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POLICY PROBLEM SOLVER

Fumie Griego, Assistant Director General, International Federation of Pharmaceutical Manufacturers & Associations

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Pharma's Marijuana Makeover

OVER THE YEARS OF BEING A BUSINESS-TO-BUSINESS EDITOR, I've stayed far away from press releases around marijuana and cannabis, for reasons of professionalism or credibility. (Also, because of the propensity for kitschy headlines). But in this month's article reviewing the media mentions around pharma (see page 26), the authors note "another area where pharma can take a leadership role is the legalization of medical marijuana. Legalization will have an impact on the sale of drugs for which marijuana is an alternative, especially for the Medicare population. Pharma is at risk of lost sales as more states approve the use of marijuana for medical purposes." So what's under the covers with cannabis?

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FDA has many responsibilities around cannabis outside of drug development. But under its drug purview, it actively supports development of drugs from marijuana. "From" being the key word: the agency hasn't yet approved a marketing application for a drug product containing or derived from botanical marijuana…the actual plant. The drugs that have been approved to date are synthetic forms of cannabidiol (CBD) and tetrahydrocannabinol (THC). THC is the major psychoactive ingredient in marijuana, and CBD is a compound that counteracts the psychoactivity of THC, while offering relief from inflammation, pain, anxiety, and more, without the sleepiness or unease associated with marijuana.

FDA also offers a guidance on the use of botanicals (e.g., marijuana) as sources for drugs (http://bit.ly/2uTakAo), quality manufacturing, activities, and applies expedited approvals, as with other drugs, using orphan disease designation, priority review, and fast-track designation. According to FDA's Marijuana Q&A web page, updated at the end of June (http://bit.ly/2vlfZQz), the agency has approved Marinol and Syndros—which include the active ingredient dronabinol, or synthetic THC—for therapeutic uses in the U.S., including the treatment of anorexia associated with weight loss in AIDS patients. FDA also approved Cesamet, containing the active ingredient nabilone, synthetically derived and chemically similar to THC, for the treatment of severe nausea and vomiting caused by cancer chemotherapy.

Pipeline and popularity

Current examples in the pipeline for cannabis include GW Pharmaceuticals' lead cannabinoid product candidate Epidiolex. This proprietary oral solution of plant-derived CBD is in development for severe, orphan, early-onset, treatment-resistant epilepsy syndromes, including Dravet syndrome, Lennox-Gastaut syndrome, tuberous sclerosis complex, and infantile spasms (IS). The company has an FDA expanded access program in place for Epidiolex. Corbus Pharmaceuticals' lead product candidate, Anabasum, is a novel synthetic oral endocannabinoid-mimetic in Phase II trials for reduction of chronic inflammation and fibrotic processes. INSYS Therapeutics is also investigating CBD for IS.

One of the main reasons for pot's popularity is the search for opioid replacements in pain management. As the pressure on pharma to address its role in the opioid epidemic increases, the industry, physicians, and science are actively seeking alternatives for patients. While it was also mentioned that pharma could take a leadership role in the legalization of medical marijuana based on its expertise with the manufacture and distribution of controlled substances, the following statistics need to be examined.

Currently, eight states have legalized recreational cannabis and 29 states allow cannabis for medical use. According to New Frontier Data, both the recreational cannabis and medical use cannabis markets are expected to grow and in 2025 will represent $10.9 billion and $13.3 billion respectively.

Cannabis considerations

Conducting a clinical trial with cannabis is not that much different, save that your investigator will need a license from the DEA and clinical trial supplies need to come from qualified sources, with recent reports indicating shortages in that area.

The percentage of people who conceivably could use medical marijuana as an alternative to a prescription cannabis-derived drug should be weighed. However, this is also part of what pharma is experiencing anyway in regard to its drugs, differentiating outcomes in the market. In this case, for example, FDA doesn't examine actual marijuana because it can't quantify the quality of the plant. Synthetically-derived compounds are consistent and can lend credence to the data. Additionally, FDA approves drugs that meet safety and efficacy rquirements in clinical trials, which still means something to physicians and patients in search of cures, symptom management, or improved quality of life.

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Health Policy Problem Solver

Julian Upton, European and Online Editor

Dr. Fumie Griego, the International Federation of Pharmaceutical Manufacturers and Associations' new Assistant Director General, speaks with *Pharm Exec* about her mission to use IFPMA's international reach to find real and practical solutions to the most pressing global healthcare challenges.

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Cover Photo: Max Taylor

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Readers Weigh In

As a food and drug lawyer and life science compliance officer for the past 25 years, much of the author's expressed frustrations have merit. However, those frustrations do not address the challenge, but merely perpetuate the complaints with the current state of compliance. In large measure, the current compliance paradigm is the product of its environment, where government regulators push companies to write more rules to address perceived infractions.

Anonymous, 7/15/2017
"Challenging the Current Compliance Paradigm"
bit.ly/2uxrfs5

Twitter Talk

■ New skills and expertise will be needed. But what you propose is MSLs (medical science liaisons)? Right? Navigating payer groups may become the most valuable skill.

j. cameron tew, @jcamerontew, 7/25/2017
"News Sales Reps for a New Era"
bit.ly/2uCA7v6

■ Outrageous fact: People die from ALS w/o ever having been diagnosed.

ALS Advocacy, @alsadvocacy, 7/5/2017
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Pressure Mounts on FDA, Pharma to Tackle Opioid Abuse

The growing toll requires new assessment of risks, expanded provider education, and more scrutiny of marketed products

The steady rise in deaths, injuries, and treatment costs related to the abuse and misuse of opioid painkillers has increased calls for FDA and drug companies to more forcefully limit use of harmful medicines while ensuring access to effective analgesics for patients suffering from pain. With the opioid epidemic linked to some 180,000 overdose deaths between 2000 and 2015, public health officials are demanding more effective action to curb the prescribing and dispensing of some 200 million pain pills to Americans each year. Federal and state health officials, moreover, seek to prevent further opioid diversion and to expand treatment of addicts to prevent overdoses and to better educate health professionals on appropriate opioid prescribing and dispensing.

Lawsuits & settlements

The escalating crisis is drawing attention of Congressional committees and federal and state prosecutors to the role of pharmaceutical companies in promoting opioid prescribing. The Department of Justice recently reached a $35 million settlement with Mallinkrondt Pharmaceuticals to resolve allegations of failing to track or report the apparent diversion of millions of pain pills. And former sales executives at Insys Therapeutics have pled guilty to violating the federal anti-kickback statute by inducing physicians to prescribe its fentanyl spray Subsys beyond its approved use of treating serious short-term cancer pain.

More than 25 states, cities, and counties have filed charges that opioid producers allegedly downplayed the addictive nature of these pain meds. A California lawsuit claims that Endo and Perdue Pharma knew that their abuse-deterrent formulations (ADFs) could be abused, but hid that information. Some states are considering taxes on pharma company opioid sales and examining industry efforts to block states from setting limits on pill dispensing or prescribing. And high prices for overdose antidotes such as naloxone are attracting scrutiny.

The legal action may increase as states seek resources to fund drug abuse programs cut by tight Medicaid funding, as discussed at a recent hearing before the House Energy & Commerce Oversight & Investigations subcommittee on state initiatives to prevent and treat opioid addiction. The Senate Homeland Security and Governmental Affairs Committee is investigating opioid drug diversion, including the failure of drug wholesalers to identify excessive shipments and the obligations of manufacturers to track and report suspicious activity by distributors, doctors, and pharmacies. Congress is considering a range of legislative proposals for curbing opioid use, including expanded physician training on prescribing of pain therapies and limits or caps on opioid prescribing and dispensing. And the HHS Inspector General is examining excessive opioid use by Medicare patients and physicians with questionable prescribing patterns.

New framework

A main issue is whether FDA appropriately evaluates new pain medicines for market and does all it can to prevent excess opioid prescribing and distribution. A new report from The National Academies of Sciences, Engineering and Medicine (NASEM), which FDA requested as part of its February 2016 opioid action plan, outlines a "public health" framework for FDA review of new pain treatments (view the report here: http://bit.ly/2sYmwfR). In weighing the risks and benefits of medicines for treating serious pain, the experts want FDA to consider clearly a drug's impact on families and communities and the risk of abuse and addiction and of diversion to illicit markets.

The panel urges FDA to release summary versions of complete response letters to ensure transparency in decision-making and calls for stronger FDA post-approval oversight, with periodic evaluations of marketed products to ensure continued safe and appropriate use. Following a full "re-review" of all marketed opioids, those medicines found to raise high risks should be withdrawn from the market.

A controversial proposal is to restrict opioid advertising and promotion to "responsible"

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messages that include public health issues, to be outlined in new FDA guidance. Off-label marketing would be prohibited, and direct-to-consumer (DTC) broadcast advertising limited. And while the expert panel supports mandatory education for all health professionals on pain management and opioid use, the role of pharma in supporting provider education is open for discussion.

Many of the NASEM recommendations are similar to initiatives announced by FDA commissioner Scott Gottlieb to update FDA's response to the opioid crisis. Gottlieb and Janet Woodcock, director of the Center for Drug Evaluation and Research (CDER), outlined a quantitative framework for assessing opioid product risks, as seen in the NASEM report recommendation, in an article posted by the *Journal of the American Medical Association* (JAMA) on July 6 (view here: http://bit.ly/2viq6SY).

The ultimate solution to opioid misuse is to replace these dangerous therapies with more effective, non-addictive pain medicines. Experts question whether newer extended-release opioids are really beneficial or actually worsen pain

Gottlieb opened last month's workshop on evaluating opioid ADFs by urging a "fresh look" at how FDA balances patient access to appropriate painkillers with efforts to ensure public safety. He announced an update to the opioid risk evaluation and mitigation strategy (REMS) for extended-release opioids to also cover immediate-release products, which account for more than 90% of pain prescriptions. Gottlieb also expanded provider training under the REMS to a broader range of health professionals and raised the possibility of making such provider education mandatory. A new FDA Opioid Policy Steering Committee headed by deputy commissioner Rachel Sherman will examine that issue, as well as the impact of limits or caps on pills and prescriptions and FDA's consideration of risk of abuse in evaluating new drug applications.

The ultimate solution to opioid misuse is to replace these dangerous therapies with more effective, non-addictive pain medicines. Experts question whether newer extended-release opioids are really beneficial or actually worsen pain. The National Institutes of Health has formed a public-private partnership to speed development of new pain therapies and addiction treatments, including opioids with less euphoric effect and fewer side effects for chronic pain patients. There's growing excitement over experimental drugs and gene therapies that block nerve pathways of pain and hope that precision medicine may lead to tailored pain treatments for individuals. PE

Rethinking ADFs

A main FDA strategy for combating opioid abuse has been to encourage development of abuse-deterrent formulations (ADFs) of extended-release therapies. FDA issued guidance in April 2015 on ADF testing and development, which has led to the approval of 10 products. A draft guidance published in March 2016 advises on developing generic ADFs, seeking to resolve disagreement over appropriate testing of copycat versions of these drugs.

Now the agency is examining more closely whether ADFs actually resist misuse or aggravate overdosing, as discussed at an FDA workshop in July. Public health officials and research experts discussed data sources and methodology for assessing the impact and value of ADFs in the "real world." One issue is whether ADF labels provide a false sense of security that such products are "abuse proof." FDA will weigh the need to remove some ADFs from the market, as it did recently with Endo Pharmaceuticals' Opana ER based on evidence that abusers merely shifted from snorting the reformulated product to injecting it, igniting outbreaks of HIV, hepatitis C, and blood disorders.

Competitive issues also play a role in ADF development and marketing. Disputes over three-year exclusivity for new ADFs complicates FDA approval of additional abuse-resistant products. And manufacturers of brand ADFs have petitioned FDA to require removal of older opioids from the market once three ADFs for the same active component become available.

Brexit and the EMA: Bidding and Betting on an Uncertain Future

Review of top contenders to land agency as decision draws closer


The EMA's current head office in Canary Wharf, London.

The end of July was the deadline for submissions from countries bidding to host the relocated European Medicines Agency (EMA) when the UK withdraws from the European Union (EU), and the competition was fierce in the final weeks of bid preparation. As many as 20 EU member states were likely to put themselves forward before the gate came down on applications and the real work begins of lobbying to win the prize—a decision scheduled to be made just a dozen or so weeks later, in November.

Netherlands

Plenty of the candidates have already set out their stalls in advance, with glossy brochures and picture-laden websites.

Among the most likely candidates, the Netherlands is stressing its ability to deliver on "commitment, continuity, connectivity, and community." When its health minister, Edith Schippers, presented the bid in Brussels recently, she emphasized the country's capacity to deliver a "smooth transition," spicing up the offer with "a tailor-made building in Amsterdam's business district," and a beefed-up national drug evaluation board, with a promise of €10 million to expand its scientific capacity "and to help strengthen other national medicines agencies across Europe." And anticipating the tough deal-making that will go on among heads of government as the decision is made, she warned that the EMA's "critical work cannot be disrupted. We cannot allow patients to pay the price for political horse-trading."

The Dutch offer also includes a "high-quality working environment and workforce, dedicated expat centers and one of the highest concentrations of life sciences and health activities in Europe." It flags up the region's international credentials, advanced Internet coverage, fast rail connections, and the number of direct European connections from Amsterdam's Schiphol airport as "superior to the agency's current UK location." The city's deputy mayor even suggests that "as it is only a short distance from London, employees can, if necessary, choose to commute during the early phases. No other city can offer that level of connectivity."

Sweden

Sweden, one of the first countries to put in a bid after the UK's Brexit referendum, is touting the Stockholm-Uppsala region for "a seamless transition into a world-leading scientific environment, with life science collaborations between healthcare, the university sector, and industry." It is not just keen. It is, according to its promotional material, "determined" to host the EMA, and the country's prime minister has "written to the President of the European Council, Mr. Tusk, expressing Sweden's wholehearted ambition to host the EMA."

There are no limits to the optimism of Sweden's bid. "We are certain that we are the best country to host the EMA. I am sure that we can convince the other European governments of this," according to Minister for Social Security Annika Strandhäll. The package highlights "options for EMA headquarters in Hagastaden, Stockholm, well embedded in the life sciences center near Karolinska Institutet, one of the most renowned medical universities in the world, and the Science for Life Laboratory (SciLifeLab), an elite research center for molecular biosciences." It emphasizes the "leading research environment," with "some of Europe's best researchers" and three university hospitals. Basking in a

REFLECTOR is *Pharmaceutical Executive*'s correspondent in Brussels

little reflected glory, it also suggests that since Stockholm is already the host to the European Center for Prevention and Disease Control, there is a chance for synergies.

It also gives close attention to personal matters, including "a housing provision service" and rapid growth of construction of new housing in the region, or "a one-stop shop, including a specially developed mobile phone application, to guide EMA employees and their families through the steps to take as they settle into life in Sweden." And it boasts of being "within easy reach of two international airports."

Belgium

Belgium has also thrown its hat into the ring, offering Brussels as the location. It is "the ideal place" for the EMA. The city offers "a smooth transition from London"—because Brussels is "centrally located in the heart of Europe and close to the current EMA headquarters," so "the proximity to London and the excellent connectivity will ensure business continuity during the transition phase." Brussels claims to provide "a stable and welcoming environment," "outstanding quality of life" with "a reliable healthcare system, an affordable and varied real estate market, a large choice of international schools and ample employment opportunities for family members."

The Belgian bid doesn't hesitate to trump Stockholm's pretensions to consolidating existing assets. Brussels, says the Belgian government, is "a perfect breeding ground for the European Medicines Agency to develop," because of the "large availability of conference venues and hotel rooms at affordable prices," and "the cluster effect due to the proximity of EU institutions," which "facilitates dialogue, reduces travel expenses, and promotes synergies."

It also invokes Belgium's "strong reputation for R&D and innovation as well as the presence of a strong pharmaceutical sector"—"a pharmaceutical powerhouse and knowledge center." And to reinforce its bid, Brussels also offers "99 reasons why Belgium is uniquely phenomenal"—including, alongside all the predictable stuff about Brel, Magritte, and chips with mayonnaise, the distinctly non-European boasts that "every year, we reenact the Battle of Waterloo, with over 1,000 extras," and "the Battle of the Bulge kept the worlds in suspense."

> As many as 20 EU member states were likely to put themselves forward before the gate came down on applications and the real work begins of lobbying to win the prize

Other scenarios

But for all the ferocious positioning to pick up the spoils of Brexit (and these three bids were likely just the tip of the iceberg from the last few weeks), another curious possibility is starting to emerge. In the opinion of this author, the massive incoherence and incompetence at the heart of the British government is becoming increasingly clear—and the Brexit process is revealing that so much of the pro-Brexit rhetoric was no more than that—just rhetoric. Less diplomatically, the crude mendacity of the pro-Brexit campaign is now clearly on show. Two *hitherto* unimagined scenarios are conceivable at this stage.

One is that the UK, faced with the tough reality of negotiating withdrawal, recognizes that it has to make compromises to avoid ruining the country. *Force majeure* will oblige even the most ardent Brexiteers to accept a soft Brexit—which could include any number of transitional arrangements, including the retention, at least for a time, and possibly an extended time, of the EMA in London, to minimize disruption.

Another scenario is that the kamikaze politics of the hard Brexiteers leads to a complete rupture of negotiations, and the eventuality of that "no deal better than a bad deal" that the misguided Conservative party currently embraces. But by the time that happens, the torpid British public may well have started to wake up to the enormity of the losses they would face from a non-deal Brexit, and to push their elected representatives either back to the negotiating table, or even into abandoning Brexit entirely.

Amsterdam, Brussels, Stockholm and the rest may have to wait rather longer before they get their hands on the EMA. PE


Photo/Max Taylor

Health Policy Problem Solver

Turning Ideological Challenges into Practical Solutions

The International Federation of Pharmaceutical Manufacturers and Associations' new Assistant Director General, Dr. Fumie Griego, tells *Pharm Exec* about how she wants to use IFPMA's international reach to find real solutions to the most pressing global healthcare challenges

By Julian Upton

The Geneva, Switzerland-based International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) represents research-based pharmaceutical companies and associations across the globe. It has consultative status with the United Nations and specialized agencies, including the World Health Organization (WHO), UNAIDS, the World Intellectual Property Organization (WIPO), and the United Nations Conference on Trade and Development, and has formal relationships with the World Bank and the World Trade Organization (WTO). IFPMA facilitates collaboration, dialogue, and understanding within the industry and with other global players in the health community, with the objective of bringing "the industry and broader health community together to foster innovation, promote resilient regulatory systems and high standards of quality, uphold ethical practices, and advocate sustainable health policies to meet global needs."

IFPMA was established almost 50 years ago, but recent appointments to its leadership team indicate new efforts to expand its visibility both in Geneva and beyond. In February, Thomas B. Cueni—previously secretary general of Switzerland's Interpharma and a former journalist and diplomat—was appointed IFPMA's new director general; he told *Intellectual Property Watch* in May that he would like to see IFPMA's ideas gain more exposure. Also in May, Cueni appointed Dr. Fumie Griego as assistant director general for strategic planning, policy, and research. Citing Griego's industry and policy-level experience—including tenures as head of global oncology policy and strategy, global government affairs and policy, at Merck KGaA, Darmstadt, Germany; as vice president for international health policy at Pharmaceutical Research and Manufacturers of America (PhRMA); and as a senior economist in the White House's Office of Management and Budget—Cueni welcomed

Griego as "a strong asset to help IFPMA bring thought leadership in addressing global health challenges."

Soon after Griego's appointment, she spoke to *Pharm Exec* about how she sees her role with IFPMA as helping to shift the global healthcare debate from ideological concerns to a more pragmatic and solutions-oriented focus.

PE: *How have your roles as an economist and working for a big pharma company prepared you for your position at IFPMA?*

GRIEGO: I've always been interested in the intersection of science, policy, and economics. I started my career in environmental health regulation, but over time I became a little frustrated with the environmental field. We're willing to spend so much of society's resources regulating what are vanishingly small risks to health, but at the same time there are public health investments that are not being addressed in an adequate way. That dilemma drew me into the pharmaceutical space. There are policy drivers and a lot of evidence-based decision-making in this space that you don't see in other sectors. Given my background and interests, I wanted to see what I could contribute to the policy discussion.

What I appreciate about my experience working within a company (Merck KGaA) is that it drew me closer into the product-level decisions that needed to be made, how policy influences those kinds of decisions, and meeting patients' needs from the business side of things. Now that I have that company perspective, what I hope to bring to IFPMA is the ability to translate some of the policy dimensions into some of the commercial implications for companies, and vice versa.

"What I hope to bring to IFPMA is the ability to translate some of the policy dimensions into some of the commercial implications for companies, and vice versa."

PE: *What are your chief areas of concern from an IFPMA perspective?*

GRIEGO: Part of the reason I was brought into IFPMA is because there is much more interest now in talking about drug pricing at a global level. We have seen across various countries a real concern about the potential cost of new therapies and how that might impact national budgets. But it's becoming more of a global conversation now, and you see institutions like WHO and OECD (Organization for Economic Co-operation and Development) venturing into this space, which they haven't done before. You also see developed markets raising issues related to their concerns about the high cost of medicines, which you didn't see before. For me, the focus is about trying to unpack what the actual problems are, rather than just the perception of what the problems are.

PE: *You've suggested that there is too much attention on the issue of drug pricing in the global industry. Can you elaborate?*

GRIEGO: There is a lot of focus on drug prices, but if you look at the proportion of healthcare spending devoted to pharmaceuticals, it's fairly small, particularly in OECD and developed countries. But there's the perception that the drug costs are driving the healthcare costs. There are a lot of misperceptions that need to be dispelled, particularly at the global level; it's becoming a kind of negative feedback loop, where the conversation at the global level is impacting national level discussions, and vice versa.

There is a lot of evidence and information that needs to be communicated, such as how the business actually works. At the national level, there are regular interactions between payers and companies to address some of these pricing and cost issues, but at the global level there isn't that same experience. We're having these conversations at these multilateral institutions, but there's a lot of education that needs to happen about the differences across countries, across companies, and across different portfolios that get muddled during these conversations.

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» The International Federation of Pharmaceutical Manufacturers and Associations is based in Geneva, considered the "public health capital of the world," where many organizations are engaged in the interface between public health, development, and innovation.

» In her time as senior economist in the White House's Office of Management and Budget, Dr. Fumie Griego provided US senior officials in both the Bush and Obama administrations with advice on a range of health policy issues.

» Griego holds a PhD in Health Policy from Harvard University and Bachelor and Master of Science degrees in Earth Systems from Stanford University.

"There should be a focus more on broader health-system-improvement topics rather than a narrow focus on pricing."

There are certainly concerns about cost of treatment and affordability that need to be addressed. But if you look at it more holistically and systematically, there are other things driving healthcare cost: aging populations and a growing incidence of chronic diseases, for example. In these areas, appropriate use of medicines is actually the solution to the projected healthcare-cost problem, not the problem itself. There needs to be that holistic view across the developed markets; there should be a focus more on broader health-system-improvement topics rather than a narrow focus on pricing.

If you look at the developing countries, there are so many other barriers to access and affordability. In many countries, even very cheap generics are often not accessible because the infrastructure is not there. There is no mechanism for pooling risk and avoiding the out-of-pocket costs of healthcare spending. Those things need to be addressed before we can even talk about pricing of innovative drugs.

PE: *How in this respect does IPFMA balance its focus on prioritizing the challenges of both the developed and developing pharma markets?*

GRIEGO: Pricing and reimbursement are very much national-level decisions and discussions. In terms of solutions, in the developed world we defer to sister associations such as PhRMA, EFPIA (European Federation of Pharmaceutical Industries and Associations), and JPMA (Juvenile Products Manufacturers Association) so that they have the lead in developing the right policies for the right context. It's much more of a collaborative, convening role than trying to focus our attention on solutions for those types of issues.

That said, for developing markets, there is a much more active role that we need to play in influencing some of the policies being developed through and influence by the multilateral institutions. That's where our core mission is in terms of facilitating development. However, there are issues—for example, public health emergencies—that are more truly global in scope and don't fit into a developing-versus-developed country template.

Take, for example, the industry's partnerships with the Union of International Cancer Control (UICC) through the Access Accelerated Initiative. The focus is on creating the infrastructure that's necessary to deliver high-quality cancer care in low- and middle-income countries. What are the investments that need to be made? What needs to be in place in terms of specialists, diagnostics, surgeries, and radiation treatment? Then we can have a conversation about how specific treatments fit into the overall cancer control plan.

There's a lot of good work being done that is trying to address the root cause of the access barriers. A key component of what IFPMA is trying to do—along with our colleagues in PhRMA, EFPIA, JPMA, and all the other associations—is to reframe the debate and focus on the key issues that will address the problems at hand.

PE: *What do you hope to accomplish in your role?*

GRIEGO: During my short time in Geneva I have noticed, shall we say, a lot of trench warfare on ideological topics. Not that there isn't ideology and politics involved in national-level discussions, but the nature of it is a bit different in Geneva. What I want to do is to move away from some of those ideological, no-win conversations to something much more pragmatic and solutions-oriented.

For areas like global health, with respect to security and preparedness, there is a lot of common ground on the need for global-level solutions around issues like antimicrobial resistance. That is a space where there is a lot of clear understanding of the need for more cross-industry collaboration, not just in the research industry but also across the diagnostics and generics sectors, and a real partnership between the public and private sectors. An organization like IFPMA is very well placed to facilitate this, not only bringing the global perspective but also drawing on connections to the national and regional associations, where we can translate some of the global health conversations in to national actions.

What I'm hoping to accomplish is to help to build that bridge, identifying common ground and offering a solutions-oriented action plan where the industry can contribute to the overall global health agenda. PE

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The Hear and Now for Pharma and Social Media

For the life sciences industry, engaging and communicating across the vast social media sphere in 2017 means less talking—and more listening

By Peter Houston

Good news—the pharmaceutical industry is finally catching on to the social side of social media. Just a decade or so after Facebook, YouTube, and Twitter gave everyone the opportunity to share their own stories, pharma businesses are actually starting to listen.

Of course, there is still a broad spectrum of social media capabilities within the industry, from companies that are all in on the social scene to those who still haven't managed to set up a basic account. Even within businesses, skills and usage can vary greatly between countries, therapeutic areas, or corporate functions such as HR and commercial.

The vast majority of pharma companies also still use social media as just another broadcast channel—a cheap alternative to direct mail. But the green shoots of sociability are starting to show through.

Less is more

One recent shining example is AstraZeneca's Twitter strategy at June's American Society of Clinical Oncology (ASCO) 2017 meeting in Chicago. Ahead of the meeting, the company released a statement saying that it would be tweeting less and engaging more with retweets and comments.

The business was reacting to concerns expressed at 2016's ASCO meeting, when some attendees worried that vital social media conversations

The vast majority of companies still use social media as just another broadcast channel—a cheap alternative to direct mail. But the green shoots of sociability are starting to show through

around the event were getting lost among louder industry voices. The worry was that paid promotions were threatening to crowd out valuable scientific conversations.

AstraZeneca's response was to publish a set of commitments to be "Being a Better Social Media Citizen." In a five-point pledge, the company promised to preserve the social media space around the conference and allow the oncology community to "learn, discuss, and share the science that excites them at ASCO 2017."

Key to this was "talking less and listening more," meaning a significant reduction in tweets sent. The flip side of that was "elevating important voices," sharing tweets sent by researchers, patient organizations, doctors, and patients.

AstraZeneca also drew back from frivolous content like quizzes or fun facts to "be sensitive" and acknowledge that oncology is a serious business. And the drugmaker stopped paid promotion of tweets for the duration of the meeting to "respect the organic conversation" taking place on Twitter among ASCO attendees and the broader medical community.

Finally, the company's social media team committed to focus on explaining its own science in formats that were easy to digest and understand and "make complex science accessible."

Contributing to the conversation

AstraZeneca's "less is more" strategy appears to have contributed to a better online experience at ASCO 2017.

More than half of the 200-plus respondents to a Twitter poll by ASCO member Dr. Mike Thompson, with the University of Wisconsin School of Medicine, thought the 2017 meeting had a better "signal-to-noise ratio" than the previous year's meeting.

Dr. Paul Tunnah, CEO of healthcare engagement agency Pharmaphorum Connect, was encouraged that AstraZeneca had carried through on its promises. "This is a good example of progressive social media," he says. "They received positive feedback from the medical audience and stood out as being engaging rather than broadcasting."

Annie Sullivan, director of corporate social media, AstraZeneca, says that while it approaches every congress or campaign with a fresh lens, being a "good citizen" is now central to the company's social media strategy.

She explains that the business wants to deliver content that has a value through its social media channels, making its science accessible, highlighting important professional voices and sharing patient perspectives. "We are focused on remaining relevant to the ever-changing social media landscape," says Sullivan.

Crafting campaigns

The issue of relevancy features in Tunnah's 2017 formula for the ideal social media campaign: "Integrated, relevant, and long-term."

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» Some pharma companies are realizing the value of reducing the number of tweets they send out, and, instead, elevating other voices by sharing tweets sent by researchers, patient groups, physicians, and patients.

» It is important for pharma social media campaigns to be integrated, linking to other digital and non-digital content that takes customers on a clear journey to learn more about the company or a specific therapeutic franchise.

» According to a report by Unimetric, since 2014, across social networks, there has been a 36% drop in the amount of content published by pharma companies. Bucking this trend, however, Unimetric says, has been pharma career portals, which published 37% more content in 2016 compared to 2013. Videos are also on the rise, now accounting for 16% of all content published by drugmakers on Facebook.

Being relevant, according to Tunnah, means that campaigns need to provide information that is useful to the target audience. He says corporate objectives and messaging can be encapsulated in valuable information, but that marketers must avoid "corporate-speak."

Being integrated requires social media linking to other digital and non-digital content that takes the customer on a clear journey to learn more about the company or a specific therapeutic franchise. And to be long-term, Tunnah says that pharma needs to be ever-present on social media, not just when it wants something.

Long-term commitment and social media marketing don't always sit well together. Corporate concerns over ROI that is not always easy to prove and the frequent pivots of the social platforms conspire to shorten campaign time frames. But Tunnah advises the long view.

"Short-term campaigns will not deliver results without significant paid promotion, which may not deliver relevant audience," he explains. "Trust takes time and the authenticity that being there more persistently provides is very powerful in building better customer relationships."

Making connections

According to Jordan Deatherage, senior director, social media, at Intouch Solutions, the ideal social media campaign also needs to make a connection, regardless of the platforms or the technology being used.

She advocates a consistent and connected customer experience, not a mismatch of information or user experience. "Each messaging point of contact should be intentional and function in an expected way," says Deatherage.

She believes it is possible for companies to be social without building a branded presence on specific platforms, so long as they understand that social media is an important part of people's day-to-day communication.

"Information on the Internet is social if it's shareable," says Deatherage. "By providing valuable content and enabling visitors to cleanly share it, companies can implement a compliant, inherently social experience."

In this way, companies can take on social media without

Listening for Opportunities to Bridge Gaps


Annie Sullivan

According to Annie Sullivan, AstraZeneca's director of corporate social media, understanding how to deliver fresh, relevant content that will engage different communities is critical for the future effectiveness and credibility of pharmaceutical companies' social media channels.

"Underpinning our whole approach for ASCO (American Society of Clinical Oncology) 2017 was the belief that the pharmaceutical industry should embrace listening and become more comfortable engaging, rather than projecting a one-way message," says Sullivan.

She explains that AstraZeneca is taking the common thread from its ASCO 2017 strategy into other disease areas.

"That thread is listening," says Sullivan. "Paying attention to the community—noticing what they respond to, what's missing, and seeing how we can provide value to address those gaps."

This means avoiding a "one-size-fits-all" approach to communicating with different communities and being in-tune with specific information needs. An example of the tuned-in approach is an initiative to improve how people follow and participate in online conversations around asthma.

"Through a social listening project, we learned that the respiratory community was using inconsistent and disjointed language online to describe symptoms and experiences," explains Sullivan.

Where some disease communities online, such as those around breast cancer, for example, have established hashtags to help people organize and track topics of conversation, the online respiratory community has room to grow.

AstraZeneca is now collaborating with patient advocates and professionals active on Twitter to develop a disease-specific hashtag vocabulary for the respiratory community to help bridge gaps between asthma patients, caregivers, healthcare professionals, and researchers.

"We believe that as a partner in healthcare we can add value by listening to these conversations in social media and by looking for opportunities to connect ideas or bridge gaps," says Sullivan.

setting up an owned brand presence like a Facebook page. But that doesn't mean there is no value in developing an owned social presence.

Deatherage points to the work Intouch has done with Teva to develop its Lift MS Facebook page and blog. The award-winning Facebook page has almost 320,000 followers and hosts patient resources, discussions, and supporting videos and photos. "The Lift MS Facebook page and blog have contributed in a relevant way to this community in a very crowded category," says Deatherage.

Teva previously had success with the "You Don't Know Jack About MS" YouTube channel fronted by multiple sclerosis sufferer Jack Osborne. The channel gained 11,000 subscribers and the most popular of the 16 episodes clocked up almost half-a-million views.

"The two campaigns aren't linked, but they are both a testament to a client that understands the impact of social media, especially in a very crowded disease state," says Deatherage.

Making progress

In general, pharma is making inroads with social media. But there's more that could be done.

Tunnah believes there is a big opportunity for pharma companies to embrace using social media for proper "customer service"—for doctors and patients—in the same way consumer companies are doing. "No one has made this bold move yet, but it is possible, provided compliance processes are mapped out the right way and non-compliant/product conversations are directed off social media," says Tunnah.

> "By providing valuable content and enabling visitors to cleanly share it, companies can implement a compliant, inherently social experience."

Deatherage is excited by the prospect of clients embracing a more robust digital presence and thinks that most of the brands participating seriously on social media are doing a decent job, given drug industry constraints, as compared to other industries. "You're never going to see campaigns like Wendy's has done in the pharma space and we all know that," says Deatherage.

Where she does see scope for improvement is how pharma companies are handling their corporate social media presence. "Corporate accounts often set the tone for how brands can behave online," says Deatherage. "Seeing companies only push out boring press releases or canned stock footage videos is disheartening."

AstraZeneca, continuing discussions with influencers around best practices, also sees broader opportunities to engage with stakeholder groups through social media.

Sullivan highlights patients sharing their experiences with diseases, the impact on their lives, and documenting their treatment journey; physicians using social media to stay current on the latest research and to connect with patients; and researchers taking to social media to find collaborators and "talk shop" with fellow scientists.

"And all our key audiences have a stake in the future of scientific advancement," says Sullivan.

Preferred platforms

Pharma has traditionally focused on Twitter and Facebook, but Deatherage believes Facebook is the best social platform for the industry, both from reach and compliance perspectives. "It gives pharma brands the most options when it comes to settings and ISI (important safety information)," she explains.

Tunnah doesn't disagree, but says there may also be a major opportunity on LinkedIn, due to the level of engagement it offers and differentiation of the data the platform can deliver due to its unique role as a "professional" social network.

Returning to the listening theme that has come to underpin so much modern social media planning, Deatherage says Intouch is consistently providing clients with social listening research and insights around patient and healthcare professional comments. "Updates based on that research may take a while to implement, but it is a requested feedback loop right now."

And will need to be for a long time to come, if pharma wants to be truly social on social media. PE

Social media's importance in push for value-based healthcare

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Status Report: Top Platforms

A look at the most popular social media platforms and where each stands today from business and engagement standpoints.

Facebook dominates

Facebook is still, by far, the biggest social media network on the planet. In June, the firm announced that, 13 years after launch and five years after reaching one billion users, it had two billion active monthly users. With almost a quarter of the world's population using the platform, it's no surprise that Facebook also claims a huge percentage of the world's digital marketing budgets—alongside Google, it claims an estimated 90% of all new digital ad spend.

Increasingly sophisticated tools to target individual users, a restated mission to "give people the power to build community and bring the world closer together," and an accompanying focus on private groups will feed into pharma marketing opportunities on the network in the future.

Twitter searching for its place

Twitter has had a tough time over the last couple of years. Revenue falls and slow user growth—flat at about 330 million users—has seen investors cool on the platform. But, bizarrely, the US election campaign and presidency of Donald Trump have revived interest. Twitter's "Trump Bump" has increased usage and highlighted the public information aspect of content on the network.

Although there are still huge problems with extremists and trolls, some see Twitter developing a role in the distribution of information important to the public good and have even suggested developing a public ownership model for the platform. Whether that ever happens, careful use of hashtags and lists can help pharma target information on Twitter to leverage the platform's immediacy.

LinkedIn reaches professionals

LinkedIn is different from most other social networks in its primary focus as a professional network. There are plenty of LinkedIn users that would complain that the network is becoming more like Facebook every day, but feed-driven changes have helped LinkedIn achieve significant improvements in user engagement.

At its core, however, LinkedIn remains an online space defined for its users by the work they do. Now owned by Microsoft, the future for the network will include more video, more professional training options, and more collaboration tools. As the platform network develops, it could become the ideal place for pharma to engage healthcare professionals with research updates, product introductions, and continuing professional development efforts.

YouTube leads video revolution

Video is as hot as it gets in digital marketing, with all the social platforms boosting video content in their feeds and some even predicting that, one day, all content will be video content. As the oldest video platform out there, YouTube boasts 1.5 billion monthly users. Although native video is being developed on other platforms, YouTube has become the *de facto* host for much video content.

That dominance hasn't come without its problems, though. This year, several major organizations, from AT&T to the British Government, pulled their advertising from YouTube over concerns that ads were running ahead of extremist content. Owner Google has committed to fixing the algorithms that place the advertising, but pharma marketers are still nervous about brand safety.

Can Snapchat deliver millennials?

Snapchat is more a messaging app than a social network, used most often to share photos or videos between friends, primarily teenagers. The addition of the "Stories" feature, which allows users to store and broadcast collections of content, moved the platform beyond its "disappearing messages" starting point, but it's still very early days for marketing efforts on Snapchat.

The platform's $28 billion IPO was focused on user growth rather than profitability, but slowing user growth has put pressure on the share price. Future revenue may lie in the targeting of TV advertising budgets, as video has come to dominate the platform and the business is partnering with content producers from NBC to Vice looking to place three-to-five-minute shows in the Stories stream.

Influencers on Instagram

Instagram has been aggressively releasing new features over the last year or so to improve advertising opportunities for the 48% of consumer brands that are already present on the platform. The mostly mobile photo-sharing network is securing its place in the digital marketing landscape by making it easier for marketers to build content packages and use clickable links and shoppable tags.

Instagram dominates influencer marketing online, with the world's beautiful people promoting everything from eyeliner to the failed Fyre music festival. But influencers can bring their own problems. Self-Promoter-in-Chief Kim Kardashian has avoided getting in trouble with the FDA again by listing potential side effects from anti-nausea drug Diclegis to her Instagram posts. Unfortunately, her fans are now accusing her of shilling for pharma.

— Peter Houston

AI-based Social Listening as Aid to Pharmacovigilance

Unless pharma companies can find ways to filter the high volumes of online noise, their ability to stay on top of postmarketing safety signals as they emerge across the web will be near impossible. A look at how artificial intelligence can transform this challenging scenario through the application of reliable life sciences web and social listening as integral parts of safety monitoring.

By Christopher Rudolf and Adam Sherlock

Good pharmacovigilance practice demands that life sciences manufacturers go further and become more proactive in keeping patients safe. But that's easier said than done, as potential postmarketing feedback channels multiply across the Internet. Monitoring all of them is a vast undertaking for even the best-resourced safety teams.

Beyond manufacturers' websites, forums, incoming e-mail, and the scientific literature, important safety signals could manifest in Twitter and public Facebook posts, in independent patient forums, through special interest groups, in blog articles and comments published on platforms like WordPress, and via more-visual channels such as YouTube and Pinterest. Signals could also appear in any language, anywhere in the world.

Monitoring scientific studies and the channels under brands' control is mandatory, but extending the same vigilance across the whole of the public web is recommended to build a more complete picture—and ensure that no adverse events are being missed. Estimates suggest that 10% to 17% of adverse events go undetected today because companies are not "listening" to social media and other web channels outside those currently mandated by regulators.

But how can companies reliably and efficiently achieve complete digital vigilance? Until now, the life sciences industry hasn't found a definitive way to overcome that challenge—despite high levels of concern about it. (It was a hot topic at last March's DIA EuroMeeting in Glasgow). To date, the main options have been to buy very expensive proprietary turnkey analytics solutions such as IBM Watson Analytics or to patch something together from a series of tools designed for other purposes, such as for mainstream social listening. But what's suitable for trawling Twitter is going to differ greatly from tools capable of scanning scientific literature or capturing the sentiment and context of online discussion forums, opinionated blog posts, or photo and video posts, whose potential signals are typically visually based rather than text based.

Unless their monitoring efforts are holistic and deliver something both meaningful and reliable, companies will be wasting their time and their budgets. With so many channels to keep track of, life sciences firms need a more intelligent and focused approach.

Speed and selection require intelligence and learning

This is where artificial intelligence (AI) comes in: by offering to take the strain off human teams so they can focus their time and budgets more productively. As optimized solutions for life sciences become available, AI is beginning to transform what pharmacovigilance and safety teams can do.

Natural-language-processing algorithms and artificial intelligence have made it now possible to sift and clean data, thereby reducing irrelevant or false-positive content by looking for the right signals that match teams' criteria. The ability to interpret natural human language and semantics means the technology isn't merely following blind search rules; it can identify mentions in context, and it can read into subtext to determine how relevant the mentions

Estimates suggest that 10% to 17% of adverse events go undetected because companies are not "listening" to social media and other Web channels outside those mandated by regulators

are. The parameters for that ability might vary between those needed to analyze a short mention on Twitter and those required to interrogate longer narratives on WordPress, but the technology is sophisticated enough to recognize those differences and adapt to them.

As teams interact with and classify data, machine-learning algorithms enable the software to observe and adapt to teams' preferences and then hone the next iterations of findings accordingly. An added benefit is that different teams, with their own individual tasks and interests, can train a system in their own priorities and preferences so that the system supports their own particular purpose based on the same master data.

Filtered, meaningful data gets served to users via the equivalent of an e-mail in-box, with options to both share findings with the team and feed important adverse-event findings into regulatory processes for urgent action. Incredibly, all of this can happen in near real time because the latest technology is capable of returning comprehensive but accurately filtered findings from entire global web and social media searches within just 90 seconds, and red-flag events can be escalated to supervisors just as quickly. That kind of responsiveness to adverse events is unprecedented.

Achieving what humans can't

Although many industries are concerned about AI undermining people's jobs, in a skilled and resource-pressed environment like the one found in life sciences quality/safety/regulatory affairs, time is of the essence and AI's role is to free up biopharma teams to focus on what's important. Given that the Internet never sleeps, another advantage of AI-based web and social monitoring is that it keeps working continuously—outside of office hours—so there's much

less danger of falling behind. What used to be an insurmountable task for humans has now become viable.

AI-based web and social listening can also significantly improve levels of accuracy and reliability of human-directed monitoring, so as to make sure nothing critical goes under the radar. Systems that have been built specifically for life sciences and that are supplied with preloaded algorithms have levels of accuracy that start high—above 80%—even before the software has been trained in what's of interest to a particular company and business function. That's a substantial advantage in winning the big-data war.

Without AI, firms would have to hire more and more people to trawl Google, look through individual websites and forums, capture reports, highlight what's of interest, enter findings into a database manually, and pass anything important on to decision-makers. It could take days to find something of value. And in the meantime, more could be missed.

To maximize the impact of AI-based web and social monitoring, life sciences companies must track everything holistically rather than in silos. There also has to be efficient work flow that feeds straight into established systems and processes—that is, existing pharmacovigilance systems and recognized regulatory procedures.

Another critical capability that an AI-based approach brings to the table is the ability to adhere to strict rules designed to protect patient privacy—rules that can differ from one international market to another. The technology can monitor for when relevant social media or web forum posts get subsequently deleted by the poster, for instance, and it can flag that in the pharmacovigilance database so that compliant processes around patients' data privacy can be applied. Staying on the right side of regulators is essential in managing risk and maintaining public confidence.

Once companies can monitor and cross-analyze all of those health signals, they can start to predict adverse events before events happen in an individual

Other AI applications

Once companies have seen the potential of AI-based web and social monitoring for the area of safety management, they start to realize its scope and ways it can be used in additional applications. With consent, firms have an opportunity to become more proactive in monitoring patient user groups about diseases those firms are interested in—for example, discussions about hay fever—to get a clearer picture of where they stand in the market and where needs are not being met.

Feedback, too, could help in the design of more-rounded clinical trials, which would supplement clinical data points, biomarkers, and reported outcomes with feedback from patients about how they are feeling and measurements from connected devices that track key health statistics. Once companies can monitor and cross-analyze all of those signals, they can start to predict adverse events before events happen in an individual and can then intervene preemptively.

Even if some of this feels a bit futuristic, intelligent web and social monitoring can add plenty of other value right now—for example, by helping companies keep track of regulatory changes and revisions to timelines, which are things that are hard to keep track of globally. Commercially, meanwhile, the ability to monitor how a brand or product is perceived in the market and how its safety profile measures up to the competition offers invaluable insights that could be fed back to product development and marketing teams.

Certainly a wealth of executable intelligence is out there—if companies can find efficient ways to extract and harness it. The good news is that all of the challenges companies are trying to meet can be overcome today. AI-based data monitoring and analytics for life sciences are becoming increasingly accessible and affordable, too, thanks to the emergence of open-source solutions that can be run in the cloud and operated as a managed service on companies' behalf, if needed.

Recent news reports have illustrated how AI and machine learning might help speed up patient diagnoses in the future because of the ability to reference and learn from patterns in global data at great speed. That ability has powerful potential in helping clinicians recognize rare conditions so that the conditions can be treated much earlier. And AI's potential to transform life sciences insights and proactivity is exactly the same. PE

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News Spotlight: Pharma

With media coverage of pharma the highest in a decade, *Pharm Exec*'s latest annual press audit reveals a tonal undercurrent in sync with an industry unable to escape the glare of scrutiny while navigating its own operational challenges

By George Sillup, Stephen Porth, and Cynthia Slater

If it feels like the media's scrutiny of the pharmaceutical industry has intensified recently, there is a reason—it has. The results of *Pharm Exec*'s 13th Annual Press Audit of issues in the drug industry indicate that media coverage of pharma jumped in 2016 and reached a 10-year high. Not since 2006 have the top five-selling newspapers published more articles on pharma. Our audit identified 214 articles in 2016 compared to 159 the previous year, an increase of 34.6%. The change reflects increased coverage across all but one of the major newspapers. High drug prices, a perennial hot-button issue, tops the list of issues most heavily covered, followed by the emergence of two new and related issues: misuse and abuse of prescription drugs and opioid addiction. Not surprisingly, given these areas of focus, the

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» *Pharm Exec*'s 13th Annual Press Audit analyzed front-page and editorial articles covering the prevailing pharma industry issues from the top five US newspapers (as defined by circulation).

» Drug pricing and drug safety have consistently been among the top hot-button issues attracting the most coverage. In 2016, they were followed by prescription drug abuse and opioid addiction.

» M&As and tax inversion/evasion were also identified as high-coverage issues in pharma, with specific focus on the latter topic a newly emerging development in 2016.

news was not good. Both headlines and articles were more negative toward the industry than in the past.

The annual audit, sponsored by the Arrupe Center for Business Ethics at Saint Joseph's University in Philadelphia, Pennsylvania, tracks and analyzes the pharma industry issues covered by the media. This year's audit identifies the hot-button issues that attracted media attention in 2016, compares the issues and how they are covered to previous years, and reports on the pharma companies and brands most often cited in the news. We also updated our analysis of how healthcare reform has been reported by the press.

Some of the top findings for 2016 include:

- Coverage of the industry has been trending up and reached a 10-year high.
- High drug prices in the US rose to the top of the hot-button issues list. Misuse and abuse of prescription drugs, opioid addiction, mergers and acquisitions, and tax inversion and tax evasion also received heavy coverage in 2016.
- The focus on healthcare reform was largely around the Affordable Care and Act (ACA) and high drug prices as part of US healthcare delivery. Coverage was at 36 articles, with *The New York Times* and *Los Angeles Times* accounting for two-thirds of the articles.
- Media coverage of the industry has always been more critical than positive or neutral but the tone of the coverage was even more negative than usual in 2016. In 2016, 50.5% of articles were negative toward the industry compared to the five-year average of 45.8%.
- Healthcare reform coverage was demonstrably neutral, with 86.1% of the headlines and 69.4% of the articles neutral.

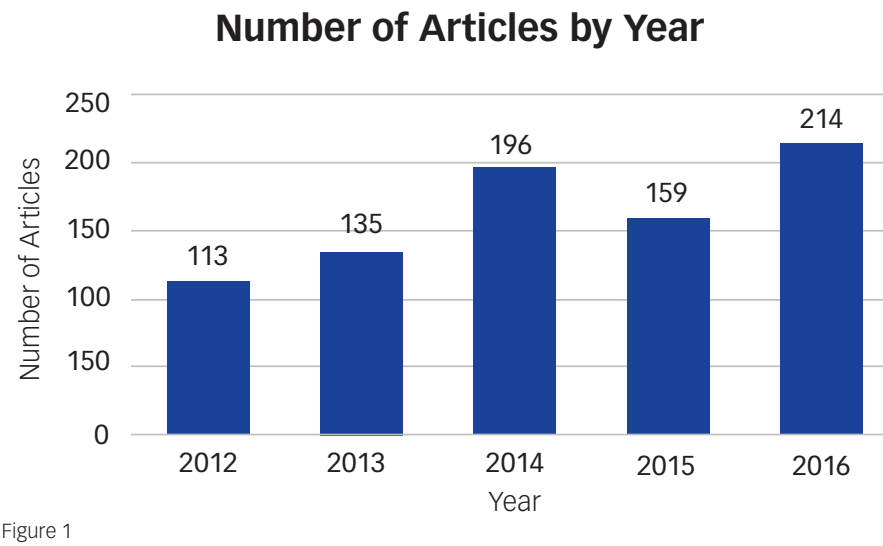

Figure 1

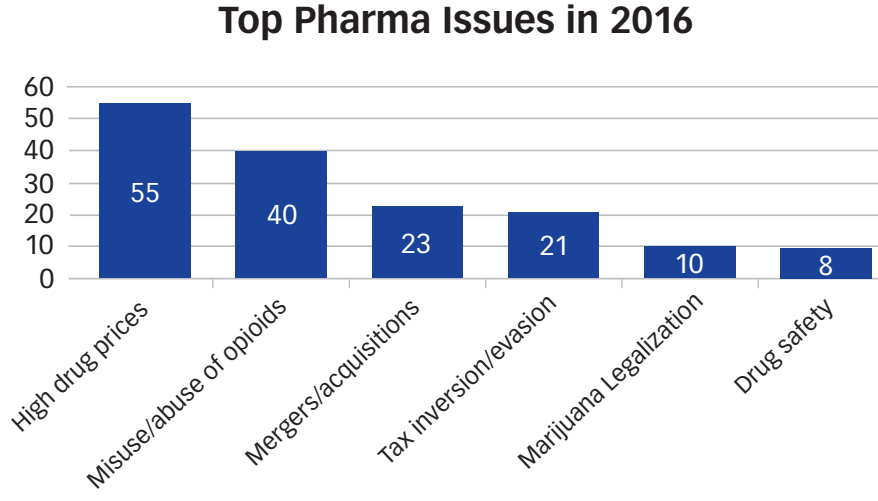

Figure 2

Processing the news

Once again, we analyzed the top five newspapers in the US as defined by circulation for a 12-month period, and identified all front-page and editorial articles pertaining to "hot-button" pharma issues. The purpose of the audit was to shed light on the following questions:

- What ethical and legal controversies face the pharma industry—and what kinds of coverage do they attract?
- Do the articles and headlines support or oppose the positions taken by the industry, as defined by the Pharmaceutical Research and Manufacturers of America (PhRMA)?
- How often do reporters include the industry's perspective in

Table 1: **Number of Articles by Newspaper and Year**

Newspaper	2016 Front Page	2016 Editorial	2016 Total	2015 Total	2014 Total	2013 Total	2012 Total	% Change from 2015–2016
USA Today	9	3	12	2	17	9	17	500.0%
Wall Street Journal	34	14	48	38	32	8	11	26.3%
New York Times	27	32	59	60	75	61	42	–1.7%
Los Angeles Times	22	18	40	23	35	24	23	73.9%
Washington Post	24	31	55	36	37	34	18	52.3%
Total	**116**	**98**	**214**	**159**	**196**	**136**	**113**	**34.6%**

Table 2: **Coverage of Top Two Issues by Other Media**

	High Drug Costs	Drug Safety
NBC Nightly News	19	6
All Things Considered (NPR)	5	12
Google	8	1
Total	**32**	**19**

the stories that cover the issues of the day?

» What pharma companies and brand names are identified and discussed in the articles?

» What are the implications of these findings for the industry?

To be included in the study and in our EthicsTrak™ database,[1] an article had to be published between October 1, 2015, and September 30, 2016, in one of the top five US newspapers (as measured by circulation): *USA Today*, *Wall Street Journal*, *New York Times*, *Los Angeles Times*, and *Washington Post*. It also had to (a) focus on an ethical or legal issue facing the pharma industry and (b) appear either as a front-page story or on the editorial page—an indication of major news and public sentiment. While we focused on daily newspapers because they include a broad range of issues with in-depth coverage, we also reviewed other media to evaluate the scope of their coverage. Specifically, we looked at three sources—the *NBC Nightly News*, NPR's *All Things Considered*, and Google Trends—and, as we discuss ahead, learned that their coverage was comparable to the newspapers.

For each article, we examined four elements:

Issues. We identified and categorized the hot-button issues that were discussed in each article. Many articles covered two or more issues that were included in relevant sections.

Headlines. We analyzed the headlines and categorized them as positive, negative, or neutral toward the industry. For example, "A Drug Company's Price Tactics Pinch Insurers and Consumers" (*New York Times*, October 5, 2015) and "Turn Down the Volume on Drug Ads" (*New York Times*, November 27, 2015) were classified as negative headlines, while "Could One Little Pill End a City's AIDS Epidemic?" (*Washington Post*, January 28, 2016) and "Optimism Increases for Cancer Treatments" (*Washington Post*, April 20, 2016) were labeled positive.

Tone. We also analyzed each complete article to determine whether it took a positive, negative, or neutral position toward the pharma industry. For example, any article that called for restrictions or a prohibition on direct-to-consumer (DTC) advertising—a position that the industry opposes—was deemed negative. In contrast, an article that claimed that DTC advertising resulted in more informed patients was designated as positive from the industry's point of view.

Balance. Regardless of the dominant position taken by the article, we also looked to see if the stories included the opposing point of view. When an explicit statement about an opposing view was included in the piece—even if the two sides did not receive equal coverage—we concluded that the article covered both sides. When no mention of the opposing view was presented, the article was labeled as one-sided.

Figure 1 (see page 27) shows the number of articles for 2016 compared to previous years. Results indicate that the amount of coverage the industry received is up 34.6% year over year and well above the five-year average of 163 articles. Table 1 (above top) shows the breakdown of coverage by newspaper. The 34.6% increase in coverage of the industry for 2016 reflects

1 The EthicsTrak database contains assessments of 2,088 newspaper articles evaluated over a 12-year period.

Table 3: **Analysis of Headlines and Full-Text Articles**

	Year	Positive	Negative	Neutral
Headlines	2012	18.6%	42.5%	38.9%
	2013	14.7%	36.8%	48.5%
	2014	16.3%	37.8%	45.9%
	2015	18.9%	32.7%	48.4%
	2016	9.8%	34.1%	56.1%
Articles	2012	23.9%	36.3%	39.8%
	2013	26.5%	47.1%	26.4%
	2014	29.1%	46.9%	24.0%
	2015	36.5%	44.7%	18.9%
	2016	13.6%	50.5%	36.0%

Table 4: **Analysis of Healthcare Reform Headlines and Articles**

	Year	Positive	Negative	Neutral
Headlines	2012	6.3%	25.0%	68.8%
	2013	21.7%	28.3%	50.0%
	2014	15.0%	28.3%	56.8%
	2015	3.3%	30.0%	66.7%
	2016	5.6%	8.3%	86.1%
Articles	2012	0.0%	25.0%	75.0%
	2013	30.0%	25.00%	45.0%
	2014	20.0%	28.3%	51.7%
	2015	26.7%	33.3%	40.0%
	2016	5.6%	25.0%	69.4%

increased coverage across all of the newspapers except *The New York Times*.

What are the hot buttons?

Figure 2 (see page 27) identifies the issues most frequently covered in the articles and the frequency of their coverage. High drug prices and drug safety have consistently been among the top hot-button issues attracting coverage, and 2016 was no exception. Articles about drug prices rose to the top of the list, addressed in 55 articles, as shown in Figure 2. Indeed, over a quarter (25.7%) of all stories we tracked last year on the pharma industry discussed drug pricing. Examples include "Another Drug Pricing Ripoff" (*Los Angeles Time*s, August 25, 2016), "Patients Struggle with High Drug Prices" (*Wall Street Journal*, December 31, 2015), and "The EpiPen Outrage Continues" (*New York Times*, September 22, 2016).

Drug safety, an issue that typically signals bad news for the industry, has held the number one or two spot on the list in eight of the last nine years. In the latest audit, we identified and tracked a new category of drug safety articles that focused specifically on the opioid crisis. This topic emerged from obscurity in past years to the number two spot on the list, with a count of 40 articles. Combining the pieces focused on the misuse/abuse of opioids with other articles focused on drug safety other than opioids, the two groups accounted for a total of 48 articles focused on drug safety or 22.4% of all articles in the sample. Examples of these include "What Do I Tell My Patients Who Want Opioids?" (*Washington Post*, June 12, 2016), "Pfizer Agrees to Limit Opioid Marketing" (*Washington Post*, July 6, 2016), and "OxyContin and Addiction" (*Los Angeles Times*, May 8, 2016).

When the three media sources—*NBC Nightly News*, *All Things Considered*, and Google—were investigated for the top two issues, we learned that they identified the two issues with coverage that spanned the entire year of this audit (October 1, 2015, to September 30, 2016). The range of this coverage is depicted in Table 2 (see facing page).

The next two issues on the hot-button list—M&As and tax inversion/evasion—are also overlapping in many cases. While the merger topic has consistently appeared on the list over the years of this study, the specific focus on tax inversion and/or evasion is a newly emerging topic. The tax inversion theme resulted in a mix of articles that offered opposing views on the topic. Examples include "Bring the Corporate Tax Exiles Home" (*New York Times*, December 14, 2015), "An Rx for Tax Avoidance" (*Los Angeles Times*, November 25, 2015), and "US Tax Drives Firms Away" (*Washington Post*, November 9, 2015).

The legalization of marijuana is another issue that emerged from insignificance in 2016. Not surprisingly, the coverage included both pro and con positions with, for example, the *Los Angeles Times* reporting "Pot Policies Mired in the '70s" (August 12, 2016) and *The Washington Post* calling for caution in a trio of articles ("Don't Reclassify Marijuana Yet—Research It" (August 16, 2016), "One Reason for Cannabis Caution" (July 31, 2016), and "What

Table 5: **Number of Healthcare Articles by Year**

Newspaper	2016 Front Page	2016 Editorial	2016 Total	2015 Total	2014 Total	2013 Total	2012 Total	% Change from 2015–2016
USA Today	1	0	1	2	6	3	0	-50.0%
Wall Street Journal	1	2	3	5	4	1	0	-40.0%
New York Times	6	7	13	8	30	21	6	62.5%
Los Angeles Times	3	8	11	9	11	20	5	22.2%
Washington Post	1	7	8	6	9	15	5	33.3%
Total	**12**	**24**	**36**	**30**	**60**	**60**	**16**	**20.0%**

Table 6: **Ranking of Ethical Issues in Healthcare Reform**

Ethical Issues in Healthcare Reform	2016 Ranking	2015 Ranking	2014 Ranking	2013 Ranking	2012 Ranking
Healthcare Reform	1	1	1	1	1
High Drug Prices in the US	2	2	3	2	N/A
Medicare/Medicaid Coverage for Drugs	N/A	3	5	4	2
Research and Development for New Drugs	N/A	3	N/A	N/A	N/A
Drug Safety	N/A	4	4	3	N/A
Data Disclosure	N/A	4	N/A	N/A	N/A
Developing Countries	N/A	4	N/A	N/A	N/A
Genomics and Biologics	N/A	N/A	6	5	N/A
Interaction with FDA	N/A	N/A	7	6	N/A
Generics	N/A	N/A	8	6	N/A
Reimportation/Importation	N/A	N/A	N/A	N/A	N/A

Needs to Happen Before We Legalize Marijuana" (April 30, 2016).

Articles focused on research and development of new medicines, the issue receiving the most coverage in 2015, fell off from 28 articles to only six last year. Similarly, stories focused on the Ebola virus dropped from 16 to only one. The topic of marketing and sales incentives, which used to attract coverage and was near the top of the list several years ago, fell to just one article in 2016. This lack of coverage is a positive outcome for the industry, and may reflect new policies and procedures in place to regulate incentives to physicians.

Linking pharma firms to the hot issues

For the fourth year in a row, this audit linked specific pharma companies and/or their products to the hot-button industry issues. In 2016, 77 companies accounted for 212 mentions. Of those, Pfizer was mentioned 37 times, with the content centered on price increases for 100 of its drugs, contributing to the 55-article total identified in Figure 2. Another 46 of the mentions were attributable to Allergan and Valeant, each with 23, respectively. Attention was directed to Allergan due to its failed merger with Pfizer, along with a $2 billion decrease in sales. Valeant gained attention by losing $85 billion in valuation and then failing to sell assets as proposed by their new CEO, Joe Papa. Both contributed to the third and fourth issues of M&As and tax inversion/evasion. The remaining 129 mentions, many of which were related to drug safety, were distributed among 74 other companies.

Coverage

Our 13 years of analysis has found that the tone of headlines and articles tends to be more negative than positive toward the industry. In 2016, headline tone was mixed. On one hand, there were fewer positive headlines. In fact, positive headlines hit a five-year low of only 9.8% of all articles. Furthermore, the proportion of negative headlines increased slightly in 2016 to 34.1%. On the other hand, headlines were not as consistently negative in 2016 as they were in the years 2012 through 2014. In addition, more headlines were neutral to the industry (56.1%) as compared to previous years.

In terms of the tone of full-text articles, the trends weren't as favorable. As shown in Table 3 (see page 29), only 13.6% of articles took a positive tone toward the industry, the lowest level in the past five years. Likewise, the proportion of articles taking negative positions toward the industry is at a five-year high of 50.5%.

Regardless of whether the article takes a primarily positive

or negative tone toward the positions of the industry, our audit analyzes whether both sides of the disputed issue are at least acknowledged. In 2016, 31.8% (68 of 214) of articles mentioned both sides, a drop from 52.8% the previous year.

Analyzing healthcare reform coverage

Consistent with previous years, we analyzed the top five US newspapers and answered the following questions:

- Do the healthcare articles and headlines support or oppose the positions taken by the pharma industry?
- What ethical issues face the pharma industry in these articles on reform?
- How often are the industry's perspectives included in the articles?
- What pharma companies and/or brand names are identified in the articles?
- What are the implications of these findings for the industry?

Headlines and articles related to healthcare reform were analyzed as positive, negative, or neutral toward the pharma industry. There was a neutral bent to 2016's headlines, with 86.1% of them neutral (see Table 4 on page 29). When the full articles were assessed, 69.4% were neutral. These results are consistent with results from prior years, but are the highest percentage of neutral headlines in the last five years and the highest percentage of neutral articles since 2013.

Four of the five newspapers were consistent with the neutral coverage. The exception was *USA Today*, which published only one article on healthcare reform—and that was negative: "VA Watchdog Great 'Failure' to Vets Problems' Allowed to Fester; Inspector General's Office Rejected Evidence, Sat on Report, Senate Investigation Finds" (May 31, 2016).

Coverage in 2016 increased slightly from the year before, from 30 to 36 healthcare reform articles. All papers had a least one article and *The New York Times* and *Los Angeles Times* had the most coverage with 13 and 11 articles, respectively. Examples include "The Fallacy of the Latest Contraception Case" (*New York Times*, November 7, 2015) and "End-of-Life Law May Stir Ethical Debates; Cost Controls Emphasize Lethal Pills over More-Expensive Life-Extending Drugs, Medical Experts Say" (*Los Angeles Times*, October 19, 2015). See Table 5 on facing page for a breakdown of the coverage.

Last year's articles focused primarily on healthcare reform (including the ACA) and, not surprisingly, high drug prices, which were also the top two issues in 2015 (see Table 6 on facing page).

The pharma industry's perspective was not in the healthcare reform articles. But, as discussed earlier, the link between pharma companies and/or their products and the ethical issues did occur in the articles (77 companies; 122 mentions).

Implications for pharma

As the case in past press audit features, the latest analysis of newspaper coverage of issues that affect drug manufacturers and issues related to healthcare reform has implications for the broader pharma industry. The sector continues to attract attention at a time when it is under scrutiny concerning the pricing of drugs. For example, after announcing that it would increase the price of 100 of its drugs in the fourth quarter of 2016, Pfizer reportedly raised prices an average of 20% between January and June 2017.

Some issues identified in this audit are within the pharma industry's capability to address (e.g., drug safety) and others are the harbingers of potential future impact (e.g., opioid epidemic). Based on its expertise in the manufacture and distribution of controlled substances, another area where pharma can take a leadership role is the legalization of medical marijuana. Legalization would have an impact on the sale of drugs for which marijuana is an alternative, especially for the Medicare population. The industry is at risk of lost sales as more states approve the use of marijuana for medical purposes.

Finally, the healthcare reform findings suggest an opportunity for pharma to play a greater role in this area. While there is considerable wrangling around the latest version of the reform of the ACA, the industry needs to continue to be proactive in shaping the attempted revisions in healthcare reform. As one of the key stakeholders in healthcare delivery, along with patients, payers, policymakers, and providers, pharma's actions over the next months can contribute to the stability of US healthcare delivery as Congress wrestles with the latest version of healthcare legislative reform. PE

** Saint Joseph's University students Caitlin Smith, Olivia Capperella, and Claudia Barbiero also contributed to this research.*

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Dealmaking in 2017: Striking a Balance

inVentiv Health Consulting's Neel Patel tells *Pharm Exec* that biopharma dealmaking in 2017 is robust and generally immune to external pressures in the short term—but the art of the deal is still being compromised by factors under the buyer and seller's control

By Julian Upton

While life sciences dealmaking in 2016 fell short of matching 2015—when deal value stood at approximately $425 billion, more than double the deals seen in 2014—it was "still high in historical terms," according to inVentiv Health Consulting's latest Dealmakers' Intentions Study, released at a Super Session at this year's BIO International Convention in San Francisco, CA. The drop in value to $275 billion—primarily attributed to 2016 M&A activity, which fell to $114 billion from $278 billion the year before—shows deal activity "leveling out" and moving closer to historical norms. The study forecasts that 2017, however, will still rank among the top three in value since inVentiv issued its first dealmakers report in 2008.

The study—which surveyed 107 members of the biopharma community "who participate on both sides of deals and who have predominantly executive-level influence on decision-making"—points to the continued growth of financing to small-cap and private biopharma companies in 2015, which remained steady through 2016 at $20 billion. "Financing in this range—far above the $6 billion to $8 billion range that we saw from 2009 to 2012—appears to be the new normal," the study reports. Driving this trend is the emergence of new buyers and more financing options, from venture capital and other vehicles that are available to

emerging companies and innovators. "Decision-makers are continuing to think creatively about new partnership opportunities. True innovators can expect to benefit from the emergence of new buyers and more financing options from the capital markets, permitting them to hold on to assets through commercialization in some disease areas," said the study's co-author Neel Patel, managing director, inVentiv Health Consulting, part of INC Research/inVentiv Health. However, he added, "Success with this strategy requires a clear understanding of the long-term potential of their assets in a rapidly evolving buyer's market and payer landscape."

Supply and demand

Both the seller's and buyer's markets continue to be shaped by imbalances in supply and demand and the continued struggle for both sides to reach a common understanding of an asset's value. Where there is a seller's market for all areas of hepatic disease (including non-alcoholic steatohepatitis [NASH]), women's health and CNS-neurology assets, a buyer's market exists in cardiovascular, oncology, CNS-psychiatry, inflammation, and autoimmune disease. Oncology, according to the report, is one area where "buyer enthusiasm appears to have tapered relative to supply;" however, "the volume of development activity has kept this therapeutic area in a buyer's market mode overall for the second year in a row."

Speaking to *Pharm Exec*, Patel noted that oncology had been for several years a seller's market, largely driven by the high demand among buyers, but this has now been "somewhat eclipsed by the sheer volume of assets available." He adds: "It is going to be important for buyers to understand where there is value among all the assets available, and sellers need to understand that oncology can be a challenging place for dealmaking, despite the high interest."


Neel Patel

Noting also that in 2016 there were many deals related to CNS and NASH, Patel says: "Buyers need to be careful in those areas where asset value has risen tremendously and maybe look at areas where there is relatively less demand, if it sits within their strategic remit, for areas where they may be able to get assets at better value for the money they're spending."

Sellers have less flexibility, says Patel, but being aware of where they sit and being able to drive negotiations and drive more value are important in terms of their therapeutic area and the relative demand. He adds: "Every year we track the total opportunities considered by buyers, and how each of these moves from entering a confidential discussion to issuing a term sheet to a completed transaction. The probability of progressing to a deal is between 4% and 8%. Compare that to the probability of a Phase I product across all therapeutic areas getting to approval, which is about 10%. It is about being aware how difficult the process is from start to finish. Having a sense of the magnitude of the effort required to successfully get a deal in place is important for sellers."

Deal or no deal: Influencing factors

Given the heated public debates and increasing political pressure in areas such as drug pricing, it is perhaps surprising that inVentiv's study shows that deal failures are driven mainly by internal factors, i.e., those under the dealmakers' control. Buyers and sellers report similar pitfalls in the dealmaking environment, the study reports. "More than 75% of respondents zeroed in on two main reasons for deal failure: differing opinions about an asset's commercial potential and unreasonable term expectations." (See chart on page 34).

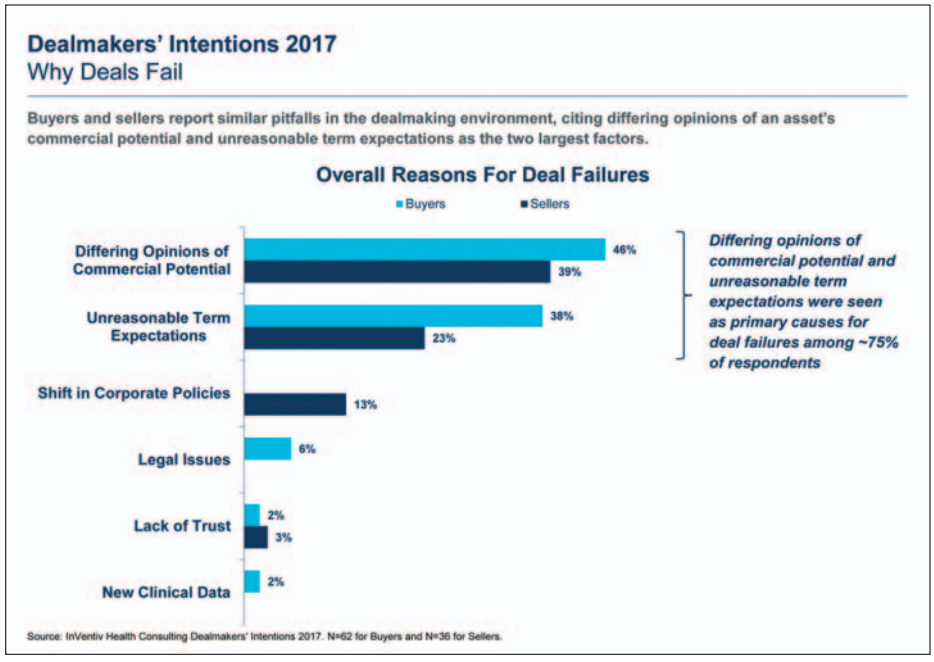
For Cliff Kalb, *Pharm Exec* Editorial Advisory Board (EAB) member and president, C. Kalb and Associates, it seems "ironic that, just as pharma has struggled with defining value for their products with stakeholders, settling on a common understanding of an asset's value is a major obstacle to dealmaking."

FAST FOCUS

» Oncology has traditionally been a seller's market, driven by high demand among buyers; however, this has shifted due to the volume of assets available—and the need now for buyers to better target where true value exists among the large pool of oncology assets.

» The probability of an M&A or licensing opportunity progressing to a formal deal is reportedly between 4% and 8%. Those odds are even less than the chances of a Phase I drug candidate successfully advancing through clinical development to approval, which is about 10%.

» Experts believe that the life sciences space, overall, remains a seller's market in many regards. Decisions will continue to come down to the confidence selling-company CEOs have in their clinical and commercial capabilities and ability to scale.



However, he adds, "This has never been easy, and it appears that will remain the case. The devil is always in the details of these transactions."

Indeed, Patel says that internal factors—which also include cash balance and access to capital—have "consistently been the drivers for deals since we began doing the surveys." The major factor affecting deal failure is differing opinions of asset value. This factor can be mitigated, within reason, by deal structure, he adds, but it is still one of the main reasons why deals fail. Pricing pressures, the effect of the political landscape and changes to affordable care, for example, continue to score relatively low in the study as far as affecting dealmaking is concerned. Regarding pricing, Patel notes that buyers, in particular, "have been incorporating these concerns in their modeling and their commercial diligence for several years, maybe for as long as a decade. Sellers have also realized that this is the new world order, and have had a couple of years to incorporate it into their thinking."

As Patel explains, the inVentiv study is focused on the dealmaking outlook in the short term. While, to his surprise, one external factor—the number of FDA product approvals—was regarded as affecting dealmaking in the short term, such external drivers generally present more long-term concerns.

Dealmaking horizon

Some "outside forces," however, may yet prove influential in the shorter term. The inVentiv study notes that "the Trump administration's stated intention to incentivize US companies to repatriate their overseas cash could spark a new wave of life science dealmaking." This could be one of the "catalysts for upside," adds Patel, that may fuel "major M&A consolidation among bigger companies that are rumored to be on a take-out list."

Conversely, Peter Young, of Young and Partners and *Pharm Exec* EAB member, notes that "uncertainty about what will happen with drug pricing and Trump's tax reforms, particularly around the repatriation of foreign earnings, has contributed to some of the slowdown in pharma and biotech M&A deals." Young points out that the blocking of tax inversion transactions by the US Treasury Department has "clearly halted almost all of the tax inversion-motivated deals, many of which were quite large." The "Trump bounce" and its influence on the dealmaking landscape seems open to interpretation. For Ipsos Healthcare president and *Pharm Exec* EAB member Steve Girling, the "trickle-down effect has been positive." He explains: "The balance of buyers and sellers is undoubtedly better because of the strength of the economy and its overall momentum, which underpins stock price and gives both parties in any transaction more confidence."

The Dealmakers' Intentions Study concludes that, "in many respects, this is still a seller's market." Girling adds that "the rationale for a deal may continue to hinge on seller CEO confidence in their company's clinical/commercial capabilities and ability to scale." The survey states that the widening discount rate gap between in-licensers and out-licensers in 2017 (4% spread vs. 2% in 2016) "potentially indicates an acceleration in dealmaking activity over time," adding that "a similar trend occurred in 2013 and catalyzed the unprecedented activity observed in 2015."

Given this scenario, comparable growth can be anticipated in 2019—but even then, dealmaking is unlikely to reach the giddy heights of 2015. PE

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Syncing Social Media With Value-Care Model

Outlining the new communication priorities necessary to excel in the emerging outcomes-based healthcare landscape

While nobody can predict what changes the American Health Care Act may eventually bring, two healthcare trends seem certain to continue under any environment: the move toward more value and outcomes-based care, and health consumers' growing adoption of digital and social media tools. Though motivated by different forces, I see these trends as deeply intertwined, and predict their continued convergence will have major implications for healthcare communications.

In a fee-for-service environment, everybody is incentivized based on the volume of care they provide. When a previously treated patient returns to the hospital, the hospital gets to perform more services and send a new bill. But increasingly now, doctors and hospitals' incentives are becoming aligned with the quality of the care and overall population health outcomes. In Medicare accountable care organization (ACO) arrangements, for example, health systems that cut costs while meeting health benchmarks for their patients get to share in the savings. A patient's readmission eats away at profits.

We're seeing a similar trend in pharma, too, where drug companies are experimenting with value-based contracts with insurers that require them to return money if patients fail to achieve expected results. Pressure on pricing is also shifting attention to outcomes.

For providers and drugmakers alike, this new environment means it's no longer enough to simply market and sell treatments. Our industry must also think holistically about patients. If you sell a drug that a patient forgets to take, or if a patient's poor health habits erode the benefits of his or her treatment, outcomes will suffer. Factors like adherence and lifestyle become as central to the equation as sales volume and efficacy.

It's well established that communication skills and regular contact between provider and patient help improve these outcomes. And that's where the second trend comes in: the rise of mobile health (mHealth) and healthcare social media. Patients are adopting a stunning new range of interactive tools like medication reminder apps, activity trackers, social media channels, and online forums to help themselves manage daily health needs. Much has been written about how these tools are empowering patients to become more active participants in their care. But less appreciated is how these digital and social tools can also bring efficiency and scale to healthcare communications. Patient-doctor relationships were once confined to exam room visits and Sunday newspaper columns. Today's digital world offers hundreds—if not thousands—of additional touch points.

These tools offer tremendous opportunities to deepen relationships and communication, but also add to the skills clinicians, insurers, and pharma companies must master.

Let's take a closer look at the new communication priorities required to thrive in the new value landscape.

Understand patient needs

Drug manufacturers convene patient focus groups to test ad campaigns, but this level of examination can be applied to all parts of the patient experience. Social listening is one powerful tool to accomplish this. You'd be surprised at how much detail people share about their conditions in online forums. Through these messages, we can construct intimate portraits of a condition, including what information people seek at different stages of their disease and treatment journeys and the common pitfalls where their adherence gets disrupted.

Engage directly with consumers

Although more and more healthcare industry companies are becoming active on social media channels, few are truly exploring the possibilities of two-way communications. We can improve by asking open-ended questions on Facebook, for example, and then listen to the responses. We can look for people seeking help online, then leverage company expertise to provide answers. We can produce live streaming events that use social media to

Continued on Page 47

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Marcks' VENUS

kimia farma

Triple Action :

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HEALTHCARE & LIFE SCIENCES REVIEW

INDONESIA

The Awakening Giant?

Not so long ago dismissed by international investors as Asia's "great underachiever", Indonesia, complete with its sprawling population of 260 million and blossoming middle class, tends to elicit great enthusiasm and fanfare these days. Nowhere is this truer than in the pharmaceuticals and life sciences sectors. Valued at USD 5.5 billion, and registering an impressive seven percent annual growth, the local pharma market stands out as being one of the best performing in the entire region.

Moreover, with a much acclaimed universal healthcare coverage scheme inching towards completion and a singularly unorthodox and vigorous president promising to trim Indonesia's negative investment list and return the economy to heady seven percent growth rates through business-friendly policies, many analysts are justifiably wondering whether South East Asia's 'forgotten giant' could finally be beginning to awake from its long slumber.

At a first glance, the raw figures certainly do look pretty enticing. "Indonesia ranks as a heavyweight market in its region, contributing one third of ASEAN's total GDP, and is developing rapidly… We're talking about the fourth largest population on the planet, expanding at a rate of about five million people every year, a sustainable five percent GDP growth rate, and a pharmaceutical market forecast to double in size by 2020. What is there not to like?" asks Servier's managing director, Alban Nérot. "We simply cannot afford to ignore such obvious potential and thus my primary objective has to be to ensure that this is reflected within our corporate ambitions and results," he enthusiastically adds.

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Other actors, however, are proceeding rather more cautiously. "While it is true that an increase in disposable incomes has resulted in a surge of sales for beauty and personal care products and in spite of there being much clamour and hubbub about Indonesia breaking into the top ten global skincare markets by 2019, we still perceive complexities in the day-to-day dynamics of the local marketplace," contemplates Holger Welters, president director of the skincare specialist Beiersdorf, another prolific investor in the Indonesian life sciences space. "It is clear to me that while the underlying potential certainly exists, this potential has not yet been converted into a reality," he warns. "Thus, we have to be highly selective when approaching this kind of opportunity, keep our feet on the ground and set about evaluating these forecasts carefully and pragmatically."

GREAT EXPECTATIONS

Perhaps the single issue that has served to whip up investor confidence more than anything else has been the Joko Widodo administration's ambitious reform of the country's national health service. Indonesian healthcare has traditionally been notorious for its fragmentation. However, in the fall of 2014, Indonesia's government surprised many by launching a radical initiative to establish a compulsory national health insurance system with the aim of providing basic care for all by 2019. Nila Moloek, Minister of Health, reaffirms "The Indonesian government is committed to achieving its goals in the health sector […] among other things, the JKN program, which has drawn in more than 175 million people."

The scheme, known as 'Jaminan Kesehatan Nasional' or 'JKN,' primarily seeks to improve the livelihoods of citizens stuck in the middle – namely those too poor to afford health insurance, but deemed not poor enough for state support. Under the provisions of JKN, all citizens would now be able to access a tranche of basic health services provided by public facilities, and certain specially designated private ones too, covering treatment for everyday illnesses from chest infections to surgery and chronic diseases.

Dr. Nila Moeloek, minister of health; Maura Linda Sitanggang, director general of pharmaceuticals and medical devices, ministry of health; Penny Lukito, head, BPOM; Agus Prabowo, chairman, National Public Procurement Agency (LKPP)

Rolling out a grandiose welfare program on this scale has logically gone hand in hand with considerably higher state expenditure on public health. "Prior to implementation, annual health insurance for the poor ran to the tune of some IDR eight trillion (USD 602 million). Nowadays this budget for the poor and nearly poor, known as the 'Contribution Assistance Recipient,' has shot up to approximately IDR 25 trillion (USD 1.8 billion)," affirms Dede Yusuf, chairman of Commission IX, the Health and Manpower commission

These developments, logically, represent quite a game changer for a pharmaceutical industry long critical of anaemic public spending on healthcare. "Our clients have been much encouraged by the sheer opportunities generated by JKN: the market has overnight become considerably more attractive for them and we are witnessing a surge in investments, acquisitions and joint ventures, all of which affords local companies the prospect to acquire technology and know-how hitherto out of reach. Taking all of this into account, our calculations now place Indonesia's pharma sector as growing at a rate of around seven percent annually over the next four to five years," recounts Wiwy Sasongko, managing director of QuintilesIMS.

The Only Certainty is Uncertainty!

Q&A with Milan Paleja, president director, CPO head & country president, Novartis

Milan Paleja, president director, CPO head & country president, Novartis

What is your strategy to successfully navigate within a dynamic environment like Indonesia?

Our business expansion strategy is based on enhancing patient access in both public and private sectors, and providing Continuing Medical Education (CME).

We are focused on providing our innovative and effective medicines to more Indonesian patients, particularly in new therapeutic areas and for diseases that have a heavy socio-economic burden such as Heart Failure. For the public market, we have 28 SKUs listed in the national formulary, available for all Indonesians who are covered by the Indonesia's National Health Insurance Program.

On a parallel and complementary track, we run CME programs to inform doctors and other healthcare professionals in both public and private sectors about our innovative products.

Our goal is twofold: to make the right medicines available and to enable the right healthcare professionals to prescribe them, i.e. enhance the skills of doctors in Indonesia and bring innovative medicines to the country.

What are your key areas of focus in this pursuit?

Novartis is committed to improving and extending patient lives by providing patients with access to our innovative medicines. When I was appointed to lead Novartis Indonesia, I had four priorities.

First, enhance our operational efficiency and motivate our team. Second, drive the growth of Novartis Indonesia by increasing access to our products in both public and private sectors. Third, position Novartis as the government's partner in implementing the Universal Healthcare Coverage Program or JKN. Fourth, diversify our product offerings to different therapeutic areas.

Other commentators have been quick to concur. "I know of one medical device company whose products are registered on the government's reimbursement list that has registered a leap in their revenues of 50 percent in the last year alone," confides AmCham managing director, Lin Neumann. "There is no doubt that this reform heralds a very positive step for the industry as a whole" agrees Chris Wren, executive director of the British Chamber of Commerce, "multinationals right now enjoy the largest share of the therapies being reimbursed under the system and they are seeing the public sector outpace the private in terms of growth rate, which is tremendous news when you consider Indonesia's mammoth untapped market."

Siemens Healthineers' country lead, Steven Lee, is equally forthright. "This decisive boost to the purchasing power of the public hospital apparatus marks a golden opportunity for Siemens to deliver up new innovations and methodologies and to simultaneously furnish both private and public arenas with state of the art solutions that can radically improve the patient experience. It also fosters the right receiving environment for us to be able to extend beyond an essentially product-oriented approach towards a more holistic offering in which we can act as a true healthcare solutions provider rather than merely a piece-by-piece equipment seller" he observes.

PLUNGING INTO THE RED

Materializing JKN's lofty ambitions, however, is proving to be a formidable task for a national treasury already under increasing strain. "As of today, JKN covers some 178.2 million citizens which is roughly equivalent to 70 percent of the national population, but there remain big question marks over how to render the system financially sustainable in 2019 when it is supposed to be catering for 260 million," admits Fachmi Idris, president director of Badan Penyelenggara Jaminan Sosial Kesehatan (BPJS), the social security agency charged with implementation, "we are fully aware that we will need to do much better in attracting and registering the non-poor segment if we are to properly balance the books and render the program financially stable." Indeed, at present, JKN is running at a chronic deficit with state coffers making up the shortfall.

What, then, is the solution to resolving this systemic financial mismatch? Three solutions have been mooted: increased premiums, reducing the pack of healthcare services, or external capital injections. Increasing the premiums paid by society in order to minimize the economic gap between the premium and the actuarial would, however, compromise the principle of universal coverage because a large segment of the population simply cannot afford any increase. Similarly any reduction in the healthcare package would also leave patients untreated. So far, therefore, the Widodo administration, ever attentive to courting popular opinion, has resorted to option three: injecting whatever cash is needed to breach the gap, in the full knowledge that this cannot be sustainable in the long run.

For Sigit Priohutomo, chairman of the National Social Security Council or 'DJSN,' the only feasible way to square the circle will be to "establish a co-payment arrangement with private industry." "Even though all citizens and employees are obligated to join the system by law, some companies have yet to register their staff, so we need to work towards enforcing the rules," he avows. "As the Indonesian state clearly does not possess sufficient resources to fulfil the national healthcare objective, public and private partnerships (PPPs) would seem to be obvious pathway forward by leveraging private capital and resources to the purpose of enlarging government reach," concedes Philips' Suryo Suwignjo.

Parulian Simanjuntak, executive director, IPMG; Darodjatun Sanusi, executive director, GP Farmasi; Dr. Kuntjoro Adi Purjanto, chairman, PERSI; Dede Yusuf, chairman, Commission IX

"We've noted that the JKN is struggling in three fundamental areas: infrastructure overload, budget deficit, and implementation," reveals QuintilesIMS' Sasongko. "The state is going to have to take a deeper look into how they are spending the money, how much reaches the patient in the end and how they can generate a

Sigit Priohutomo, chairman, National Social Security Council (DJSN); Fachmi Idris, president director, BPJS Kesehatan

bigger bang for their buck. Then, on top of all of that, there are going to be some basic structural issues that will need to be surmounted. For instance, the ratio of hospitals and doctors per citizen in Indonesia is clearly too low and unfit for purpose. Right now, Indonesia possesses a comparable number of oncologists to Singapore, which has only five million inhabitants to Indonesia's 250 million!" he exclaims.

Many key opinion leaders agree with this stark assessment. "People appear to forget that the universal healthcare program is not only about providing coverage to everyone, but also about ensuring a certain level of quality in health provision delivered at the right time to ensure that there are no catastrophic out of pocket expenses in the event of requiring extensive medical attention; thus it is essential to get a grip on the financial sustainability of the program and start embracing pharmaco-economics in order to align financial restrictions with national health goals," argues Dr. Hasbullah Thabrany, chairman at the Center for Social Security Studies of the University of Indonesia (CSSUI).

Hasbullah Thabrany, chairman, Center for Social Security Studies of the University of Indonesia (CSSUI)

"Already we are noticing a strong shift towards cost containment with regards to the procurement of medicines within the program and a clear preference for use of cheap, non-branded generics which will ultimately pose a challenge for multinationals whose prices tend to be set higher than the local ones," acknowledges Parulian Simanjuntak, executive director of the International Pharmaceutical Manufacturers Group (IPMG). He has, therefore, been lobbying policymakers to understand that merely focusing on the cheapest therapies is not necessarily the most cost-effective way in the long run and that Health Technology Assessment (HTA) should be deployed to ascertain the added value of latest-generation innovations.

Shifts to the procurement system have, indeed, already been enacted in a bid to take costs out of the system. "Formerly, when the procurement system was still fully based on tenders, the process was supply-oriented but, by implementing an e-catalogue, we have managed to shift the paradigm so it is demand driven," points out Agus Prabowo, chairman of the Public Procurement Agency (LKPP).

In view of the scheme's unsteady economic outlook, some of the more wary pharmaceutical actors have been adopting a 'wait-and-see' posture. "To date, we have been hesitant to create any significant dependency on JKN until we can gain greater clarity on pricing rules and timeframes for payment," confides Servier's Alban Nérot. "Although JKN could potentially represent a decent mid-term opportunity for us, it could equally instead adversely

TOP 15 PHARMA COMPANIES IN INDONESIA

RANKING BASED ON RX + OTC SALES (2016)

#1	KALBE FARMA		
#2	SANBE	#9	SOHO
#3	DEXA MEDICA	#10	NOVELL PHARM
#4	PHAROS INDONESIA	#11	BIOFARMA
#5	TEMPO SCAN PACIFIC	#12	DARYA VARIA
#6	KIMIA FARMA	#13	KONIMEX
#7	FAHRENHEIT	#14	MERCK INDONESIA
#8	SANOFI-AVENTIS	#15	HEXPHARM JAYA

Source: QuintilesIMS

impact the P&L of multinational innovative drug developers, by favouring locally sourced generics…and with the on-going uncertainty surrounding its financial viability we prefer to exercise prudence and stick with the tried and tested private market for the time being."

CREEPING PROTECTIONISM

Meanwhile, there are a handful of market distortions that threaten to take some of the shine off the initial jubilance over the JKN displayed by many international companies contemplating market entry. First and foremost has been successive Indonesian governments' longstanding dalliance with nationalism and protectionist measures.

The Widodo administration remains true to the stereotype on this count with a special division having been set up within the Ministry of Health explicitly dedicated towards cultivating a local pharma manufacturing industry, import-substitution industrialization and a spirit of self reliance. "We have designed a 15-year roadmap to transform the Indonesian pharma industry into an innovative industry. This plan consists of three stages of five years respectively. We would focus on cooperation and transfer of technology in the first five years. The second period of five years would focus on acquiring and developing the technology, and the last five years would be to witness the local industries launch their own, locally manufactured products by mastering their own innovative technologies. And, overall, we would like to see the local companies invest higher percentages of their revenues into their R&D divisions", declared Maura Linda Sitanggang, director general of pharmaceuticals and medical devices at the Ministry of Health.

Steven Lee, country lead, Siemens Healthineers; Suryo Suwignjo, president director, Philips

Wiwy Sasongko, managing director, QuintilesIMS

"We are collaborating closely with the government to increase the power of indigenous pharmaceutical firms and have set a target of increasing the exports of local players to 30 percent of production capacity. Meanwhile we are pulling out all the stops to promote Indonesian self-sufficiency of raw materials such as active pharmaceutical ingredients," attests Darodjatun Sanusi, executive director of GP Farmasi, the National Association of Local Companies in Indonesia.

Forging a Powerful Indigenous Manufacturing Base

High up on the populist agenda of the Widodo administration is a staunch commitment to developing Indonesia's own localized industrial bases for strategic sectors such as pharmaceuticals. "We are concerned that a full 95 percent of the active pharmaceutical ingredients (APIs) that our nation presently consumes are, in fact, imported from countries such as India and China and have thus made it our goal to reduce this dependency through shrewd regulation and incentives to encourage our very own indigenous pharma industry to integrate vertically," confirms Minister of Industry, Airlangga Hartarto.

Honesti Basyir, president director, PT Kimia Farma (Persero) Tbk

One company that has been especially receptive to this clarion call has been Kimia Farma, the top performer on the local market in 2016, according to QuintilesIMS statistics. "Consciously aligned with the government's objective of reducing the disproportionate dependence of Indonesia on API imports, we have been constructing the first real API manufacturing plant in the country which is expected to attain completion by mid-2018," proudly affirms Honesti Basyir, president director of the company.

"Today our pharmaceutical manufacturing unit constitutes the main contributor to our profit and loss (P&L), representing some 34.25 percent of our revenues and growing more than 30 percent last year," explains Basyir. "Our short-term strategy is going to focus on strengthening our position in the pharmaceutical manufacturing division so as to be able to cope with the projected growing demand coming from universal health insurance coverage. We have recently built up a new cutting-edge manufacturing plant in Bandung, in West Java, that has tripled our manufacturing capabilities and our API fabrication capabilities will simultaneously be backing up the government in achieving financial sustainability within the JKN scheme, as it will drastically lower the costs of production," he elaborates.

Airlangga Hartarto, minister of industry

MARKET DISTORTIONS

Beyond needing to align with evermore-stringent local content regulations, many new market entrants also report finding themselves having to contend with a myriad of local idiosyncrasies that hamper their efforts to establish a smooth-running business. "Indonesia's drug registration timeframe, for instance, stands as one of the slowest in the region and, consequently, products are not introduced in the country as fast as they should be to the extent that medical tourism is starting to become a concern with affluent Indonesians instead opting to be treated abroad in countries such as Thailand, Malaysia or Singapore where they can more easily access latest-generation, innovative treatments," warns Simanjuntak.

At the same time, many international drug developers have noticed an erosion of in-country profit margins as a result of a proliferation of counterfeit medicines. The National Association of Hospitals (PERSI), for example, estimates that unregistered drugs represented as much as 10 percent of the total Indonesian pharmaceutical value in 2016.

Meanwhile many new entrants severely underestimate the losses incurred from navigating the country's patchy infrastructure and logistical complexities. "It's important to consider that Indonesia constitutes the world's largest archipelago composed of more than 17,000 disparate, diverse and in some cases poorly connected islands and, therefore, entails significant distribution and patient access barriers. Even once you've secured all the requisite approvals, physically getting your product to the intended market place can be an expensive, time-consuming and logistically tricky business," warns PERSI's chairman, Dr. Kuntjoro Adi Purjanto.

"There's no denying that Indonesia has always been very challenging in terms of regulatory and structural issues; it has not wrongly earned the reputation of being an unpredictable business environment with certain lack of transparency, but those issues are now gradually being resolved and the commitment to universal healthcare is certainly a very strong statement of intent," reassures idsMED's president (core markets) and senior managing director for Indonesia, Rufi Susanto.

Benoit Martineau, president director, Sanofi; Mada Shinta Dewi, country manager, Mundipharma

WINNING STRATAGEMS

What, then, are the secrets to making a success out of Indonesia's high-risk, high-reward business environment? For Benoit Martineau, president director of Sanofi, flexibility and adaptability are two useful assets. "Despite our positioning as the number one MNC in the country, I would say that Indonesia still represents one of the most challenging markets in the South East Asian theatre of operations. This is the type of market where you have to be quick on your toes… being able to anticipating future dynamics in a fast-changing, fluid environment and react rapidly is highly advantageous."

Being able to spot emerging trends and being a first mover in aligning to them has certainly proved lucrative for many actors. Mindful of Indonesia's rapid economic development, Siemens has been astutely re-orientating its offering to cater to the needs of a brand new middle class in the ascendancy. "We have been increasingly pivoting towards the middle and upper-middle class private market," expounds Siemens Healthineers' Steven Lee. "Our intention is to retain those patients that are undergoing treatment abroad by offering them higher standards in technology and innovation back home in Indonesian hospitals. The industry as well as the government are endeavouring to reverse this patient outflow and we detect a real effort on the part of all parties to enhance standards of service quality so that is one specific niche that we have selected to scope in on."

Alban Nérot, managing director, Servier

Beiersdorf, which currently exhibits one of the highest growth rates in the skincare category, meanwhile puts its own success firmly down to a triple combination of sustained investment, speciality focus upon a core competency and the ability to drum up new levels of demand where previously little existed. "Providing education about the benefits of our products has been absolutely

Holger Welters, president director, Beiersdorf; Rufi Susanto, president (core market) and senior managing director, IDS Medical Systems

crucial in this market to enhance the penetration of our brands," confesses Holger Welters. "Though we encountered a pre-existing market of sorts, we found ourselves having to further develop and stimulate the customer need by communicating the importance of skincare, and raising awareness over the dangers of its negligence. For instance, the concept of sun care tends to be well ingrained in peoples' minds in developed western markets, where people are highly conscious of the risks of skin cancer, but tends to be lacking somewhat in underdeveloped, emerging markets like this. We are proud to have already attained a lead position in therapies for injured skin through our product Hansaplast®, which demonstrates that this strategy is working," he notes.

Mundipharma, a global leader in pain management, narrates a not entirely dissimilar story of having to draw attention to a very real unmet need in the market, but one that had not always been understood as such locally. "We discovered that the penetration of pain management treatment was disproportionately low in Indonesia due to a confluence of cultural, regulatory and educational factors," reveals Mada Shinta Dewi, the company's country manager. "Firstly, Asians, in general, do not tend to complain so much about pain, because in their cultures it is perceived as impolite to be making a fuss. Secondly, opioid medicines are highly restricted on the local market. Thirdly, there has barely any education of pain management in the medical universities… We have therefore made it our business to develop this arena and spread understanding about the dynamics of pain and its alleviation," she explains. Right now, Mundipharma is concentrating its efforts on applying pain management knowledge in the treatment of cancer patients, one of the primary causes of death in the country. "It's a long journey that needs to be supported by a lengthy repertoire of medical education initiatives in collaboration with the medical associations, pharmacies and hospitals. The results so far are very encouraging, but there is still a long way to go," concludes Dewi.

Christian Eberle, president director, APL

Indeed one overriding hallmark of successful ventures in Indonesia tends to be that they engage with the marketplace on its own terms instead of trying to transplant a business model devised elsewhere. "We ascertained exactly what the local market and local clients required and remodeled our offering to match accordingly. Doing business in this very young, raw market is a world away from the much more static Malaysian ecosystem or a highly developed and rigidly structured marketplace like Singapore. The demand in Indonesia right now is not necessarily for the most high-tech products, but those that fully serve their purpose with an affordable price," explains idsMED's Susanto.

THE QUEST FOR PARTNERS

Enlisting the support of local entities to assist with commercialization can also offer considerable advantages to multinationals as they set about trying to navigate the Indonesian market's highly complex contextual environment. One such outfit, Metro Drug Indonesia (MDI), has positioned itself as a partner of choice within the 'commercial sales organization arena,' under which its clients maintain their business license and distribution activities, but outsource the task of fostering demand for their products. "Though we also offer full-agency end-to-end solutions, we identified considerable demand on the part of the MNCs for a local mentor with expertise in marketing value-added services that overcome the inherent challenges of the market," recalls president director, Agus Darjono. "Clients predominantly demand our marketing insights as well as commercial actions that will create demand for their products through stronger penetration rates in different channels like clinics, hospitals, and other healthcare institutions. MDI's network with key customers and opinion leaders is one of our fundamental operational underpinnings since they ensure the accurateness of our commercial insights and ultimately, the success of our demand creation initiatives," he elaborates.

Leading the Charge Against NCDs

As Indonesia's middle class mushrooms, the demography of disease has undergone a sharp transformation with a steep reduction in incidence of infectious diseases, but at the same time, an alarming increase in non-transmissible, chronic, so-called lifestyle disease including diabetes, cancer, respiratory conditions and cardiovascular disorders. Long considered maladies of affluent urban populations in mature, developed economies, these non-communicable diseases have been spreading silently and, in many cases, largely unchecked to the point where they are now becoming a significant burden on social welfare and economic growth. Fortunately international drug developers such as MSD are now engaging vigorously with the local market in a bid to turn the situation around.

"MSD in Indonesia has been on an exciting transformational journey…our local portfolio today is specifically tailored to address growing chronic diseases such as diabetes and cancer," declares the company's president director, Ashish D. Pal. Indeed, with the International Diabetes Federation recently estimating that there are more than 10 million people living with diabetes in Indonesia, some 90 percent of whom are believed to be suffering from the Type-2 version, the company has won acclaim for bringing in an innovative therapy combining Sitagliptin and extended-release Metformin, which helps patients to effectively lower blood sugar and avoid serious complications.

Ashish Pal, president director, MSD

So too has the company been at the forefront of efforts to combat cancer. "Aware that lung cancer constitutes the leading cause of cancer morbidity in Indonesia with over 20,000 deaths annually – the highest in Southeast Asia – we were very proud to receive approval for Pembrolizumab, the first ever immunotherapeutic agent for non-small cell lung cancer to enter the market," he exclaims. At the same time the company has been collaborating closely with the Ministry of Health to roll out its Human Papillomavirus (HPV) vaccine program. "The stark reality is that 26 women in Indonesia are dying each day from cervical cancer, so we are doing what we can to arrest this development," he sighs.


Djonny Hartono, president director, Enseval; Agus Darjono, president director, Metro Drug Indonesia

Indonesia's single largest distributor, Enseval, has also been noticing the impact of the implementation of JKN. "Geographically we have seen an increasing demand for our services in more remote provinces like Kalimantan, Sulawesi and Papua," observes president director, Djonny Hartono, "and also registering rising demand according to socio-economic strata. The poor are discovering their right to healthcare while a growing middle class is seeking higher-quality treatment. The task at hand for a distributor like us is to ensure the appropriate supply of pharmaceuticals, medical devices and equipment to ensure that the appropriate healthcare demand can be met on all levels."

Conscious that, while digital disruption and mobile health can represent important breakthroughs in any emerging economy, the potential is amplified in the fragmented geography of Indonesia, Enseval has been investing heavily in modernizing and upgrading its processes. "In the sales and distribution side, we have already introduced our 'Enseval network order system' that eases our client commands through web and mobile applications without any geographic and time restrictions.

Jorge Wagner, president director, Boehringer Ingelheim

Meanwhile, Anugerah Pharmindo Lestari (APL) plays a significant role in assisting drugs companies and healthcare providers alike with the distribution and logistics part of the value chain. "While JKN represents a great step forward for the Indonesian people, its implementation does pose new challenges in the activities of administration and collection management so APL has been taking a proactive stance to streamline these processes through optimized cold chain management, a consolidation of our national distribution centers and the integration of latest digital technologies," confirms Eberle, president director of APL.

At the same time, APL has also been experiencing a significant upswing in demand for its commercialization and marketing services. "We deploy a unique market insight and benchmarking tool, which gives clients strategic and tactical information to support their decision-making. Through our insider understanding of the rapidly evolving regulatory environment and our extensive business intelligence capabilities, we are uniquely positioned to execute an effective sales, brand development, channel management and marketing strategy," proclaims president director, Christian Eberle.

THERE FOR THE TAKING

What, then, to make of a market that seems to promise so much, yet simultaneously poses such glaring drawbacks? While it remains a complicated place for doing business for the uninitiated, there can be no doubt that those companies that have cracked the market are generating good returns.

Boehringer Ingelheim is perhaps a good illustration of this point. The company has been staunchly and resolutely believing in the potential of the archipelago since the 1960s, even acquiring a manufacturing plant in the early 2000s and continuing to invest heavily in developing its local footprint. This perseverance has, indeed, been paying off and the company now finds itself one of the fastest-growing players within the top 20 for the second year in succession.

"Indonesia remains a tricky market for MNCs because local players still dominate some 70 percent of the pharmaceutical value and the pressures on the public purse are clear for all to see…Nevertheless, when you peer deeper into how the industry is organized, it becomes clear that the local players are actually dominating the OTC segment, whereas the prescription market is much more finely balanced with 45 percent of the branded prescription medicines value in the hands of MNCs," assesses Jorge Wagner president director of Boehringer Ingelheim.

"Yes, compared to other markets, innovative medicine remains poorly represented on the national pharmaceutical agenda, so there is a massive amount still to do, yet it is precisely because of this that Indonesia constitutes a market where we can make a big difference and where a company like ours, so long as it perseveres and conducts itself smartly, can reap real rewards," he concludes.

Continued from Page 35

facilitate dialogue that builds relationships and trust.

Organizations can also help by training doctors—the most trusted figures in the health ecosystem—to be more involved with patient communities on social media. The primary care visit offers doctors a face-to-face opportunity to explain the importance of diet and exercise to patients. But imagine how much more adherent patients might be if the doctor could reinforce this message continually throughout the year? Or how we could improve population health if reminders about routine screenings came from intimately trusted authorities. With strategic use of Twitter, Facebook, or Snapchat for educational messaging, this becomes easy—and efficient.

Create content that resonates

The Internet is full of factual information that nobody actually reads because they're too busy devouring misinformation that's fun to share and click on. But when health outcomes matter, we must compel patients to tune in to health messaging they might otherwise ignore. We can compete in this battle for mindshare by weaving health issues into evocative narratives of real people, or by expressing complicated scientific concepts in relatable everyday terms. Selecting the right spokesperson is another way to capture attention.

Meet people where they are

We already know that well-run patient service programs help people navigate the obstacles of starting a new treatment. The next step is to make sure these programs integrate seamlessly into patients' lives. For most demographics, this means optimizing for smartphone use. As mobile messaging continues to grow, we should explore chat extensions for nurse navigator hotlines.

Similarly, it's important to make sure information and programs are available on the platforms our audiences use most. More pharma companies are establishing branded presences on Facebook, the world's most popular social media platform. And now that scrolling important safety information (ISI) is available in Facebook ads, it is getting easier for pharma to participate.

Don't shy away from difficult topics

Increasingly, social media is becoming the place where patients go to sound off about concerns with pricing and access. Meg Alexander, head of risk and reputation management at inVentiv Health Communications, recommends companies be prepared to communicate about the value their medicines deliver to stakeholders who use Twitter or Facebook to raise concerns about affordability. They must also make out-of-pocket cost assistance information easier to find and simpler to understand. In terms of building relationships, there's a world of difference between demonstrating you are listening and appearing to dodge difficult questions. Furthermore, patients cite drug costs as a major factor in nonadherence, so raising the visibility of assistance programs has the potential to affect outcomes.

Don't lose sight of human element

While it's easy to get excited about new gadgets, remember that the overall goal of mHealth and social media must be to deepen relationships and communication. For example, telemedicine can connect elderly and disabled patients with specialists who would be hard to visit in person. Step counters come with apps that create social communities that encourage participation. Be wary of advances that aim to displace human interaction. The power of these new technologies is realized when there's a caring, concerned person on each end. A recent study found that simple medication reminder apps did not improve adherence. In contrast, Medisafe, a medication reminder app that alerts family or friends about missed doses, claims 71% of users improved adherence after adding its "Medfriend" feature.

> Where writing a prescription used to be the end of interaction, we should now see it as the beginning of a relationship

As the healthcare system continues its shift towards value-based models, genuine, personal communication will only increase in importance. Where writing a prescription used to be the end of interaction, we should now see it as the beginning of a relationship. Digital and social media tools must be recognized as a standard part of quality care. PE

Beyond the Science: Commercial Implications From ASCO 2017

Four strategic takeaways for pharma oncology leaders

Most years, the key learnings from the Annual Society of Clinical Oncology (ASCO) Annual Meeting revolve around what attendees are there to discuss: the science. Reflecting on the 2017 meeting in June, the takeaways that come to mind include the breakthrough assets and combinations, the missed hypotheses, the discoveries and advancements that help us get to a deeper genetic understanding of cancer—this great killer—and, lately, the financial implications of these advancements.

This year—after five solid days of walking more than 20,000 steps navigating Chicago's McCormick Place and absorbing volumes of data during each session—we definitely saw some impressive clinical advancements. However, stepping back, we think that the real story from ASCO 2017 lies in the downstream implications that science holds for companies looking to establish or sustain leadership in oncology. The following are our top four takeaways for oncology commercial leaders.

MARIA WHITMAN (maria.whitman@zs.com) and **SHARON KARLSBERG** (sharon.karlsberg@zs.com) are principals with ZS Associates

1. Become masters of selectivity

"Right patient, right drug, right time." While advancements have led to an increasingly prominent theme of personalization and targeting in recent years, ASCO placed greater emphasis on selectivity to optimize benefit at each line of therapy. In the age of personalized medicine, there's an art and a science to answering, "Which patients will benefit?"

The oncology community is broadly asking this question after the varied outcomes for pembrolizumab vs. nivolumab (PD-1 inhibitors) in front-line, non-small-cell lung cancer patients. Patient selection is a clinical question, but it's also a very important commercial question, and a foil to the traditional mindset of broader patient population strategies. Companies need to accept focused patient types—like we saw this year with olaparib in BRCA-mutated, triple-negative breast cancer patients (the OlympiAD trial)—as core to the strategy, aligning expectations to lay a solid foundation of value on which to build.

The shift in mindset and capabilities that are needed to "go small to go big" aren't trivial, but future leaders in oncology will master selectivity clinically and be okay with building beachheads from which to grow for commercial success.

2. Find your clinical and commercial differentiation

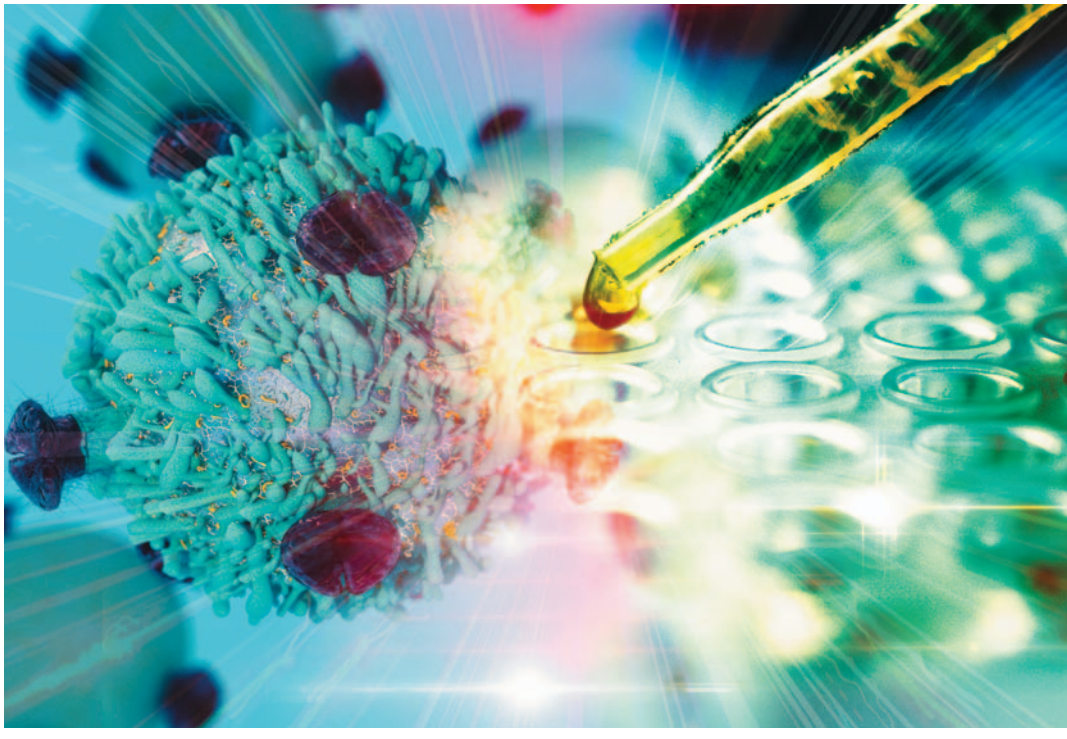
In many categories today, significant competition exists. The immunotherapy discussion around checkpoint inhibitors at ASCO, on and off the stage, gravitated to the question of whether there's meaningful clinical differentiation among the assets. This sentiment also has been raised by large provider networks and payers. While current studies don't allow for head-to-head comparisons, the challenge is compounded for anti-PD-1s/anti-PD-L1s when we look into the pipeline and see a large number of companies developing their own asset to be used in combination with another novel asset without having to partner.

If the checkpoint inhibitors are the "same" for customers, what can you do to win? Substitute CDK4/6, ALK+, etc., and the same question arises, although at a much different scale. Companies that will lead in oncology moving forward will ideally find differentiation in development and supplemental evidence, but they'll need to invest heavily in commercial differentiation as well.

The findings from ZS's 2017 Oncology Customer Experience Tracker study show that when healthcare providers have a positive experience with oncology companies—taking into account their reputation and their customers' interactions with people and support services—oncologists prescribe the company's products more, provide more access to sales reps, and have more affinity for non-personal interactions. As the care model changes and evolves, companies that will lead in oncology will be innovating and evolving their commercial deployment and emphasis on customer experience to provide differentiated partnerships.

3. Advance with the patient

Perhaps one of the most impressive pieces of data shared at



ASCO was the Memorial Sloan Kettering study demonstrating a five-month improvement in overall survival for cancer patients who self-reported their side effects and symptoms online. Compared with patients not using the tool, self-reporters also had fewer emergency department visits and hospitalizations, and they stayed on chemotherapy longer. Dr. Ethan Basch, the study's lead investigator, noted that these gains "are greater than the effect of many targeted drugs for metastatic cancers."

So how do oncology manufacturers harness this patient power? Clinical researchers should be pushing forward with new instruments to capture patient-reported outcomes, delivering better results for cancer patients, and creating opportunities for differentiation in increasingly competitive markets. The fact that ASCO featured this as a plenary session further underscores the urgent need for timely, tailored, and collaborative support for patients—from healthcare providers and drug developers alike.

Healthcare providers at ASCO are feeling the pressure, too, as they struggle to implement changes for mandatory quality reporting, alternative payment models, and new ways of delivering cancer care. For those practices taking the plunge into the oncology care model, for example, they're committed to the belief that change today will prepare them better for improved cancer care tomorrow.

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4. Innovate today to lead tomorrow

Some of the biggest news at ASCO came from some of the smallest companies, such as Loxo Oncology's larotrectinib for rare, TRK-mutated tumors or Incyte's epacadostat, an IDO inhibitor that enhanced immune responses in combination with pembrolizumab. With many emerging competitors like these, and increasing competitive pressure from traditional big pharma companies, it's more important than ever to be proactively planning where and how oncology leaders can win.

Oncology executives should take the same cue: The time to innovate is before you need it. Being competitive today doesn't equate to leadership tomorrow. Investments today in clinical and commercial excellence are essential for oncology leadership in the future. PE

The Cancer-Clues Divide

Pediatric, veterinary oncologists call for more comparative research

For most people, there isn't an immediate connection between pediatric and canine cancer—unless you're an oncologist, or researcher, who works in either of these fields. Then, the similarities are striking.

Pediatric and canine cancer doctors, researchers, health advocates, government officials, and pharma leaders gathered last month in Washington at the first Paws for a Cure Summit, presented by the Canines-n-Kids Foundation, to talk about how they can better work together—in and outside the lab—so that advances can be made in both disease areas.

It was very apparent that those working on both sides of the disease felt a disconnect from other areas of oncology research, funding, and support. In fact, the overall sentiment was that while many large pharma companies have animal health divisions, sometimes even housed in the same building, there is an enormous divide.

As a result, they called on more collaborative efforts within pharmaceutical companies and research institutions. Typically, the human and animal health sides are studying separate molecules. But, as they explained, there are many times that a human molecule could help the animal health side, and vice versa. At the very least, there should be better communications when it comes to comparative research and medicines.

The surprising thing is that the disconnect isn't just with those outside the field of oncology.

"Wait, dogs get cancer? And people pay to treat them?" recalled Dr. Matthew Breen, of the North Carolina State School of Veterinary Medicine, while relaying what becomes a common reaction from other oncologists and doctors. Another common question veterinary oncologists tend to receive from other oncologists is this: "How do you inject the dog with the cancer?"

This brought up an important point that was repeated over and over again throughout the day: Dogs and kids both spontaneously develop a number of cancers, including bone cancer, certain brain and central nervous system cancers, and lymph and blood cancers. Because of this, studying canines with cancer can be extremely beneficial, and could lead to a pediatric cure, or at the very least, better treatments.

"Humans and dogs, we are all animals, just packaged in a different way," said Breen, mentioning the One Health Initiative, a movement to unite physicians, osteopathic physicians, veterinarians, dentists, nurses, and other scientific-health and environmentally related disciplines. "The keys to unlocking some of cancer's most pressing questions are walking right beside us often with four legs, sometimes with three."

Doctors and researchers made it very clear that the pure genetic similarities between humans and dogs make canines with cancer worth studying. In fact, 84% of dog DNA has human counterparts, according to The Genomics Institute. This means humans and dogs suffer many of the same diseases, including most cancers.

One speaker went as far as saying that mice, which need to be injected with the cancer before studying them, are useless when it comes to finding successful treatments.

Studying canines with cancer can be very challenging, however, especially when it comes to clinical trials and testing new therapies. Unlike on the human side, in animal health, the veterinarian is a one-person clinical trial show.

The veterinary oncologist not only recruits the patients, they print out the consent form, collect the tissue samples, mix the drug, administer the therapy, and analyze the results. This can drain resources very quickly.

Money and funding also becomes an issue. Think about this: The animal health insurance industry is still in its infancy, and many plans don't cover cancer treatments. When a dog gets diagnosed, a majority of owners have to pay out of pocket, and as a result, they forego expensive drugs, because they can't afford them. When a human gets cancer, a majority of the time insurance kicks in to cover thousands of dollars' worth of treatments.

From a strictly business point of view, it can be difficult for the animal health side to get funding for research. And, when they do, they may make a great discovery, but the expense to create the drug for animals may not be a wise business decision. This is where comparative medicine and the push for better communication comes into play, as many of those at the Summit believed that if it works in dogs, it could have potential to help humans, especially children. PE

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