metformin Fixed Dose Combination	Dapagliflozin and metformin	Forxiga/Metformin Fixed Dose Combination is intended for the treatment of diabetes.	European Union	Bristol-Myers Squibb and AstraZeneca
Awaiting approval	Glufast	Mitiglinide calcium hydrate	Glufast, in combination with dipeptidyl peptidase-4 inhibitors or biguanides, is intended for the treatment of type 2 diabetes mellitus.	Japan	Takeda Pharmaceutical
Awaiting approval	IDegLira	Insulin degludec and liraglutide	IDegLira is intended for the treatment of type 2 diabetes.	European Union	Novo Nordisk
Awaiting approval	Invokana	Canagliflozin	Invokana is intended for the treatment of type 2 diabetes.	European Union	Janssen Research & Development
Awaiting approval	Invokana IR	Canagliflozin	Invokana IR, in combination with metformin, is intended for the treatment of type 2 diabetes.	United States, European Union	Janssen Research & Development
Awaiting approval	LY2963016	Insulin glargine	LY2963016 is intended for the treatment of type 1 diabetes and type 2 diabetes.	United States	Eli Lilly
Awaiting approval	LY2963016	Insulin glargine	LY2963016 is intended for the treatment of type 1 diabetes and type 2 diabetes.	European Union	Eli Lilly and Boehringer Ingelheim
Awaiting approval	Ryzodeg	Insulin degludec and insulin aspart	Ryzodeg is intended for the treatment of type 1 diabetes and type 2 diabetes.	United States	Novo Nordisk
Awaiting approval	TA-7284	Canagliflozin	TA-7284 is intended for the treatment of type 2 diabetes mellitus.	Japan	Mitsubishi Tanabe Pharma
Awaiting approval	Tenelia	Teneligliptin	Tenelia, in combination therapy, is intended for the treatment of type 2 diabetes mellitus.	Japan	Mitsubishi Tanabe Pharma
Awaiting approval	Tresiba	Insulin degludec	Tresiba is intended for the treatment of type 1 diabetes and type 2 diabetes.	United States	Novo Nordisk
Awaiting approval	TS-071 Oral	Luseogliflozin hydrate	TS-071 Oral is intended for the treatment of type 2 diabetes.	Japan	Taisho Pharmaceutical Holding
Phase III clinical trials	DiaPep277	Synthetic P277	DiaPep277 is intended for the treatment of type 1 diabetes.	European Union, Canada, Israel	Andromeda Biotech and Teva Pharmaceutical Industries
Phase III clinical trials	Dulaglutide	Dulaglutide	Dulaglutide is intended for the treatment of type 2 diabetes.	United States	Eli Lilly
Phase III clinical trials	Fasiglifam	Fasiglifam	Fasiglifam is intended for the treatment of diabetes mellitus.	United States, European Union, Japan	Takeda Pharmaceutical
Phase III clinical trials	Fastic	Nateglinide	Fastic, in combination with DPP-4 inhibitors, is intended for the treatment of type 2 diabetes mellitus.	Japan	Daiichi Sankyo
Phase III clinical trials	Forxiga	Dapagliflozin	Forxiga is intended for the treatment of diabetes in patients at high risk of cardiovascular disease.	United States, European Union, China, Japan	Bristol-Myers Squibb and AstraZeneca
Phase III clinical trials	Forxiga	Dapagliflozin	Forxiga, in combination with triple therapy (dapa, met and SU), is intended for the treatment of diabetes.	United States, European Union, China, Japan	Bristol-Myers Squibb and AstraZeneca
Phase III clinical trials	Forxiga	Dapagliflozin	Forxiga, as add on to insulin and metformin, is intended for the treatment of diabetes.	United States, Japan, China	Bristol-Myers Squibb and AstraZeneca
Phase III clinical trials	Forxiga	Dapagliflozin	Forxiga, as add on to DPP-4, is intended for the treatment of diabetes.	United States, Japan, China	Bristol-Myers Squibb and AstraZeneca
Phase III clinical trials	Forxiga/ Metformin Fixed Dose Combination	Dapagliflozin and metformin	Forxiga/Metformin Fixed Dose Combination is intended for the treatment of diabetes.	United States, Japan, China	Bristol-Myers Squibb and AstraZeneca
Phase III clinical trials	Glactiv	Sitagliptin phosphate	Glactiv, in combination therapy with a rapid-acting insulin, is intended for the treatment of type 2 diabetes.	Japan	Ono Pharmaceutical and Merck & Co.
Phase III clinical trials	Glactiv/Metformin Combination Tablet	Sitagliptin phosphate and metformin	Glactiv/Metformin Combination Tablet is intended for the treatment of type 2 diabetes.	Japan	Ono Pharmaceutical and Merck & Co.
Phase III clinical trials	Insulin Lispro	Insulin lispro	Insulin Lispro is intended for the treatment of type 1 diabetes and type 2 diabetes.	United States	Eli Lilly
Phase III clinical trials	Invokana XR	Canagliflozin	Invokana XR, in combination with metformin, is intended for the treatment of type 2 diabetes.	United States	Janssen Research & Development
Phase III clinical trials	ITCA 650	Exenatide	ITCA 650 is intended for the treatment of type 2 diabetes.	United States	Intarcia Therapeutics and Quintiles Laboratories
Phase III clinical trials	Komboglyze	Saxagliptin hydrochloride and metformin	Komboglyze is intended as an adjunct to diet and exercise to improve glycemic control in adult patients aged 18 years or older with type 2 diabetes.	Japan, China	Bristol-Myers Squibb and AstraZeneca
Phase III clinical trials	LY2605541	Basal insulin	LY2605541 is intended for the treatment of type 1 diabetes and type 2 diabetes.	United States	Eli Lilly
Phase III clinical trials	Metgluco	Metformin hydrochloride	Metgluco is intended for the treatment of type 2 diabetes in pediatric patients.	Japan	Dainippon Sumitomo Pharma
Phase III clinical trials	MK-3102	Omarigliptin	MK-3102 is intended for the treatment of type 2 diabetes.	United States	Merck & Co.
Phase III clinical trials	Oral-lin	Insulin	Oral-lin is intended for the treatment of type 1 diabetes and type 2 diabetes.	United States, Canada	Genex Biotechnology
Phase III clinical trials	Ranolazine	Ranolazine	Ranolazine is intended for the treatment of type 2 diabetes.	United States	Gilead Sciences
Phase III clinical trials	SaxaDapa	Saxagliptin and dapagliflozin	SaxaDapa is intended for the treatment of diabetes.	United States, European Union, China, Japan	AstraZeneca
Phase III clinical trials	Semaglutide	Semaglutide	Semaglutide is intended for the treatment of type 2 diabetes.	European Union	Novo Nordisk
Phase III clinical trials	Surepost	Repaglinide	Surepost, in combination with all therapies including DPP4 inhibitors, is intended for the treatment of diabetes.	Japan	Dainippon Sumitomo Pharma
Phase III clinical trials	Trelagliptin	Trelagliptin	Trelagliptin is intended for the treatment of diabetes mellitus.	Japan	Takeda Pharmaceutical
Phase III clinical trials	U300	Insulin glargine	U300 is intended for the treatment of type 1 diabetes and type 2 diabetes.	United States	Sanofi US

a member of one of Lilly's blockbuster diabetes franchises.

This clinical study intends to show that the combination medicine could offer diabetic patients improved glycemic control versus a premix of insulin analog such as **Humalog Mix**, based on insulin lispro, or **NovoMix**, based on Novo Nordisk's insulin aspart. Pharmacodynamic and pharmacokinetic profiles of the combination BioChaperone glargine/lispro will be compared to the pharmacodynamic and pharmacokinetic profiles of Humalog Mix in a cross-over design on diabetic patients under a euglycemic clamp.

Type 1 and type 2 diabetic patients in need of intensive insulin therapy have two treatment options: either a premix, which is a formulation of a single insulin with both fast and long actions, or a combination of a long-acting insulin and a fast-acting insulin. Premix products such as NovoMix and Humalog Mix ease daily life for diabetics, who can manage their glycemia using only one drug injected twice daily. These premix blockbusters have been on the market for more than a decade, but they reportedly put patients at higher risk of hypoglycemia compared to separate injections of Lantus and a fast-acting analog insulin.

"There is a real need to provide patients using Lantus and a fast-acting insulin with the simplicity afforded by premix products, as well as to offer premix-using patients the greater medical efficacy obtained with Lantus, a real gold-standard," noted Gerard Soula, CEO of Adocia. "This combination could therefore extend glargine's market potential towards the premix market. This combo based on insulin glargine, an insulin off-patent in 2015, has been internationally patented in 2012."

Adocia specializes in the development of 'best-in-class' medicines from already-approved therapeutic proteins. The company's BioChaperone technology makes insulin glargine compatible with fast-acting insulin analogs. Through the BioChaperone state-of-the-art technological platform, Adocia aims to enhance the effectiveness and safety of therapeutic proteins and their ease of use for patients, with the aim of making these medicines accessible to the broadest public.

"Adocia's BioChaperone proprietary technology allows for a clear and stable solution of insulin glargine and a fast-acting analog insulin, two products that are not compatible under natural conditions," commented Olivier Soula, deputy general director and R&D director at Adocia. "In this clinical trial, we are testing one of the potential combinations but alternative combinations, namely with insulin glulisine (**Apidra**, Sanofi) and insulin Aspart (NovoLog, Novo Nordisk) have also been validated in preclinics."

Results from this clinical trial are expected during the first quarter of 2014. Adocia additionally is developing a unique combination of fast-acting insulin and slow-acting insulin, for an optimal insulin therapy with one single product.

Technological advances

Scientists are developing an instrument that would allow diabetics to measure their blood-sugar level without pricking their fingers several times daily via home blood-glucose monitoring. Researchers from the Technische Universität Dresden (Germany) and Fraunhofer Electron Beam and Plasma Technology FEP are working on a spectrometer so small that it can fit into a mobile phone.

Standard spectrometers traditionally have not been built smaller because of an inherent restriction in their functional principle, so the aforementioned scientists have chosen another method. The researchers use metallic nano-

antennas for harvesting, filtering and amplifying of incoming photons. They reportedly have developed a laboratory-scaled process to electrochemically grow such gold or silver nano-rod arrays into pores of an anodized aluminum-oxide matrix, and have proven its variability and functionality. The scientists plan to upscale the manufacturing process to make it feasible for mass production.

In other groundbreaking research, breathalyzer technology is being developed to detect acetone levels to monitor blood glucose in diabetics. The novel hand-held, noninvasive monitoring device that uses multilayer nanotechnology to detect acetone has been demonstrated to correlate with blood-glucose levels in the breath of diabetes patients.

Existing technology such as a blood-glucose meter is invasive and leads to patient discomfort, often causing low compliance. That in turn can result in poor health outcomes. Other common problems with existing attempted breathalyzer technology include inconstant results due to the natural humidity of one's breath, high temperature requirements, and lack of selectivity.

Ronny Priefer, Ph.D., of Western New England University created the multilayer technology using nanometer-thick films composed of two polymers that interact with acetone. This crosslinks the polymers and changes the physicochemical nature of the film, which provides a quantification of the acetone and thus the blood-glucose levels. This technology is differ-

ent because it only accounts for acetone and does not react with other components in the breath.

The current breathalyzer is about the size of a book. Priefer's team is reportedly developing one that is smaller and more similar to the size of a breathalyzer typically used to detect blood alcohol content levels.

Western New England University clinics are anticipating performing controlled testing with patients in late 2014 or early 2015. This testing would analyze readings from the breathalyzer, finger pricking, and actual glucose levels from drawn blood. Patients are expected to use the breathalyzers in an uncontrolled setting for about two years, keep a record of their readings and report back. ■ MEDADNEWS

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ACOs rising: Strategic opportunities in the evolution of accountable care organizations

By Sana Moosa

As provider organizations mature toward implementation of accountable care organizations (ACOs), manufacturers of biopharmaceutical products will need to stay abreast of changes, set the stage for innovative partnership, and take advantage of emerging opportunities.

Federal initiatives to create shared-savings projects have been going on for some time and gave a start to shared-savings models, such as ACOs. ACO pilots originated between healthcare organizations and the Centers for Medicare & Medicaid Services; however, after showing success in improving outcomes and cost savings, they were quickly adopted by commercial payers. ACOs are collaborations of physicians, hospitals, and other providers, organized around the capacity to improve health and reduce overall costs for a population of patients. They are capable of measuring improvements in patient health and overall costs and receiving payments that increase when these improvements occur.

The drivers of ACO model adoption include rising healthcare costs and the push for greater patient accountability, shared savings incentives from reducing cost of care, and a genuine desire to improve the quality of care for patients. Providers are also being driven toward ACOs out of competitive necessity and see an opportunity for improved business strategies across the continuum of care. ACOs are viewed as a way to align payments and healthcare initiatives with measurable, meaningful progress in improving care while lowering costs. They promote accountability for a patient population, coordinate services, and redesign care processes for high quality and efficient delivery.

Impact on providers and patients

Providers and patients are the most affected by ACOs and represent the greatest opportunity for manufacturers to re-engage, provide new value, and further the business. Primary care physicians will benefit from ACOs as they will have an opportunity to play a larger role in patient care; however, specialists may see a decrease in reimbursement depending on whether ACOs hire them as employees, establish contracting arrangements, or pay for their services on a fee-for-service basis.

Hospitals most likely will be negatively affected by new regulations and will have to find new ways to adapt to the system. Hospitals will be financially motivated to provide more coordinated care to patients, but they may need to make substantial investments in infrastructure to support health information technology (HIT) systems and networks with ACOs. In the short run, hospital revenue may decline with the drive towards fewer readmissions and procedures, as they shift from volume-based to quality-based care. However, shared savings from improved quality of care may offset this in the long-term.

Patients, meanwhile, may need to share some accountability so that they become more cost-conscious and share risk with healthcare providers.

Impact on manufacturers

Overall, manufacturers will not be directly impacted by the adoption of payment reform. However, device manufacturers are expected to witness a larger impact than pharmaceutical manufacturers. Within acute episodes, pharmaceuticals make up a lower percentage to the overall cost of care than devices. Thus, devices may be more scrutinized due to price variability that is typically seen within the same device class.

Chronic conditions will be most impacted by the adoption of ACOs, but at the product level, the impact will be dependent on the type of payment model that is adopted. Even though common chronic conditions may face scrutiny under the ACO model, the emphasis is on

improving quality across the non-therapeutic aspects of care. Overall drug utilization may be more or less restricted, depending on the nature of stakeholder partnerships within the ACO.

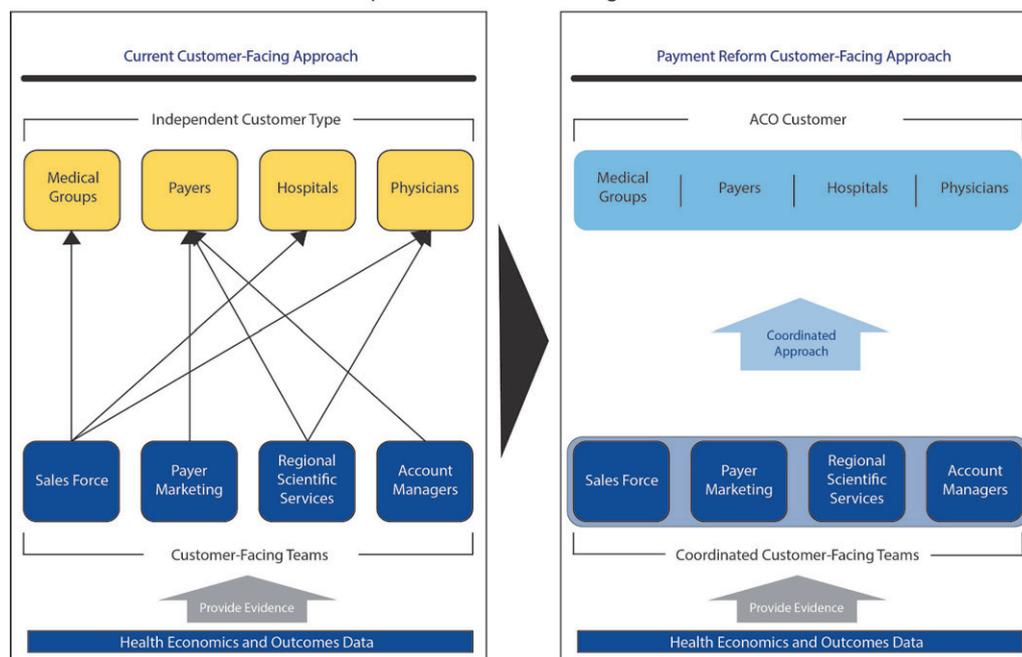
Manufacturers will have to evolve from traditional strategies and tactics, as they will have limited efficacy in a marketplace defined by accountable care. Value propositions will need to be holistic, encompassing all of a manufacturer's supporting programs, and they will need to be distinctly quality-and-outcomes-focused. The ACO concept may increase the need to develop comprehensive patient-level offerings. Quality-and-outcomes focused services offer an additional degree of differentiation. Manufacturers may also need to shift contracting resources away from plans and toward accountable care entities.

The current approach to calling on customers is siloed and focused on payers, with teams dedicated to individual customer types. But as stakeholders consolidate into ACOs, manufacturers will need to build customer-facing teams that realize the increased role of providers as well as coordinate a holistic, team-based approach in targeting customers.

Strategic options

A number of strategic options can be considered for manufacturers to implement in response to payment reform and the emergence of ACOs. These strategic options exist at the environmental, stakeholder, and therapy area/asset level.

Impact on Customer-Facing Roles



Environment level

Opportunities exist for manufacturers to influence the external environment as the ACO model evolves. Companies can help shape the standard methodology of bundling payments and other payment models through public policy advocacy, and they can reach out to "schools of thought" regarding payment reform to better understand focus areas. Companies can also communicate opinion and expertise in the context of payment reform.

Meanwhile, it is important for manufacturers to continue to monitor the environment around payment reform. This includes identifying triggers that need to be monitored as payment reform shapes the landscape and identifying new partnership opportunities with existing or emerging stakeholders.

Stakeholder level

Traditionally, manufacturers have been accustomed to selling to the payer. However, the shift of risk from payers to providers requires a change in the stakeholder engagement strategy. As provider groups become more organized and sophisticated, they will be open to more contracts and partnership opportunities with manufacturers. In fact, partnership and contracting opportunities between providers and manufacturers may become the new norm as compared with payers.

According to a QPharma survey, **25 percent** of specialists claim to fully understand the Sunshine Act and **30 percent** of primary care physicians have minimal or no understanding of the Sunshine Act. In addition, **62 percent** of doctors who stated that they accept samples were unaware that there is a section of the Sunshine Act requiring disclosure of samples, and **56 percent** did not know that a record of these samples will be provided to FDA, according to the survey.

Among respondents who stated that they fully understood the Sunshine Act at the start of the QPharma survey, **17 percent** felt that after completing it they had no understanding of the transparency laws. Regarding the respondents who stated they had no understanding of the Sunshine Act at the start of the survey, **86 percent** felt that after completing it they had some understanding of the transparency laws.

"Companies should get the word out by preparing a one sheet physician act 101 sheet," says Maria A. Galdos, senior manager, healthcare compliance, Qpharma. "CMS has provided this, but it is more than one page and the one page fact sheet could be left at the doctor's office every time a rep visits. The rep need not to comment on the piece, just leave it. Further, the one page 101 sheet should have a toll free number where physicians can call with questions."

Greater access to medicines by the world's rapidly expanding middle class, together with stronger economic prospects in developed nations, will bring total spending on medicines to the **\$1 trillion** threshold in 2014 and to **\$1.2 trillion** by 2017, according to new research by the IMS Institute for Healthcare Informatics.

IMS researchers found that growth in global spending on medicines increased **2.6 percent** to **\$965 billion** in 2012, and is forecast to grow at a **3 to 6 percent** compound annual rate over the next five years. With new product launches dominated by innovative specialty medicines, particularly for the treatment of cancer, payer concerns about rising costs for these drugs will intensify in both developed and pharmerging markets. Spending on specialty medicines is expected to reach **\$230-240 billion** in 2017, up **38 percent** from the **\$171 billion** spent in 2012.

According to IMS analysts, an increasing number of new molecular entities is expected to be approved over the next five years, similar to the levels seen in the mid-2000s. The majority of new launches will address unmet needs in specialty disease areas, orphan diseases, and small patient populations, including medicines that could transform treatments in rheumatoid arthritis, cystic fibrosis, and several tumor types. Recent and near-term launches of new medicines primarily address the disease profiles of patients in high-income countries. Although a growing number of these conditions are also prevalent across the globe, several of the most burdensome have few new treatment options, including malaria, neonatal sepsis, and tuberculosis.

Sources: QPharma (qpharma.com) and IMS Institute for Healthcare Informatics (theimsinstitute.com).

Potential partnership opportunities include patient education/advocacy, initiation of pilots with MGs, IDNs, or ACOs, and outcomes monitoring to develop a product value story. Potential contracting opportunities include risk-sharing agreements, performance-based rebates, and fixed rebates.

Therapy area/asset level

Although payment reform is not expected to impact specific products, common acute and chronic conditions are expected to be managed more tightly in order to improve quality and reduce cost. As a result, there are several strategic options manufacturers will want to consider at the therapy area level or product level in preparation for payment reform. For example, manufacturers may want to conduct market assessments to understand ACO impact on specific therapy areas (TAs), develop TA-level messaging strategy for ACOs, or partner with providers to build evidence for a future product's value story. At the product level, manufacturers may want to provide quality outcomes/value-based data on existing products, deliver patient education on behavioral modification, or solidify market positioning and value proposition.

Partnership opportunities

As ACOs develop, manufacturers can seek multiple partnership opportunities to support specific customer needs. At the lowest level

of sophistication, the business priorities of an ACO include tracking data and improving quality metrics, patient education and disease awareness, claims and reimbursement analysis and support, and metrics performance monitoring/benchmarking. Manufacturers can help by supporting basic analysis and benchmarking, performance monitoring, and patient education.

For more sophisticated ACOs, their priorities include development of disease management processes, drug monitoring at the regional/national level, standardized patient tracking process, and optimization of patient outreach and improvement of adherence. By partnering, manufacturers can lend support with disease and drug monitoring, standardization of patient-tracking processes, and patient education.

The priorities of the most advanced ACOs include the development of clinical protocols for specific disease profiles and/or patient types, collaborations in clinical trials/research and publications, negotiation of best rates with drug manufacturers for specific products, and further improvements in patient experiences and care. Manufacturers can collaborate with these more advanced ACOs on clinical trials, protocol development, and contracting.

Sana Moosa is a senior consultant with Campbell Alliance.

Consumer shift offers opportunity to pharma

Faced with rising out-of-pocket costs and complex treatment plans and armed with new social media tools and more information, pharmaceutical customers are changing the ways they purchase drugs and their role in drug use. This shift is creating valuable opportunities for the life sciences sector to benefit from deeper insights from the individuals using their products, according to a new report by PwC's Health Research Institute.

"Patients are exerting greater control over their healthcare and they want their medication experience to be effective, personalized and meaningful," says Karla Anderson, principal, PwC. "If their expectations are met, they're more likely to follow the proper course of treatment and remain engaged customers far longer. Drug makers that tap into critical information about customers and their behaviors in order to adjust business strategies will be well-positioned to demonstrate value in the new health economy."

Drug companies have long communicated directly with patients, through advertising and focus groups. But in today's complex and competitive environment, PwC analysts believe that a more sophisticated customer segmentation strategy is needed. Pharma customers expect the same focus on their needs that they experience in other industries such as retail, banking, and travel. When drug makers adopt a more customer-centric approach, the result is more engaged patients who "own" their treatment plans and better manage their conditions.

The Health Research Institute's report, "Customer experience in the pharmaceutical sector: Getting closer to the patient," includes survey results from more than 700 U.S. consumers about their prefer-

ences and behavior in drug treatment selection and use. According to the survey results, consumers are seeking the same convenience they receive in other settings. PwC's researchers found that consumers are willing to pay 19 percent more for a "no wait time" prescription, while affluent baby boomers and Gen Xers with chronic conditions are willing to pay 52 percent more. Also, treatment costs are the top reason people stop taking medications. An estimated \$213 billion is lost each year in the United States due to wasteful or unnecessary treatment linked to lack of adherence and medication mismanagement.

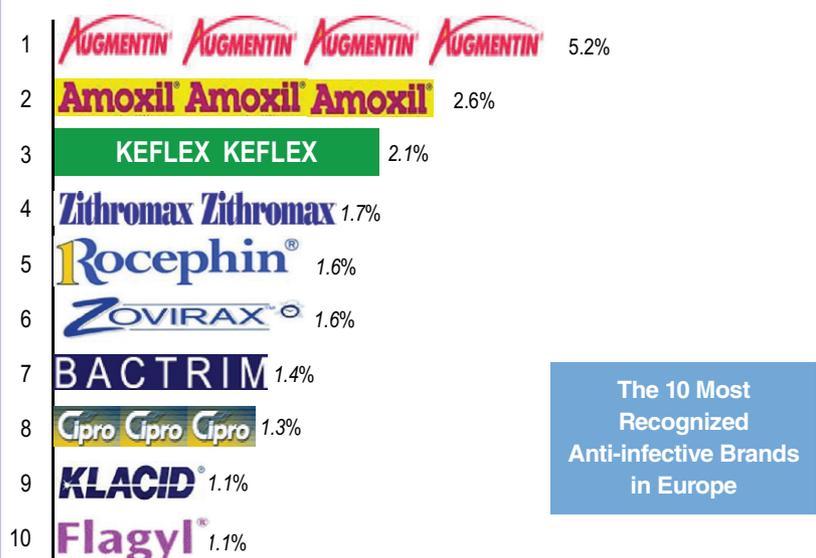
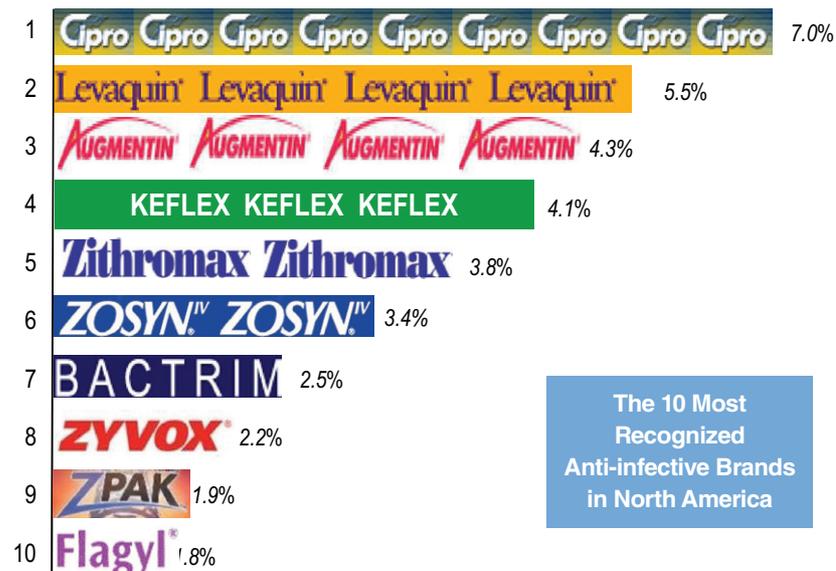
PwC's researchers also found that baby boomers with multiple chronic conditions have less medication adherence than average but are willing to do something about it. Some 41 percent want do-it-yourself pharmacy health screening stations, while 37 percent want a mobile app to monitor vitals and provide contextual understanding of their prescriptions.

Almost all of the respondents to PwC's survey said pharmaceutical companies did not play a role in their diagnosis and treatment decisions, suggesting that current pharmaceutical education and communication has had limited impact. And the company's report also highlights defining elements of the next generation patient including appetite for personalized information and real-time feedback, active participation in care and treatment, convenience and on-demand services, and options for comparison shopping.

"Understanding consumer behavior isn't a one-time event – rather, it should cover the full lifecycle of a drug," says Paul D'Alessandro, PwC principal and Customer Leader, Health Industries. "As empowered consumers take on more responsibility in their healthcare, drug makers must find ways to create meaningful experiences and relationships with them."

MOST-RECOGNIZED BRANDS

ANTI-INFECTIVES



The most-recognized anti-infective brand in North America is **Cipro**. The brand was most-recognized by 7 percent of physicians in a survey conducted by **Brand Institute Inc.** during the second quarter of 2013. Cipro, comprising ciprofloxacin, is marketed by **Bayer HealthCare Pharmaceuticals** (bayerhealthcare.com). The drug was first approved by FDA in 1987 and has earned indications for the treatment of a variety of bacterial infections, including anthrax.

Levaquin is the second most-recognized anti-infective brand in North America. About 5.5 percent of physicians recognize this brand the most. Levaquin, comprising levofloxacin, is marketed by **Ortho-McNeil Pharmaceutical Inc.** (ortho-mcneilpharmaceutical.com) and **PriCara Inc.** (pricara.com), both subsidiaries of **Johnson & Johnson** (jnj.com). The product was first approved by FDA in December 1996, and its various formulations have been approved for 28 different anti-infective indications. Levaquin's most recent new indications came in September 2007, when the drug was approved for the treatment of acute pyelonephritis and for the treatment of complicated urinary tract infection.

The third most-recognized anti-infective brand in Europe is **Augmentin**. About 4.3 percent of physicians recognize this brand the most. Augmentin, comprising amoxicillin and clavulanic acid, is marketed by **GlaxoSmithKline** (gsk.com). The drug was first approved in 1984 and has earned more than 25 anti-infective indications.

The most-recognized anti-infective brand in Europe is Augmentin. About 5.2 percent of physicians recognize this brand the most.

Amoxil is the second most-recognized anti-infective brand in Europe. About 2.6 percent of physicians recognize this brand the most. Amoxil, comprising amoxicillin, is marketed in Europe by **GlaxoSmithKline** and in the United States by **Dr. Reddy's Laboratories Inc.** (drreddys.com). Discovered by scientists at Beecham Research Laboratories in 1972, amoxicillin is one of the world's most widely used antibiotics.

The third most-recognized anti-infective brand in Europe is **Keflex**. About 2.1 percent of physicians recognize this brand the most. Keflex, comprising cefalexin, was first marketed by **Eli Lilly and Co.**, but is now available from a number of generics companies. The product was first introduced in 1967 and is used to treat a variety of infections including acute otitis media, tonsillitis, skin infections, respiratory tract infections, and urinary tract infections.

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

By Joshua Slatko joshua.slatko@ubm.com

Cegedim launches social site for docs

Cegedim Relationship Management is casting its lot in the online doctor social community category in the United States with its own offering, Docnet. The company made the announcement in November at its annual customer collaboration and charity event. Docnet is already available in four European markets (Sweden, Norway, Netherlands, and Turkey) and will become available in the United States by the beginning of February 2014.

As Docnet is going up against long-established competition such as Sermo and relative newcomers including Doximity, Cegedim did careful research to determine what physicians would want and need from such a community, and whether physicians would be receptive to communicating with life sciences companies there. The results of a 2013 Cegedim survey of about 500 healthcare professionals in the United States suggest that online communities play a pivotal role both for physicians and life sciences companies, as 89 percent of respondents stated being members of online communities, with 64 percent accessing them at least once a week. The survey also revealed the majority of healthcare professionals favor using a professional social network, which will allow them to consult on the latest medical, clinical, and drug information; to network and participate in discussions with their colleagues; to serve their patients; and to consume value-added information and services sponsored by pharma and medical device companies – all in a “one stop shop” manner.

Physicians will not only be able to communicate and consult with their peers, but depending on which pharma companies establish areas in the Docnet portal, physicians will be able to order samples, generate co-pay and discount cards for patients, and consult with medical science liaisons.

According to Angela Miccoli, president of North America for Cegedim Relationship Management, the “unique positioning” of Docnet will be its compliance standards in data security and data authentication. The community will rely on the standard defined by SAFE Bio-Pharma, Cegedim’s partner, enabling Level 2 authentication as set by the National Institute of Standards and Technology. The U.S. Drug Enforcement Agency accepts ePrescriptions for controlled substances signed with SAFE-Bio-Pharma digital signatures.

“The great value is that these standards are recognized and approved by the FDA for the United States and by the European Medicines Agency in Europe,” Miccoli says. “This is an online community for validated healthcare professionals only because patient treatment will be discussed, samples will be ordered, and dialogs with medical affairs will be enabled. So it is critically important that all members of this community are authenticated and validated as a physician or licensed healthcare professional.”

In addition to the other services life sciences companies can offer through Docnet, physicians will be able to validate their promotional spend information, which is being tracked by life sciences companies under the Sunshine Act. Before a company makes that information public (and companies are required to do so starting in March 2014), it can contact an individual physician to review the information, answer ques-

tions, and manage any disputes. Many life sciences companies already use Cegedim’s aggregate spend and data solution to track promotional spending on physicians and other healthcare professionals.

“The pre-disclosure of promotional spend is very important to our customers, who specifically requested the function be added as a service to the community in order to provide increased benefit to physicians,” Miccoli says.

SAFE Bio-Pharma was started in 2003 by a voluntary task force of IT professionals in the pharmaceutical industry. “The group has worked with FDA and the CIO Council to establish standards for digital identity trust as well as for electronic signature identification,” Miccoli says. “There are no other physician online communities that adhere to these standards.”

Most important, even with the enhanced level of security and authentication, the site will still be easy for physicians to use.

“Physicians are normal consumers, just like you, me, or anybody else out there,” Miccoli says. “So when joining a community, they need to make sure it is highly professional and secure. We are confident Docnet will quickly grow and thrive, as it will be simple to join the community in an efficient and secure manner.”

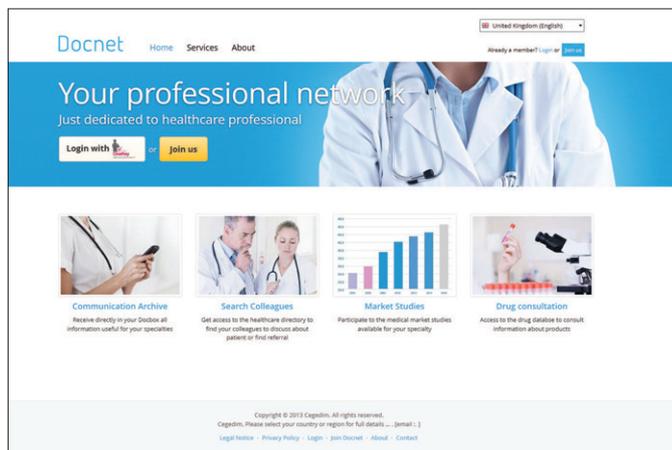
Based on Docnet’s reception in its launch markets, Cegedim is confident that the portal will gain good traction in the United States. Already, 50 percent of physicians in the Nordic markets have signed up for the community.

“We’re very excited,” Miccoli says. “For the United States, my dedicated team conducted very extensive market research, not only to understand what was already available in the market – but to ensure Docnet delivers unique value to HCPs and our life sciences customers. We wanted to deeply under-

stand HCP needs and what they really favor in terms of peer to peer and life sciences company engagement. The security of the sign-in process, as well as a one-stop-shop environment where physicians can connect with peers, advance professionally and engage with life sciences, were key drivers for us.”

Miccoli says Docnet will be promoted to physicians through several channels – not only print ads through physician journals, but through e-mails to physicians in Cegedim’s SK&A OneKey database. OneKey has 7 million validated profiles of healthcare professionals, over 1 million verified and compliant emails, NPI, DEA and state licensure data, and about 100 profiling and practice dimensions. Cegedim says OneKey serves as the initial adoption driver, pre-populating physician and healthcare professional profiles, establishing important HCP relationships and affiliations, and instantly seeding Docnet with unique value for HCPs and life sciences companies.

Cegedim is also getting some promotional help through the Boomer Esiason Foundation. Cegedim has partnered with the former NFL quarterback’s charity to raise money for cystic fibrosis research, and the foundation was the featured charity at the company’s life science forum during November. Esiason has agreed to do a promotional video aimed at physicians about Docnet.



Already available in several European markets, Cegedim’s Docnet will launch in the United States by early February 2014.

Online marketplace for physicians

Quanta has introduced the first virtual marketplace for the company’s physician community QuantaMD to connect doctors to products and services that can benefit their practice. Quanta Marketplace allows physicians to learn about various offerings directly from vendors in short, interactive programs that value their time. Using social technologies, physicians can then help each other make informed decisions by sharing advice about products they find most valuable.

“Physicians are busy and have a hard down parsing through all of the information available to them,” says Mike Coyne, CEO

of Quanta. “With the Marketplace, we saw an opportunity to help. Physicians can now learn about products and services in one place, on their time, and compare experiences with peers. We believe this will help them cut through the clutter and make the most informed decisions possible for their practices.”

Physicians typically spend 20 minutes per session interacting with peers on QuantaMD. Marketplace clients can reach these physicians as they participate and create an opt-in relationship with those who express interest in their product or service. “Participating on QuantaMD is like having a booth at the front of the largest healthcare conference in the world,

every day,” says Joe Sawyer, VP of marketing, CareCloud. “As a client, we can spend five to 10 minutes explaining the value of our cloud-based EHR, practice management, and revenue cycle management solutions, resulting in high quality leads for our organization. But unlike a conference, these interactions happen digitally – on the physician’s time – making them cost-effective and scalable.”

Sixty-one percent of physicians scan or explore social media daily or weekly and the majority of them believe that using social media improves patient care. According to Quanta executives, this is the driving force behind the growth and activity of QuantaMD, which now

FACTS & FIGURES

Thirty-eight percent of oncologists report they use four devices on a regular basis such as desktops, laptops, tablets, and phones, according to the results of Digital Insights Group’s DIG Mobile Oncologist study. **Twenty-eight percent** reported that they use three devices, and **14 percent** report they use two devices. **Eighteen percent** are using just one device.

Regarding devices used for professional purposes, oncologists reported they use a smartphone the most often (**40 percent**), and that smartphones have the greatest influence (**35 percent**) on their practice and clinical decision-making.

According to Digital Insights Group researchers, despite an overall preference for mobile, oncologists still prefer to access professional video on their desktop – with their tablet a close second. In addition, **62 percent** of oncologists state they are interested in more content from pharmaceutical and device companies tailored to mobile devices.

Oncologists are split with regard to their preference for mobile web or an app to access professional content, according to the study. Only **16 percent** reported not having a preference for mobile web versus app. Nearly three-quarters (**72 percent**) of oncologists report they use YouTube, while **57 percent** report using Facebook and **10 percent** say they use Twitter. **Twelve percent** of oncologists indicated that they regularly “prescribe” apps on their smartphone to patients to use on their own.

Among the more than 215 professional medical sites monitored by Kantar Media’s online intelligence service Evaliant, **143 companies** are advertising **310 products** online. **Seventy-one brands** ran ads on 10 or more sites. Prescription medications make up **71 percent** of all ad occurrences, pharmaceutical houses comprise **15 percent**, and medical appliances/equipment make up the final **14 percent**. **Janssen Pharmaceuticals’ Xarelto** and **Ivona’s Eisai’s Belviiq**, **AstraZeneca’s Brilinta**, and **Eli Lilly’s Alimta** and **Cymbalta** are among the top brands advertised online.

Sources: Digital Insights Group (digitalinsightsgroup.com) and Kantar Media (kantarmedia-healthcare.com)

Mobile usage transforming doc/patient relations

The dynamics in the exam room are changing rapidly and mobile is having a profound impact on how patients treat their conditions and the overall doctor-patient-caregiver relationship, according to “Consumer Mobile Health Impact Assessment: How the Use of Mobile Impacts Disease Treatment and Therapy,” a new study of mobile usage in health care undertaken by **Digitas Health**, the leading digitally native brand agency for the new era of healthcare marketing. Although the study reveals that patients using more mobile devices (smartphones, tablets, etc.) are most proactive with their own care, it also indicated that those with limited mobile device access are twice as likely to be untreated. The study results were revealed at m.2013, an invitation-only, one-day conference hosted by Digitas Health that brings together industry leaders and mobile experts to share their vision for mobile health innovation for pharma brands.

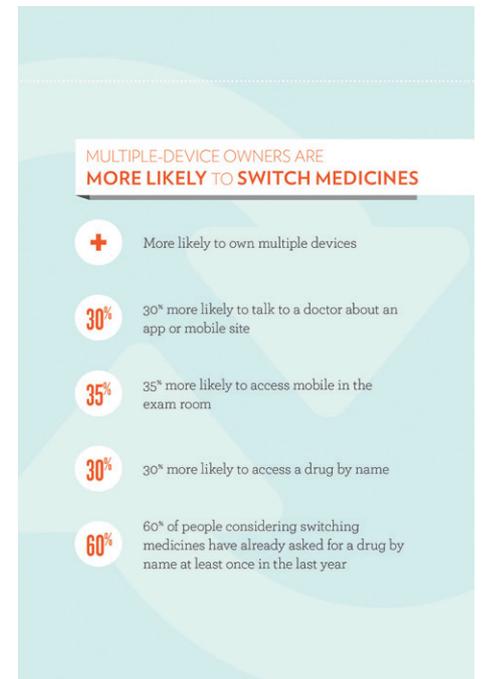
“The Digitas Health Mobile Study sheds new light on how consumers are using mobile to take charge of their health and does so at the disease-related level, which is almost unheard of in other studies,” says Alexandra von Plato, president and global chief creative officer of Publicis Healthcare Communications Group. “These findings will enable marketers to understand how to engage with patients and physicians to leverage mobile to generate better health outcomes. By understanding when, where and how mobile is being used in the healthcare treatment and decision process, marketers can provide more meaningful tools and build stronger relationships with their customers.”

Mobile in the exam room

The Digitas study finds that brands that provide mobile tools for patients and physicians to use in the exam room can have a significant advantage over those that do not provide such interactive tools. Patients and their physicians are using mobile together, which is indicative of treatment behavior and decisions. Nowhere is this influence more apparent than in the exam room itself, where more than one in three respondents report that either they or their physician has used a mobile device at the point of care. Physician use of mobile indicates increased patient use of mobile. Nearly 80 percent of mobile health users said they’ve accessed health information for their condition while in a healthcare setting; overall patient use of mobile in the physician’s office and pharmacy is 30-50 percent higher with users whose doctor has used mobile in the exam room.

The respondents also revealed that mobile in the exam room indicated switching behavior. Using their mobile in the exam room corresponds with users being 80 percent more likely to switch medications, and more than doubles the chance that they will ask for specific medications – compared to only 25 percent more likely when accessed in the waiting room alone. “Our study has brought to light the potential significant influence that apps may have for the future of healthcare for prevention, treatment and management of most disease conditions,” says Geoff McCleary, VP and director of mobile innovation at Digitas Health. In fact, 100 percent of those accessing mobile in the exam room said they would use an app, if recommended by their physician.

“The ability for app usage to affect repeat versus switching of medication is a signal to



healthcare brands and marketers that we need to act quickly and be creative to tap into this unprecedented access to patients and physicians during the exam ... or risk being locked out,” McCleary says. “We found that more than half (55 percent) of mhealth patients currently on a prescription drug were either planning on, or would consider, switching prescription medications in the next year.”

The App Rx

The study also indicated that digital tools are preferred over drugs as more (up to 90 percent) patients and caregivers say they would take an app if their physician prescribed it. Nine out of 10 patients said they did (or would) use an app when recommended by a physician compared to industry data suggesting that only two-thirds of patients will fill a prescription that is written by a physician.

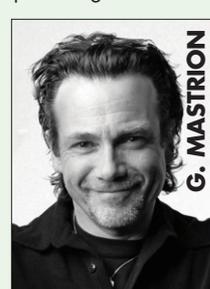
Getting mobile ready

By tracking more than 30 mobile engagement points across 20+ diseases, this research provided data that will help to better equip health and wellness brands with effective strategies for engaging with patients and physicians around mobile devices. Leveraging this new data, Digitas Health has created two new tools: The Mobile Readiness Assessment Tool and mobile IDEA Map (Insights Driven Engagement Analysis). “The connected are becoming more connected as smart device purchases are poised to increase, and consumers are depending on them to understand their disease condition, accept their diagnosis and manage their treatment,” McCleary says.

Palio+Ignite names new leaders

inVentiv Health Communications’ full-service healthcare communications agency **Palio+Ignite** has announced a new global management team. The leadership team is composed of three industry veterans focused on deepening Palio+Ignite’s capabilities to more effectively engage patients and healthcare professionals.

The management team includes Guy Mastrion, one of the original founders of the agency, who now serves as chief global creative officer; Paul Johnson, who was appointed general manager of client service;



G. MASTRION

and Andy Smith, who serves as chief operating officer. The team reports to Bob Chandler, president of inVentiv Health Communications.

With offices in Saratoga Springs, N.Y., Irvine, Calif.,

and New York City, Palio+Ignite is accelerating new opportunities for change and growth in the healthcare sector. The agency, long known for its creativity, and more recently for building an unrivaled managed care expertise, is simultaneously spearheading the use of gamification and motion-sensing technologies to benefit health-care stakeholders.

“We are excited about where we’re headed as a company,” says Mastrion, chief global creative officer, Palio+Ignite. “Our ultimate goal is to ensure that we are focused on delivering engaging brand stories with insight, innovation and execution that elevates our client brands above all others.”

“Guy, Paul, and Andy combine extraordinary strategic expertise with the creative dexterity needed to deliver what clients are demanding right now,” according to Chandler. “As a team, they will focus on growing next-generation communications initiatives that will keep our health-care clients ahead of the ever-evolving communications landscape.”

AGENCY PEOPLE ON THE MOVE



L. FISHER

Fingerpaint
Lila Fisher joins Fingerpaint’s (fingerpaintmarketing.com) account service team. Ms. Fisher was a senior account executive with Evoke Health.

Dudnyk

Kristen Casey is named VP, account director, Dudnyk (dudnyk.com). Ms. Casey joins the agency from the Publicis Group, where she was in an account leadership role. **Tim Anderson** becomes VP, account director. Mr. Anderson was at Flashpoint Medica.

Dan Gleason is appointed group copy supervisor. Mr. Gleason previously worked at Discovery USA, CDM Princeton, and Digitas Health. **Katie Neuman** is named art director. Ms. Neuman joins the agency from Vox Medica. **Steffy Barrionuevo** becomes assistant account executive. Ms. Barrionuevo previously worked at McCann Echo Torre Lazur. **Julie Martosella** is appointed assistant account executive. Ms. Martosella has four and a half years of experience as a project manager. **Crystal Peterman**



R. TREZZA

becomes assistant traffic manager. Ms. Peterman joins the agency after seven years as production coordinator at Dynamic Digital Advertising. **Amanda Eutsey** is named associate art director. Ms. Eutsey has a degree in graphic design from the University of the Arts.

Ogilvy CommonHealth Worldwide

Richard Trezza is promoted to general manager of Ogilvy CommonHealth Payer Marketing and Ogilvy Healthworld Payer Marketing, divisions of Ogilvy CommonHealth Worldwide (ogilvychw.com). Mr. Trezza was executive VP, director of client services. **Amber Gilbert** is promoted to executive VP, director of client services, Ogilvy CommonHealth Payer Marketing. Ms. Gilbert was chief strategy officer.

Heartbeat Ideas joins Publicis family

Lost business opportunities tied to clients consolidating with major holding companies coupled with the lack of a global network placed the once independently owned digital agency **Heartbeat Ideas** on the hunt for a solution. The solution has now manifested itself via a merger with the **Saatchi & Saatchi Health U.S.** entities. The merger has made Heartbeat Ideas a member of **Publicis Healthcare Communications Group**. The move creates a new market player of unparalleled vigor and depth, according to Publicis executives.

Heartbeat CEO and founder Bill Drummy

will maintain his current position in addition to joining the leadership team at **Saatchi & Saatchi Wellness** with co-managing directors Kathy Delaney and JD Cassidy. Delaney will additionally retain her role as a global chief creative officer at PHCG. The newly combined agency and team leaders will report to PHCG Global Group President Sam Welch. Heartbeat's existing management team will also remain in place, as will its independent locations in New York's Tribeca neighborhood and in Santa Monica, Calif.

Drummy launched Heartbeat Ideas in a

Hoboken, N.J., apartment 15 years ago, with his agency recently celebrating its anniversary. He told *Med Ad News* that although the agency experienced 52 percent growth last year, a trend began to emerge that he had to consider strategically. "We were seeing more and more of our clients consolidate with major holding companies," Drummy says. "We kept losing business to the point where we were not even allowed to pitch. We were not even in the door."

The second factor involved in the search for a partner was that the Heartbeat Ideas team started to notice an increase in global opportunities. Additionally, the third condition was that Heartbeat Ideas executives wanted a partner that would allow the agency to retain what



Heartbeat Ideas CEO and founder Bill Drummy will maintain his current position in addition to joining the leadership team at Saatchi & Saatchi Wellness with co-managing directors Kathy Delaney and JD Cassidy.

made it unique. "When we looked at it from that vantage point, there was an absolute clear choice, and that was Publicis," Drummy told *Med Ad News*. "Publicis really rose to the top."

New York-based **Saatchi & Saatchi Health Communications** and Saatchi & Saatchi Wellness will now operate as one entity under the latter name. Heartbeat Ideas and its sister agency, **Heartbeat West**, will operate under the names "Heartbeat Ideas, a member of Saatchi & Saatchi Wellness," and "Heartbeat West, a member of Saatchi & Saatchi Wellness."

Heartbeat employs a team of 90 members between its New York and California offices. Whether in mobile, social, or online branding campaigns, Heartbeat's work has led to measurably superior results for a broad range of world-class healthcare brands, according to the agency. Heartbeat's clientele includes Galderma, Janssen Pharmaceuticals, McNeil Consumer Healthcare, Novartis, Pfizer, Sanofi, Teva, and Xenoport.

"We are thrilled to welcome Heartbeat to the PHCG family of agencies," says Nick Colucci, president and CEO of PHCG. "Its addition to our flagship Saatchi & Saatchi Wellness brands in the U.S. demonstrates our deep understanding of our clients' need to have a communications partner that can look at their brands holistically and provide interconnected and innovative solutions."

Heartbeat executives have communicated the merger to staff and are ready to move forward to the next step. "We are going to continue to educate our own people on what the other resources are that we have to bear and we are going to educate our clients as well," Drummy told *Med Ad News*. "Also, one last big point is what I see as a real key change in the way that the industry is going. Digital revolution and the healthcare reform revolution are both coming together to make dramatic changes in the way that pharmaceuticals has to be marketed. While it may be really clear to me that it is changing, our clients have to set themselves up and react."



"We are thrilled to welcome Heartbeat to the PHCG family of agencies," says Nick Colucci, president and CEO of Publicis Healthcare Communications Group. "Its addition to our flagship Saatchi & Saatchi Wellness brands in the U.S. demonstrates our deep understanding of our clients' need to have a communications partner that can look at their brands holistically and provide interconnected and innovative solutions."



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REQUIRED EXPERIENCE FOR HEALTHY CAREERS



By Joshua Slatko joshua.slatko@ubm.com

BMS changes senior management team

Bristol-Myers Squibb has announced a series of related changes within its senior management team. To support its ongoing success as a BioPharma leader, the company is evolving its business model, creating a global integrated commercial organization and expanding the scope of its finance organization.

Giovanni Caforio has been appointed executive VP and chief commercial officer, a newly created position in which he will lead all of the company's commercial units across all geographies. Mr. Caforio will be responsible for the global commercial strategy of the company and for the performance of the company's commercial operations worldwide. He was most recently president, U.S.

Charles Bancroft, executive VP and chief financial officer, will take on an expanded role that includes the Business Development and Strategy groups. Mr. Bancroft will be responsible for developing an integrated approach to finance, business development, and strategy that will enhance the company's effectiveness in meeting its long-term goals.

Mr. Caforio and Mr. Bancroft will continue to report to CEO **Lamberto Andreotti** and will remain members of his Senior Management Team.

Murdo Gordon has been appointed president, U.S., and will report to Mr. Caforio. Mr. Gordon was most recently senior VP of U.S. Oncology.

Beatrice Cazala, executive VP of Commercial Operations in charge of Global Commercialization for Europe and China, is in the process of transitioning to a new role within the company.

"By evolving our organization and expanding the roles of Giovanni and Charlie, I feel even more confident in the strength of my management team and our ability to take advantage of the most critical opportunities to build long-term sustainable growth," Mr. Andreotti says.

PHARMA

■ **Michael Berendt**, Ph.D., is named CEO of Bioniche Life Sciences Inc. He replaces **Graeme McRae**, who assumes the role of founder and chairman emeritus. Dr. Berendt was president and CEO of Aegera. Bioniche (bioniche.com) is a research-based, technology-driven Canadian biopharmaceutical company focused on the discovery, development, manufacturing, and marketing

of proprietary and innovative products for human and animal health markets worldwide.

■ **Marc Dunoyer** has been promoted to chief financial officer of AstraZeneca. Mr. Dunoyer was previously executive VP, global portfolio and product strategy. AstraZeneca (astrazeneca.com) is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialization of prescription medicines primarily for the treatment of cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases.

■ **Jeffrey Winton** becomes senior VP, chief communications officer, Astellas US LLC, a subsidiary of Astellas Pharma Inc. Mr. Winton was VP/head, global communications, Eli Lilly and Co. Astellas (astellas.com) is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products.

BIOPHARMA

■ **Dr. Jonathan Knowles** is appointed executive chairman of the board of Immunocore Ltd. He succeeds **Nicholas Cross**, who has been chairman since the company was founded in 2008, and will remain on the board as deputy chairman. Dr. Knowles has been a non-executive director of Immunocore since 2010 and was formerly president of Group Research and a member of the executive committee at Roche. Immunocore (immunocore.com) is a privately owned, clinical-stage biotechnology company developing a highly innovative platform technology that generates novel drugs called ImmTACs for the treatment of cancer and viral infection.

■ **Damian Marron** is named CEO of TxCell SA. Mr. Marron was CEO of Cytheris SA. **Francois Meyer**, previously TxCell's CEO and chairman of the board, has been appointed executive chairman of the board. TxCell (txcell.com) is developing innovative personalized cell-based immunotherapies for the treatment of severe chronic inflammatory diseases with high medical need using the company's unique and proprietary technology platform based on the properties of autologous antigen-specific regulatory T lymphocytes.

SPECIALTY

■ **Stephen W. Zaruby** is named president and CEO of Aurinia Pharmaceuticals. Mr. Zaruby was president of ZymoGenetics Inc. Aurinia (auriniapharma.com) is a clinical-stage pharmaceutical company focused on the global nephrology market.

■ **Wendy Perrow** is promoted to CEO of Alba Therapeutics Corp. She was president and chief operating officer. Alba (albatherapeutics.com) is a privately held, clinical-stage biopharma company focused on the discovery, development, and commercialization of pharmaceutical products to treat autoimmune and inflammatory diseases.

■ **Richard P. Becker Jr.** is appointed CEO of Voltarra Pharmaceuticals Inc. Mr. Becker has assumed progressive commercial leadership roles for Alcon, Merck, Novartis, OSI Pharmaceuticals, Bayer, and BASF. Voltarra (voltarrapharma.com) features a portfolio of early-stage small molecules and late-stage novel clinical compounds for rheumatology, the central nervous system, oncology, and immunology, which the company obtained through the acquisitions of IMC Biotechnology and Renascence Pharmaceuticals.

■ **Dr. Penelope Ward** becomes chief medical officer, Karus Therapeutics. Dr. Ward was chief medical officer at NovImmune SA. Karus (karustherapeutics.com) develops innovative medicines that have breakthrough potential in treating inflammatory disease and cancer.

■ **William I. Ramage**, D.Phil., has been named chief development officer of Acusphere Inc. He was an executive consultant at Acusphere since March 2000. Acusphere (acusphere.com) is a specialty pharma company focused on the development and regulatory approval of Imagify, a cardiovascular drug for detecting coronary artery disease.

■ **Jude Dinges** becomes senior VP, chief commercial officer, Aeterna Zentaris Inc. Mr. Dinges was executive director of region sales, bone health business unit, Amgen Inc. Aeterna Zentaris (aezsinc.com) is a specialty biopharmaceutical company engaged in developing novel treatments in oncology and endocrinology.

■ **Paul Marshall** is appointed senior VP, technical operations, A.P. Pharma. Mr. Marshall was senior VP at Amylin Pharmaceuticals Inc. **Brian Drazba** becomes VP of finance and chief financial officer. Mr. Drazba



C. BANCROFT



G. CAFORIO

was VP of finance and chief accounting officer for ISTA Pharmaceuticals Inc. A.P. Pharma (appharma.com) is a specialty pharmaceutical company developing products using its proprietary Biochronomer polymer-based drug delivery platform. The platform is designed to improve the therapeutic profile of injectable pharmaceuticals by converting them from products that must be injected once or twice per day to products that need to be injected only once every one or two weeks.

■ **Philip Wood** is promoted to VP and commercial therapeutic area head hemophilia, Sobi. Mr. Wood joined the company in March 2012 as global strategic lead for the hemophilia A team. Sobi (sobi.com) is an international specialty healthcare company dedicated to rare diseases.

■ **Joseph Boyd** becomes director of medical development and advocacy at Nicox Inc., which is the U.S. subsidiary of Nicox S.A. Mr. Boyd was director of compliance operations for Astellas US LLC. Nicox (nicox.com), with headquarters in France, is an emerging international company focused on the ophthalmic market.

New emerging markets leader for Lilly

Eli Lilly has announced that **Alfonso "Chito" Zulueta** will be promoted to senior VP and president of the Emerging Markets business effective Jan. 1, 2014. Mr. Zulueta will replace **Jacques Tapiero**, who will retire Jan. 31, 2014, after 31 years of service to the company.

Mr. Zulueta has been president and general manager of Lilly Japan since 2008. In his new role, Mr. Zulueta will lead the company's efforts in many of the world's fastest-growing markets in Asia, Latin America, the Middle East, and Africa, plus Russia and Turkey. He will report to

John Lechleiter, Ph.D., chairman, president and CEO, and will serve on the company's executive committee.

Mr. Tapiero joined Lilly in 1983 as a financial analyst. He became president of Emerging Markets in 2009. Prior to that, he had served as president of the intercontinental region for Lilly, which comprised offices in Asia, Australia, Africa, the Middle East, Canada, Latin America, and Russia, and had been general manager of several affiliates.

"Jacques Tapiero has made extraordinary contributions to our company throughout his 31-year career with Lilly, culminating in 2009 with his appointment to lead our important

Emerging Markets business," Dr. Lechleiter says. "Jacques' leadership has been characterized by strong operational skills and a keen focus on the development of Lilly people around the world. Jacques has been an exemplar of our values of integrity, excellence, and respect for people."

Born in the Philippines, Mr. Zulueta received a bachelor's degree in economics from De La Salle University in the Philippines in 1982 and an MBA from the University of Virginia in 1987. In his 25-year career with Lilly, he has held several sales and marketing leadership positions in the United States before becoming general manager for the Philippines affiliate in 1995. He served as president of Asian operations prior to

being promoted in 2008 to his current role as president and general manager of Lilly Japan, the company's second largest-market and affiliate behind only the United States.

"I am delighted to welcome Chito Zulueta to the company's top management team," Dr. Lechleiter says. "Chito's previous Lilly assignments have provided him with the global experience necessary for his new role as head of our Emerging Markets business. Chito's business savvy, his insights into diverse markets and cultures, and his passion for the patients whom we serve have enabled him to deliver outstanding results throughout his career. He is the ideal candidate to assume this important position."

Be credible – or be cooked

By **Sander A. Flaum**

DO YOU REMEMBER some glowering high school teacher warning you that the next time you got in trouble it would go down on your permanent record?

I do.
Of course, I wasn't exactly sure what a permanent record was, but it sounded scary. And then there comes a time, we realize that minor infractions will actually have zero impact on the rest of our lives. We also learn that just about any setback can be reversed.

This week's fumble can be redeemed by next week's game-winning pass. And by and by, we discover that we can actually reinvent ourselves. Going off to college, enlisting in the military, or starting a new job, we have new chances to smooth over the past and expunge old failures.

Until now.
Thanks to Google, Wikipedia, Gawker, Facebook, and their ilk, today there really is a "permanent record." Anyone can find out anything about practically anybody. As a result, if you lie, exaggerate, or even just speak

thoughtlessly, not only can you be found out, but also you can be exposed to instant viral ridicule. Just ask New York's former congressman, Carlos Danger. So, is this good or bad? Who knows? It's just the way things are. For better or worse, nearly every action we take puts our credibility on the line in ways we could never have imagined.

You probably don't think much about your credibility. It might be the least exciting of all personal attributes. Compare "credible" to traits like passionate, courageous, powerful, charismatic, visionary, inspiring, and innovative. Credible barely gets a yawn. Yet the smallest crack in your credibility can spell disaster. Being caught in even a tiny lie is one of the fastest ways to end a career (or



even go to jail, if you happened to fib to an FBI agent). Although there's nothing glamorous about credibility, and it isn't the direct route to a C-suite office, it is the mortar that holds all your other attributes in place.

So here with a few tips about how not to lose your credibility and a few more about how to build or even, re-build it.

First, Three "Don'ts"

Never bluff when you're confronted with unfamiliar information. If you're behind the curve in some aspect of your work, that's embarrassing, but guess what – it happens. Just quickly admit your gap, do your homework, and get current again. But if you pretend to know what you obviously don't, not only will you look out of touch, you'll be seen as a phony.

Never lie about yourself, especially in written or recorded form. The truth is always better. Perhaps you never finished or even attended graduate school. So what? Show your expertise in the quality of your work. Even better, go back to school. It's never too late. But if you spice up your resume with a fictitious MBA, eventually, you'll be busted.

Never weasel when you made a mistake. Admit it, you flubbed. Whatever credibility you may lose in how others perceive your abilities, you will more than make up in terms of earning their respect for your honesty. Even if you are offered the chance to throw someone else under the bus, take your lumps and move on. Stand-up people are winners in the end.

Next, Three "Do's"

Keep your promises. If you can say, "my word is my bond," and know that even your enemies will not roll their eyes; you have gone a long way to establishing personal credibility. Of course, the corollary of this principle is: Do not promise what you cannot deliver!

Be yourself. If you are naturally popular and social, good for you. But what if you are not? Perhaps you are more of a private person. That's okay, too. Do what's natural and comfortable. People will respect you for being who you are. They won't be impressed if you put on an act.

Guard your credibility. For leaders, being credible is just the price of admission. You'll still need to perform, persuade, inspire, listen, innovate, communicate, and execute all of the other actions that go into being an effective leader. But of all those qualities, only your personal credibility makes it possible to look at yourself in the mirror – and be proud of what you see. And that's worth putting in your permanent record. ■ MEDADNEWS

Sander Flaum is principal of Flaum Navigators and chairman, Fordham Leadership Forum, Fordham University Graduate School of Business Administration.

Advertisers Index

December 2013

Company	Page
AbelsonTaylor	29
Concentric Health Experience	2
Drafftcb Healthcare	5
ESSRX	Cover Tip
Fingerpaint	7
HCB Health	11
Healthcare Businesswomen's Association	26
Hobart Group Holdings.....	30
Klick Health	Cover Flap
SK&A A Cegecim Company	13
Triple Threat Communications	17

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