Med Ad News
January 2014
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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, senior VP, director of strategy services, AbelsonTaylor: 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, president and chief operating officer, closerbook: 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 adjust their thinking or fall behind.

Ed Mitzen, partner, Fingerpaint: As a small business owner, we will continue to provide health insurance for our staff. We are expecting that it will cost us more to serve our general practitioner clients 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.

Dan Renick, president of Precision for Value and Hobart Group Holdings: The ACA, from its passage, has intensified the strategic focus required to help clients navigate the evolving healthcare landscape. Beyond developing a deep understanding of the Act and reimbursement, and within which channels. For example, next year will primarily see an increase in the number of launches could decrease as compared to prior years.

Adam Gelling, principal, Giant Creative/Strategy: On the surface more insured patients should be a boon for pharmaceutical companies, and stock performances over the past year seems to bear this out, but the ACA will change the way products are marketed. Marketing agencies and their sponsors will need to expand their promotion and support throughout the continuum of therapy. It will no longer be about just obtaining prescriptions. Support and access strategies will be elevated alongside clinical benefits; validating positive outcomes and providing mechanisms to report those outcomes among HCP’s, patients, and caregivers will be a necessary component of persistence and brand use. Also, new product approvals will face increased scrutiny from payers to demonstrate a significant benefit over other available therapies, so the number of launches could decrease as compared to prior years.

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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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, I 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 change, 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 Tesiba 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 trends 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.

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

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

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Geoff McCleary of @digitas_health talks about the “Own It” program for #ADHD with @adamlevine http://ow.ly/r1sM1 #pharma

@DRPENZESJANOS:
The #mHealth App Market is Primarily Useless (For Now) http://ow.ly/27ijx #hcsmeu #pharmamktg #socpharm #epharma

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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-str … #socialmedia

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

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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
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. Go to page 25

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We are 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 health and “successful” care becoming increasingly quantified with hard metrics. One important way 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.

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. This includes reimbursement and reimbursement subtypes. The ACA has even more fragmented the implementation of the new state Market-place 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 popu-
tar topic in the news of late. What do you think went wrong, and how would your agency have handled it differently?

Kyle Barich, president, CDM New York: Of course it’s easy to pass judge-ment in hindsight, but no agency would be proud of the HealthCare.gov rollout to find a scenario that an agency and were able to manage through the likely inflexible contracting process, we would have put a lot of effort behind behind the scenes to ensure that all the 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 it isn’t cooked, it shouldn’t be served. Once the site was launched, we would have developed broad and compelling driv-ers to get people to the site. Finally, if things didn’t go as planned, we would face harsh reality with some good old-fashioned truthful-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 con-ditions for success. The bottom line is, regardless of the scope or size, if you can’t execute without an equally colossal QA/QC procedure. It also feels there were way too many “cooks in the kitchen.” A strong, single, well-organized team is necessary.

Ed Mitzen: It would be incredibly arrogant of me to think that my agency could produce a website that is on this order of mag-nitude. And we are an incredibly talented digital shop. I would like to think that more time would have been allocated to test-ing and QA control. The massive integration project between HealthCare.gov and all of the various insurance carriers (all with different back-end technologies) is not something that can be ex-ecuted without an equally colossal QA/QC procedure.
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 create a better product than a huge team of moderately skilled people.

**Mod 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 buying themselves bigger in order to meet that demand – appears to be accelerating. What is your response to that point of view?**

**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 that were contemplating a diminution 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 mid-sized agency that looked 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 be continue to change in the way 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 taking the joint. At the same time however, several are in the process of unweaving 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’re seeing that consolidation is not the right answer for everyone, because for large manufacturers’ organization has 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 communications management and isn’t finding one. 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 greater 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 believe 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 the same boat. 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 leverage their network and avoid all the corporate bureaucracy.

**Adam Selligent:** Sponsors commoditizing the brands they hire to make their products shine. Handled procurement is extremely short sighted and ignores the forest through the trees. Switching or excluding agencies over a nominal discount in hourly rates disregards 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. An agency that has the front lines of client business to ultimately reduce client budgets and accelerate brand performance gets lost in a straight procurement rate war. What is a great brand is that great brands work to bring the procurement and appreciate their support and guidance, but encourage them to do so in a way that they don’t feel like the pendulum swings the other way, and no one is getting from their arranged-marriage agencies.

**Dan Renieki:** 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 exception 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, president, ILT:** How marketing and commercial organizations are under significant pressure to drive increased ROI on a range of initiatives. Investing into this dynamic requires our bringing together broader complementary, non-duplicative skill sets and knowledge that allows us to act as a single small company that can help 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.

**Renée Wills, president, ICC Lowe Trio:** Agencies that are consolidating to achieve cost efficiencies and round out their capabilities must keep this in mind: Big isn’t necessarily better. While change is a natural side effect of any consolidation, it is 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, agencies are carefully observing before joining the trend.**

**Kyle Barich:** Most of our senior clients grew up in a world in which the message, reach, and frequency, share of voice, and outboard marketing, and then most everything changed. For those agencies that understand the digital world, they have to engage in social media. So we started with social listening, whether passive or active (research). Then we helped some of our major clients launch companies that cover platforms and YouTube channels. But the magic two-way conversation about our brands or disease content across social media channels remains elusive for the majority. We’re working on the 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 the sense of risk and increase our collective sophistication in healthcare social marketing.

**What will they be asking for in 2014?**

**Kyle Barich:** Mobile, apps, social media, responsive web, design, virtual conference support, in-app branded experiences, and continued improvement over the iPod 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 there 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 not get fixated on whether the sauce.” Agencies also need to make sure our digital media partners 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.

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**Loren 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 the right person, at the right time, might sound like old news, but it’s more important than ever and it ultimately comes down to a predictable and consistent execution capability.

**Kim Wishnow-Pereira:** Will the consolidation trend continue? Yes. Will it accelerate? I think so. For our clients, the trend is less about “more” and “less” and more about “better” and “more.” It’s about efficiency, efficacy, and productivity. The ability to get to 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 marketing agency. 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 one 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 are the keys to successful mobile and social strategies for pharma brands?**

**Kyle Barich:** Most of our senior clients grew up in a world in which the message, reach, and frequency, share of voice, and outboard marketing, and then most everything changed. For those agencies that understand the digital world, they have to engage in social media. So we started with social listening, whether passive or active (research). Then we helped some of our major clients launch companies that cover platforms and YouTube channels. But the magic two-way conversation about our brands or disease content across social media channels remains elusive for the majority. We’re working on the 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 the sense of risk and increase our collective sophistication in healthcare social marketing.

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**Erin Keefe, senior VP group director, digital strategy, McCann Erickson, 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 solutions. 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” experience where they want iPad experiences that offer more customization, utility, and convenience. So the task at hand for
the next generation of pharma’s iPad applications is how to best leverage both the front- and back-end technology. This means the continuation 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 communications; more closed loop and relationship-oriented marketing. The end goal is an experience that leaves the physician and rep more satisfied while improving the performance of iPad-based marketing efforts.

Another mobile SLA is one 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 HIPAA Act, mobile is a world larger 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 DTIC side, the question is no longer focused on how can I do social in the current regulatory environment, but where, when and with what messengers that will align with a broader integrated marketing strategy? Two-way, patient-focused social is on the rise. FDA ambiguity continues to be a concern 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.

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Jay Carter: Ad Age says that in 2012 one-third of agency revenues came from digital services. Our agencies are feeling the pressure. Is the proper place of print in a modern brand marketing strategy, and what are customers seeking—or not seeking—in this area?

Bruce Rooke, chief creative officer, GS&G: There is no place left for the aggrandized print ad. There is, however, a place for a new-fashioned print ad: one that reaches and spreads awareness beyond the 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. In the print ad of today, which is unrestricted and unperverted, we can still capture behavior and attitudes that may be missed by digital analytics models. We can use print to gather data 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 plasma 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 experiences. Opportunities like interactive embedded ads within the digital version of a traditional journal are just the first step.

AGENCY ROUNDTABLE

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.

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 the message 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 overall 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? 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, 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 meet their customer relationships, to differentiate themselves from the competition and to feel more comfortable with a meaningful value proposition rather than a product-selling role. 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 model. The interactive marketing approach 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 whether the pharmaceutical and biotech companies will require the investments.
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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 at a lower cost than an alternative. “It’s actually about, ‘Am I making the patient better and at particular therapeutic regiment to accomplish only this outcomes-based model, everyone really is incented now to move from a pay-for-performance model to more of an epharmacoeconomic 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 ad in 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.”
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 we work to build awareness among the healthcare consumer, there’s depth of information that must be conveyed and a higher level of engagement, beyond just driving them to 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 the consolidation of buying products with more niche indications, however, tradition- al DTC will not be cost effective for these brands.

What is clear is that being said, all brands need to engage with the customer on their terms and the customer, and the patient, and the con- sumer is using multiple channels and mul- tiple points of reference and they 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 it 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 $5.10 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 dropped 16 percent to $1.01 billion. Radio advertising spending dropped 21 percent to $192.3 million. Radio advertising spending had the biggest decline, 34 percent to $23.1 million. Spending on online 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, Real- tor.com, Yahoo! Mail and YouTube), with the 2011 figure not reported. Citing Nielsen statistics, Richard Meyer, blogger at World of DTC Marketing, re- ported in April that DTC Internet media spending went down 33 percent in 2012. He had heard from agency contacts that spending went down 33 percent in 2012.

“TV is great for building awareness but with more and more consumers multi-task- ing and tuning out 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 ‘turning off’ the sound and watching with captions... 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 condi- tion states 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 much more satisfying way 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 in a much more effective way in the digital realm.

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 wouldn’t do unbranded’. They’re finding a way to use unbranded to connect with their audiences, may different segments of their audi- ence 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, es- pecially unidentified audiences. “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 they do with wellness or lifestyle,” von Plato says.

Part of that digital expansion is the use of mobile, according to Drummy. “With more and more patients connecting to digital campaigns on their cellphones, this means that how healthcare information is being consumed, and how we are able to add value to the rela- tionship between the physician and the pa- tient, we see that as a huge area of growth for pharmaceutical companies and other health- care providers,” he says. “And it’s showing that different ways of approaching the question how do we help and we are really only about advertising, or are about something broader.”

Traditional forms of advertising are lim- ited, Drummy says, and he believes com- munications with consumers and patients should also 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 prac- ticing medicine for the course, but we are trying to enable better outcomes through a conver- sation 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 mobile space and these 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 well- ness 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. “TV is great for building awareness but marketers will rely more on organic search,” he says. “TV is great for building awareness but they are going to continue to be far less relevant today.”

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“The biggest decline in Internet spend- ing, I believe, will be in paid search and mar- keters will rely more on organic search,” he says. “TV is great for building awareness but with more and more consumers multi-task- ing and tuning out 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 ‘turning off’ the sound and watching with captions... Additionally, newspapers and magazine will continue to decline and dollars will be shifted more to targeted health magazines, he says.”

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“Te Afordable 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 marketing to 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 promot- ing 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 cre- ated a role for the brand itself both in the context of fitness, in what the word fitness means to people and households,” he says. “This device be- comes part of a much bigger or ongoing relationship than just a brand purchase or anything like that. It’s how integrated into their fitness regime and health and wellness, and some of the consumer products that have succeeded.”

Von Plato points to a “beautiful” campa- ghn done for Special K cereal. “It’s about numbers and women, how we’ve 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 Spe- cial K, I believe, they became 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 buys cereals, for someone who has hypertension, depression, is tens and tens of thousands of dollars,” according to von Plato. “But this territory of wellness and health awareness is a whole new area. They can claim the virtue of health over wealth, the value system that says being healthy is important, it’s important as being wealthy, it’s impor- tant as being employed, it’s important as be- ing 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 our- selves and to help ourselves and get in and take it right out from under us.”
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

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 copycat or cost-share offset programs underlines 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...
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 relationship 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 pharmaceutical 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 email 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.

Larry Blandford, PharmD, is a Managing Partner at Hobart Innovation, a Hobart Group Holdings company.
**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 PSRMA, 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 $56.3 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 phosphinate) was introduced 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 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 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 $9.9 billion in 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 improved 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 Tosciano. “The combination of this next-gen insulin with lixisenatide 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 ongoing 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 will expect the NDA for lixisenatide 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

**MDLinx – STAT**

**MEDICATIONS ENDOCRINOLIGISTS VALUE**

<table>
<thead>
<tr>
<th><strong>24 MARKETED PRODUCTS</strong></th>
<th><strong>16 PIPELINE PRODUCTS</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>3 of the 24 marketed products yearly used considered to have a positive impact</td>
<td>4 of the 16 products had a positive impact</td>
</tr>
<tr>
<td>%94</td>
<td>%89</td>
</tr>
<tr>
<td>%93</td>
<td>%70</td>
</tr>
</tbody>
</table>

Endocrinologists largely agree optimistic about pipeline products

*In the STAT (standing for statistics) graphic above, we’ve presented an overview that is typically used to compare different insulin products. It indicates the proportion of endocrinologists who believe that a particular insulin product has a positive impact. We’ve also included a list of marketed and pipeline products labeled with a percentage indicating how many endocrinologists believe them to have a positive impact.*
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 Ghirri, 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 the FDA and was granted clearance by the European Commission under the trade name Lixydia 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 gastrointestinal 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 1/1b clinical trial confirmed previous studies demonstrating that NewMet reduced fasting plasma glucose to a similar extent 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 requiring 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/DPPI4 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...
## SELECT DIABETES PRESCRIPTION MEDICINES IN LATE-STAGE DEVELOPMENT

<table>
<thead>
<tr>
<th>Product Status</th>
<th>Product</th>
<th>Chemical</th>
<th>Intended Indication</th>
<th>Countries</th>
<th>Developers</th>
</tr>
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<tbody>
<tr>
<td>Awaiting approval</td>
<td>Afrezza</td>
<td>Insulin human ([rDNA origin])</td>
<td>Afrezza is intended for the treatment of type 1 diabetes and type 2 diabetes.</td>
<td>United States</td>
<td>MannKind</td>
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<tr>
<td>Awaiting approval</td>
<td>Alogliptin</td>
<td>Alogliptin</td>
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<td>Taiwan, Indonesia</td>
<td>Takeda Pharmaceutical</td>
</tr>
<tr>
<td>Awaiting approval</td>
<td>ASP1941</td>
<td>Ipragliflozin</td>
<td>ASP1941 is intended for the treatment of type 2 diabetes.</td>
<td>Japan</td>
<td>Astellas Pharma</td>
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<tr>
<td>Awaiting approval</td>
<td>CS5452</td>
<td>Telagliflozin hydrate</td>
<td>CS5452 is intended for the treatment of type 2 diabetes.</td>
<td>Japan</td>
<td>Chugai Pharmaceutical and Kowa</td>
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<td>Awaiting approval</td>
<td>Empagliflozin</td>
<td>Empagliflozin</td>
<td>Empagliflozin is intended for the treatment of type 2 diabetes mellitus in adults.</td>
<td>United States, European Union</td>
<td>Eli Lilly and Boehringer Ingelheim</td>
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<td>Eperazin</td>
<td>Eperazin</td>
<td>Eperazin is intended for the treatment of type 2 diabetes.</td>
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<td>GlaxoSmithKline</td>
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<tr>
<td>Awaiting approval</td>
<td>Forxiga</td>
<td>Dapagliflozin</td>
<td>Forxiga is intended for the treatment of adults with type 2 diabetes.</td>
<td>United States, Japan and China</td>
<td>Bristol-Myers Squibb and AstraZeneca</td>
</tr>
<tr>
<td>Awaiting approval</td>
<td>Forxiga</td>
<td>Dapagliflozin</td>
<td>Forxiga, as add on to DPP4, is intended for the treatment of diabetes.</td>
<td>European Union</td>
<td>Bristol-Myers Squibb and AstraZeneca</td>
</tr>
<tr>
<td>Awaiting approval</td>
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<td>Dapagliflozin</td>
<td>Forxiga, as add on to insulin and metformin, is intended for the treatment of diabetes.</td>
<td>European Union</td>
<td>Bristol-Myers Squibb and AstraZeneca</td>
</tr>
<tr>
<td>Awaiting approval</td>
<td>Forxiga/ Metformin Fixed Dose Combination</td>
<td>Dapagliflozin and metformin</td>
<td>Forxiga/Metformin Fixed Dose Combination is intended for the treatment of diabetes.</td>
<td>European Union</td>
<td>Bristol-Myers Squibb and AstraZeneca</td>
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<tr>
<td>Awaiting approval</td>
<td>Glifast</td>
<td>Mitiglitude calcium hydrate</td>
<td>Glifast, in combination with dipeptidyl peptidase-4 inhibitors or biguanides, is intended for the treatment of type 2 diabetes mellitus.</td>
<td>Japan</td>
<td>Takeda Pharmaceutical</td>
</tr>
<tr>
<td>Awaiting approval</td>
<td>Deglina</td>
<td>Degluride</td>
<td>Deglina is intended for the treatment of type 2 diabetes.</td>
<td>European Union</td>
<td>Novo Nordisk</td>
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<tr>
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<td>Ipragliflozin</td>
<td>Ipragliflozin</td>
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<td>Astellas Pharma</td>
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<tr>
<td>Awaiting approval</td>
<td>Invokana</td>
<td>Canagliflozin</td>
<td>Invokana is intended for the treatment of type 2 diabetes.</td>
<td>European Union</td>
<td>Janssen Research &amp; Development</td>
</tr>
<tr>
<td>Awaiting approval</td>
<td>IDegLira</td>
<td>Insulin degludec</td>
<td>IDegLira is intended for the treatment of type 2 diabetes.</td>
<td>United States</td>
<td>Eli Lilly</td>
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<tr>
<td>Awaiting approval</td>
<td>TA-7284</td>
<td>Canagliflozin</td>
<td>TA-7284 is intended for the treatment of type 2 diabetes mellitus.</td>
<td>Japan</td>
<td>Mitsubishi Tanabe Pharma</td>
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<tr>
<td>Awaiting approval</td>
<td>Tresiba</td>
<td>Insulin degludec</td>
<td>Tresiba is intended for the treatment of type 1 diabetes and type 2 diabetes.</td>
<td>Japan</td>
<td>Mitsubishi Tanabe Pharma</td>
</tr>
<tr>
<td>Awaiting approval</td>
<td>Tresiba</td>
<td>Insulin degludec</td>
<td>Tresiba is intended for the treatment of type 1 diabetes and type 2 diabetes.</td>
<td>Japan</td>
<td>Mitsubishi Tanabe Pharma</td>
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<tr>
<td>Awaiting approval</td>
<td>TS-071 Oral</td>
<td>Lusogluflazone hydrate</td>
<td>TS-071 Oral is intended for the treatment of type 2 diabetes.</td>
<td>United States</td>
<td>Novo Nordisk</td>
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<tr>
<td>Phase III clinical trials</td>
<td>Dapagliflozin</td>
<td>Dapagliflozin</td>
<td>Dapagliflozin is intended for the treatment of type 2 diabetes.</td>
<td>United States, European Union, China, Japan</td>
<td>Bristol-Myers Squibb and AstraZeneca</td>
</tr>
<tr>
<td>Phase III clinical trials</td>
<td>Dapagliflozin</td>
<td>Dapagliflozin</td>
<td>Dapagliflozin, in combination with triple therapy (dapo, met and SU), is intended for the treatment of type 2 diabetes.</td>
<td>United States, European Union, China, Japan</td>
<td>Bristol-Myers Squibb and AstraZeneca</td>
</tr>
<tr>
<td>Phase III clinical trials</td>
<td>Dapagliflozin</td>
<td>Dapagliflozin</td>
<td>Dapagliflozin, as add on to insulin and metformin, is intended for the treatment of diabetes.</td>
<td>United States, Japan, China</td>
<td>Bristol-Myers Squibb and AstraZeneca</td>
</tr>
<tr>
<td>Phase III clinical trials</td>
<td>Dapagliflozin</td>
<td>Dapagliflozin</td>
<td>Dapagliflozin, as add on to DPP4, is intended for the treatment of diabetes.</td>
<td>United States, Japan, China</td>
<td>Bristol-Myers Squibb and AstraZeneca</td>
</tr>
<tr>
<td>Phase III clinical trials</td>
<td>Forxiga/ Metformin Fixed Dose Combination</td>
<td>Dapagliflozin and metformin</td>
<td>Forxiga/Metformin Fixed Dose Combination is intended for the treatment of diabetes.</td>
<td>United States, Japan, China</td>
<td>Bristol-Myers Squibb and AstraZeneca</td>
</tr>
<tr>
<td>Phase III clinical trials</td>
<td>Glucytr/Metformin Combination Tablet</td>
<td>Sitagliptin phosphate and metformin</td>
<td>Glucytr/Metformin Combination Tablet is intended for the treatment of type 2 diabetes.</td>
<td>Japan</td>
<td>Ono Pharmaceutical and Merck &amp; Co.</td>
</tr>
<tr>
<td>Phase III clinical trials</td>
<td>Insulin Lispro</td>
<td>Insulin lispro</td>
<td>Insulin Lispro is intended for the treatment of type 1 diabetes and type 2 diabetes.</td>
<td>United States</td>
<td>Eli Lilly</td>
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<tr>
<td>Phase III clinical trials</td>
<td>Invokana XR</td>
<td>Canagliflozin</td>
<td>Invokana XR is intended for the treatment of type 2 diabetes.</td>
<td>United States</td>
<td>Janssen Research &amp; Development</td>
</tr>
<tr>
<td>Phase III clinical trials</td>
<td>ITCa 650</td>
<td>Etanbate</td>
<td>ITCa 650 is intended for the treatment of type 2 diabetes.</td>
<td>United States</td>
<td>Intarcia Therapeutics and Quintiles Laboratories</td>
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<td>Phase III clinical trials</td>
<td>Komboglyze</td>
<td>Saxagliflozin hydrochloride and metformin</td>
<td>Komboglyze is intended for the treatment of type 2 diabetes.</td>
<td>United States, China, Japan</td>
<td>Bristol-Myers Squibb and AstraZeneca</td>
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<td>Phase III clinical trials</td>
<td>U2605541</td>
<td>Basal insulin</td>
<td>U2605541 is intended for the treatment of type 1 diabetes and type 2 diabetes.</td>
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<td>Eli Lilly</td>
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<td>Phase III clinical trials</td>
<td>Metlicro</td>
<td>Metformin hydrochloride</td>
<td>Metlicro is intended for the treatment of type 2 diabetes in pediatric patients.</td>
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<td>Dainippon Sumitomo Pharma</td>
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<td>Phase III clinical trials</td>
<td>Oraplyn</td>
<td>Insulin</td>
<td>Oraplyn is intended for the treatment of type 1 diabetes and type 2 diabetes.</td>
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<td>Celsius Biotechnology</td>
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<td>Racolazine</td>
<td>Racolazine</td>
<td>Racolazine is intended for the treatment of type 2 diabetes.</td>
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<td>Otsuka Science</td>
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<td>SanaDopa</td>
<td>Saxagliptin and dapagliflozin</td>
<td>SanaDopa is intended for the treatment of diabetes.</td>
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<td>AstaZeneca</td>
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<td>Surepost</td>
<td>Repaglinide</td>
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<td>Trelaglin</td>
<td>Trelaglin</td>
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<td>Phase III clinical trials</td>
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<td>Insulin glargine</td>
<td>U300 is intended for the treatment of type 1 diabetes and type 2 diabetes.</td>
<td>United States</td>
<td>Sanofi US</td>
</tr>
</tbody>
</table>

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*Note: The above table provides a list of diabetes prescription medicines in late-stage development as of the publication date.*
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 crossover 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 blockbuster medicines 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 (Apidea, Sanofi) and insulin Aspart (NovoLog, Novo Nordisk) have also been validated in preclinical studies.

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-scale process to electrochemically grow such gold or silver nano-rod arrays into pores of an anodized aluminium-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 inconsistent results due to the natural humidity of one’s breath, high temperature requirements, and lack of selectivity.

Ronny Prieler, 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 different 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. Prieler’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.
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 partnerships, and take advantage of emerging opportunities.

Federal initiatives to create shared-savings projects have been ongoing for some time and gave a start to shared-savings models, such as ACOs. ACO pilots originated within 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 stakeholders 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 offer 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 the degree to which 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.

Environmental level

Opportunities exist for manufacturers to influence the external environment as the ACO model evolves. Companies can help shape the standard and methodology of bundled 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 norms as compared with payers.

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, payers concerns about rising costs for these drugs will intensify in both developed and emerging markets. Spending on specialty medicines is expected to reach $320-240 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 for rheumatoid arthritis, cystic fibrosis, and several tumor types. Recent and near-term launches of new medicines primarily associated with 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 world’s poorest have few new treatment options, including malaria, neonatal sepsis, and tuberculosis.

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

FACTS & FIGURES

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 some understanding of the transparency laws. Regard to 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. Gallos, senior manager, health economics, QPharma. “CMS has provided this, but it is more than one page and one page fact sheet could be left at the doctor’s office every time a rep visits. The 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.”
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-level 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 (TAAs), develop TA-level messaging strategy for ACOs, or part-pact on specific therapy areas (TAs), develop example, manufacturers may want to conduct strategic options manufacturers will want to aged more tightly in order to improve quality rebates, and fixed rebates.

**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 populations, collaborations in clinical trials, research and publications, negotiation of best rates with drug manufacturer 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 Mona is a senior consultant with Campbell Alliance.
Cegedim launches social site for docs

By Joshua Slotko

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 health care professionals in the United States suggest that online communities play a pivotal role both for physicians and for the 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 valuable 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-BioPharma 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 health care professionals only because patient treatment will be discussed, samples will be ordered, and dialog 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 questions, 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 BioPharma 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 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 site 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 understand HCPS 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 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.

“Physicians typically spend 20 minutes per day, on their time, and compare experiences with peers. We believe this will help them cut their time, and make the most informed decisions possible for their practices,”

Physicians typically spend 20 minutes per session interacting with peers on QuantiaMD. 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 QuantiaMD 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 Quantia executives, this is the driving force behind the growth and activity of QuantiaMD, which now reaches 70 percent of U.S. physicians with one in three viewing during the last quarter alone.

“The Marketplace houses interactive presentations from vendors offering electronic health records, medical billing, reputation management, malpractice insurance, as well as a variety of medical apps,” Coyne told Med Ad News. “We make it easy for physicians across the country to connect and help each other become better doctors. They can solve cases together, and learn from leading experts through interactive programs and Q&As. Comparing experiences about products and services for its practice is a natural extension to that.”

Online marketplace for physicians

Quantia has introduced the first virtual marketplace for the company’s physician community. QuantiaMD 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.”

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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 more 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 brands to understand how to engage with patients and physicians to leverage mobile to generate better health outcomes. By understanding where, when 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

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.

Getting mobile ready

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Palo+Ignite names new leaders

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

The management team includes Goy Mastriano, 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; and Andy Smith, who serves as chief operating officer. The team reports to Bob Chandler, president of InVentional Health Communications.

“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.”
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 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 measurable 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.”
Bristol-Myers Squibb has announced a series of related changes with corporate and divisional management. 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, commercial operations, 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 & Co. Astellas (astellas.com) is a pharmaceutical company dedicated to improving the health of people around the world. Mr. Winton is responsible for creating a global integrated commercial organization.

Dr. Jonathan Knowles is appointed executive chair 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 and CEO 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.

Damin Marron is named CEO of Txl Cell SA. Mr. Marron was CEO of Cytheris SA. Francois Meyer, previously Txl Cell's CEO and chairman of the board, has been appointed executive chairman of the board. Txl Cell (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.

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 Latin America, the Middle East, Africa and Russia, plus Turkey. He will report to John Lachleiter, 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 or wraps of several affiliates.

"Jacques Tapiero has made extraordinary contributions to our company throughout his 31 years of service with Lilly, culminating in 2009 with his appointment to lead our important Emerging Markets business," Dr. Lachleiter says. "I want to thank him for his 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 office 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. Lachleiter 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."

SPECIALTY

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

Wendy Perrow is promoted to CEO of Althea Therapeutics Corp. She was president and chief operating officer. Althea (altheaphar.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 Voltartrak Pharmaceuticals Inc. Mr. Becker has assumed progressive commercial leadership roles for Alcon, Merck, Novartis, OSI Pharmaceuticals, Bayer, and BASF. Voltartrak (voltartrakah.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 L. Ramage, D.Phil., has been named chief development officer of Auroc- sphere Inc. Dr. Ramage was executive director at Aucuphere since 2000. Aucuphere (aucuphere.com) is a specialty pharmaceutical company focused on the development and regulatory approval of Imagly, a cardiovascular drug for detecting coronary artery disease.

Jude Dinges becomes senior VP, chief commercial officer, Arterna Zentaris Inc. Mr. Dinges was executive director of region sales, bone health business unit, Amgen Inc. Arterna Zentaris (aerxinc.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 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 Nice Inc., which is the U.S. subsidiary of Nice S.A. Mr. Boyd was director of compliance operations for Astellas US LLC. Nice (nicex.com), with headquarters in France, is an emerging international company focused on the ophthalmic market.
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 ex-punge 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, 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 fubbed. 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.

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

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