Taren Grom

PHARMA 3.0 — The Continuum

Concentrating on patient needs as well as the needs of the other stakeholders integral to a product's success may just be the ticket the industry needs to re-energize its efforts.

As the industry evolves to address a new ecosystem within the complex and global drug development and commercialization arena, companies will need to be open to using new technologies, thinking, and processes to make healthcare more sustainable, affordable, and accessible; improve the efficiency of development to reduce timelines and costs; improve the speed of product adoption; and to realign incentives across all of their business practices.

Analysts say the industry also must ready itself for a third transformative shift, which will come from behavioral changes, as all participants — patients, payers, physicians, companies, etc. — realign their processes to improve health outcomes.

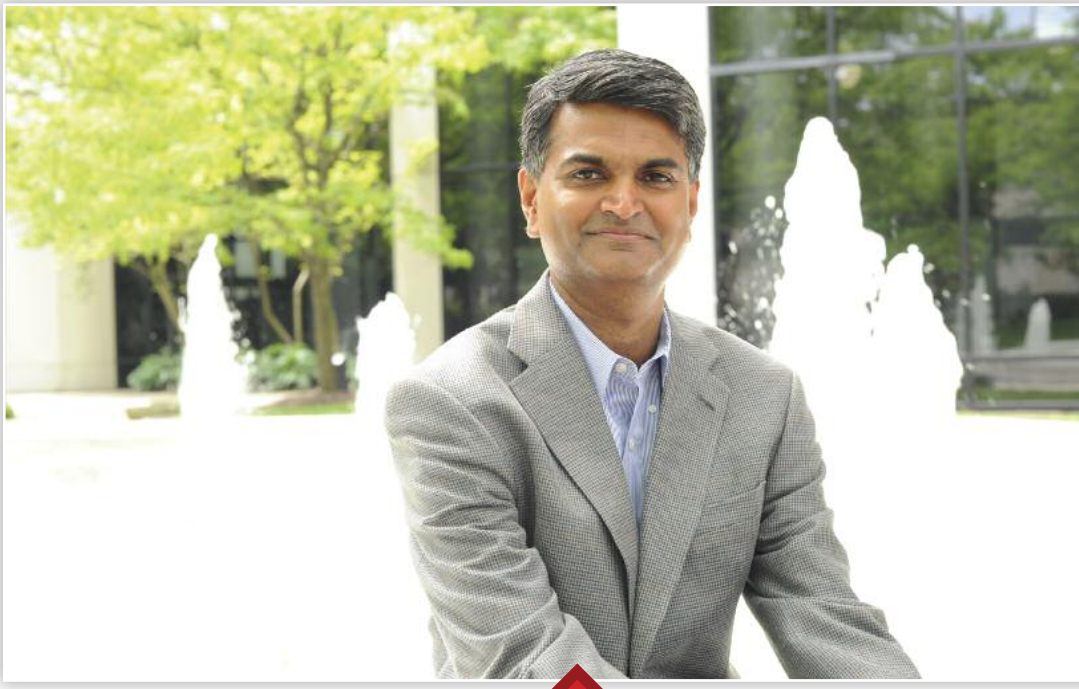
To succeed in a new ecosystem, companies will need to re-evaluate a couple of key areas: collaborating, operating multiple business models, and connecting data throughout the value chain, EY analysts say.

Collaboration: More Important Than Ever

Karla Anderson, partner, advisory pharmaceutical and life sciences practice, PwC, says market collaborations are taking shape in many unique and unprecedented ways within healthcare as traditional players acknowledge the issues are too complex, costly, and diverse to address alone.

"Some of the emerging collaborations, like provider and payer integration, are designed to address fundamental issues that exist in the industry, such as a lack of aligned incentives," Ms. Anderson says. "Other collaborations are being established to leverage leading practices from other industries and apply them in the context of healthcare as seen in the telecommunication and disease management market collaborations that are occurring."

She says another category of valuable market collaboration is where related technologies and treatments join together to impact the market in a more organized and impactful way, for example collaborations between diagnostic testing companies and drug manufacturers.



NAGARAJA SRIVATSAN ▪ *Cognizant*

"The new Pharma 3.0 model makes life-sciences companies both product and services organizations. They not only have to manufacture the drug, but they need to manage its use, effectiveness, and help the patients to better leverage its use."

"Even the significant number of co-promotion and co-development collaborations among pharmaceutical manufacturers in the industry are examples of how going it alone is less popular than ever before," she says. "In all cases these collaborations take effort from the most basic elements of alignment of objectives and expectations to detailed operational processes and controls to make sure the collaborations work effectively and that the true value of the collaboration can be realized. In general, collaborations get a significant amount of focus at the start with a lesser degree of focus over time. There does need to be a more significant investment in making market collaborations effective and sustainable as they are a critical component to the future success of the industry."

Because pharmaceutical manufacturers are in a struggle between having to continue to drive the business on fewer resources — both human and financial — and, on top of that, embrace this new 3.0 business approach, they need to realign resources, pilot, measure, and assess, says Liz Kay, VP, business development, healthcare, Cramer.

"New initiatives take time and resources and everyone can feel the stretch to make it happen," Ms. Kay says. "The best intentions are in place; it is just a matter of planning, timing, and having the resources to move forward as effectively as possible. Innovation needs to be supported throughout the organization as it is not only a strategic pillar of Pharma 3.0, but also a change in behavior. To this end, one of the biggest obstacles to creat-

ing sustainable systemwide innovation is having a champion and education across the organization; leaders need to walk the talk over and over and over again."

Martha Sloboda, business manager, at ARx LLC, says the Pharma 3.0 model is even evolving to the point of influencing how companies are talking about product design.

"A decade ago, companies would come to us at the onset of a project with a predetermined path for integrating a molecule into a delivery platform technology," she says. "Today the conversation is much more open from the start of a project and is first focused on understanding the improved therapeutic outcome followed by evaluating the various technologies available for delivery. Basically, the conversation has evolved to a broader dialogue in which we evaluate the best delivery options, which may include transdermal, sublingual, drug-loaded oral thin films or other specialty delivery methods from our portfolio of capabilities, based on the patient population we are targeting.

"This presents its own challenges in modeling what may add significant value in the delivery space," she continues. "However, recognizing the importance of this approach in the era of Pharm 3.0 positions us to bring our partners a potential stream of improved therapeutic outcomes, whether those outcomes address chemistry, cost, or compliance."

Ms. Sloboda says the concept of how a successful product is conceived is changing.

"Certainly the collaboration aspect is one part of what is changing, but cost pressures also play a role in determining the final outcome of what is deemed a successful project in terms of yield and throughput," she says. "Not only do we have the challenge of formulating the ideal delivery platform, but we also have the opportunity to leverage our manufacturing processes for an improved product outcome from a cost perspective — both at clinical and commercial scales."

Operating Multiple Business Models

Nagaraja Srivatsan, senior VP, head of life sciences, North America, Cognizant, says the new Pharma 3.0 model makes life-sciences companies both product and services organizations.

"They not only have to manufacture the drug, but they need to manage its use, effectiveness, and help the patients to better leverage its use," he says. "This change in the model will make each organization build skill sets that not only deliver the product, but ensure that the use of the product is streamlined all through the process."

JIM WALKER ▪ *Cadient Group*

"A patient-centric approach not only sustains the patient's brand attention forward in time, after the script is written; this approach can also expand patients' brand engagement backward in time."

Neil MacAllister, chief business officer, INC Research and president, AVOS Consulting, says the business models necessary within Pharma 3.0 are stemming from a clearer understanding of evolving pharma portfolios within the total healthcare dollar.

"Today, healthcare payers have the best vantage point on the overall impact on dollars spent across the healthcare spectrum," he says. "In a single payer system it is easier to analyze the data, but in the United States there is a fragmented system with many companies pursuing their own interests. Most pharmaceutical companies do not have a good read on the total spend as they focus only on a small segment of healthcare. We need a better idea of payer interests and an understanding of the clinical and economic evidence to justify further investment.

Mr. MacAllister says for the Pharma 3.0 model to be practical, there will need to be a "mass customization of care."

"This means healthcare payers, together with the biopharmaceutical development industry, must find a balance between individualized care and the economies of scale that make drug development and treatments economically viable," he says. "This balance will be described in terms of patient sub-populations within a disease state, and will vary by therapeutic indication. The implications for effective drug development and optimal commercialization within micro-markets set up a significant change agenda for biopharmaceutical companies."

KELLY GRATZ ▪ *inVentiv Health Commercial Solutions*

"The biggest barrier to fully embracing an outcomes model is the misalignment of economic incentives for the key healthcare stakeholders that need to embrace a new ecosystem of care."

To be successful, metrics and analytics will need to be developed to properly measure the impact of such an approach on the total health spend.

Mr. MacAllister says remote monitoring, for instance, is making analysis much more practical.

"For example, if an asthmatic uses an inhaler or other breathing device with an imbedded Bluetooth connection, the usage of the drug or device can be monitored remotely," he explains. "If the prescribed treatment is not being used correctly, healthcare professionals can step in to contact a patient before a serious problem develops. This approach would save trips to emergency rooms and offer significant savings in the overall cost of care."

Cognizant's Mr. Srivatsan, says the collaborations between payers, providers, patients, and life-sciences organizations are going to redefine how healthcare is going to be consumed.

"Providers are already looking at the cost of

multiple treatment regimens to decide on set playbooks that they can adopt to deliver better health outcomes but at reduced costs," he says. "Payers are already doing their analytics on treatment regimens across providers to establish what are best practices in patient care. The information payers and government agencies are developing will definitely drive pricing and formulary management for life-sciences companies."

This collaborative approach will need to have constant and near real-time feedback to help improve the health outcomes for patients as well as to reduce the overall cost of healthcare.

Nontraditional Partnerships and Players

Many experts say nontraditional entrants will impact business processes across all areas, including technologies, disease categories, and stages of development throughout the cycle of care.

Nontraditional entrants will start to become information intermediaries that can, in near real time bring information across all stakeholders to make sure that all of them have an open and non-biased view about disease states and treatment regimens.

Mr. MacAllister. says the nontraditional entrants, particularly tech and IT companies, are making significant strides and really driving the move to Pharma 3.0.

"These companies are looking for ways to use technology innovation to bridge the gaps between existing systems and are developing new platforms that help these independent facets of healthcare work together," he says "A company may, for example, bridge hospital care to follow-up care — often treated as completely separate under the current system — by using new mobile health platforms that link into electronic medical records. As more technologies come online and more evidence is gathered that this approach saves healthcare dollars, this approach will gain more supporters, including stakeholders willing to fund these approaches and thus gain wider acceptance."

Ms. Anderson agrees that telecommunications companies and specialty technology manufacturers are good examples of nontraditional entrants that are boldly approaching the market.

"The combination of nontraditional entrants with established players that can combine new thinking with established industry knowledge can drive significant innovation," she says. "These nontraditional entrants are creating a disruptive force in the market as they have recognized the significant potential in healthcare. Furthermore, they commonly approach the business issues of healthcare without the biases and constrained thinking that working in a highly regulated environment typically yields. Although they are constrained by the same regulations, there are many cases where they approach the issue in a more innovative manner."

Connecting Data for Improved Outcomes

Kirk Gallion, president, Octagon Research Solutions Inc., sees new business models emerging as organizations contemplate how best to use their information assets.

"Companies that understand the value of metadata and how to leverage it across disciplines and throughout cross-functional processes will continue to leapfrog the companies that struggle to access global information or that still view content and metadata as regional assets," he says. "The key to success will be found in two converging trends: metadata management and IT consolidation.

Moving Toward a Biological Definition of Disease

In 2011, Pieter Muntendam, M.D., executive VP, chief medical officer, BG Medicine, participated in a meeting between the FDA, a leading global pharmaceutical company, and his company. The meeting pertained to a device-drug combination in heart failure. In the opening comments the FDA stated something to this effect: "We should stop approving drugs for heart failure. Heart failure is not a disease. An 8% improvement in a 5,000 patient trial is no longer acceptable. We need to find the subgroups of patients where the drug really works."

"This matching patients and treatments fits the concept of the Pharma 3.0 model, while the drug-centric give-it-to-as-many-as-possible model belongs to the traditional pharma model," Dr. Muntendam says.

The core concept of matching patients and treatments benefits all, including the pharmaceutical manufacturer. It de-risks development, reduces trial size, albeit may increase screening; reduces regulatory risks by offering greater benefit-risk; and supports market acceptance by both patients and physicians of drugs that are very likely to offer a material benefit to well-defined patients, he says.

So What is Holding Us Back?

Let's look at an example. By the mid-1970s the existence of a third viral cause of hepatitis was suspected. After a long and winding road the hepatitis C virus was identified in 1989 at the laboratories of Chiron. The discovery of the virus enabled a new and targeted pharmaceutical approach to hepatitis C. The market for hepatitis C drugs is estimated to grow to $16 billion by 2015. And pharma thought it was an effort to "find the disease in hepatitis."

"In 2006, we launched a similar initiative for heart failure — finding the disease in heart failure," he says. "It had long been known that about half of the common heart failure patients have a disorder of the extracellular matrix. Until that time the blame for heart failure largely focused on the myocyte — the cell that makes the heart muscle contract. We now know that a large portion of heart failure is due to a stiffening of the extracellular matrix that surrounds these contracting cells. As with hepatitis C, we expect that this one day will give rise to a large and profitable pharmaceutical market."


Dr. Pieter Muntendam

There are many similar examples and opportunities. Maybe the Pharma 3.0 model should include pre-competitive collaboration between pharmaceutical companies, diagnostic companies, and maybe even payers and patient advocacy groups to find and validate these new biological definitions so that each of the parties can then pursue the development of their own product candidates to concurrently solve an important need and create a new commercial opportunity.

"R&D organizations must invert the traditional effort-to-value equation associated with metadata management," he continues. "Traditional data entry time and tasks will be replaced by automation and metadata inheritance models that shepherd these information assets through complex processes, minimizing effort while providing needed context and added value. Simultaneously, these organizations are trending toward IT consolidation, which will support the demand for broader and more insightful reporting, while minimizing the need for import, export or re-entry of data between systems. These two shifts will combine to reduce the likelihood of stale or inaccurate information, improve management reporting capabilities and move teams away from maintenance tasks and toward analysis, awareness and understanding of global information."

Gadi Saarony, corporate VP and worldwide head, Parexel Consulting and Medical Communications Services, says more than ever biopharmaceutical companies are faced with the acute need to prove that their products demonstrate value, in addition to safety and efficacy.

"Biopharmaceutical companies need to address commercialization goals as early as possible to develop products and acquire the right data to receive reimbursement approval in the most efficient way," he says. "The focus is to prepare the product for the market and the market for the product through the alignment and integration of regulatory, clinical, and commercialization strategies. This way, products can be optimized for efficient development and regulatory approval, as well as to achieve commercial success."

Kelly Gratz, president, inVentiv Health Commercial Solutions, says by focusing on health outcomes, the whole market reaps the rewards.

"However, to first understand what's best for the customer, the industry must focus on better analyzing and using data to drive the entire commercialization process," she says. "To do that, we need to continually tweak all aspects of commercialization to help optimize product value and, at the end of the day, to ensure better patient outcomes. And one of the key factors involved in building a successful model is data analysis, another is asking ourselves the right fundamental questions."

For example, Ms. Gratz says there is a need to evaluate if the right analysis of the brands and their sales and marketing activities is being done by taking into account therapeutic differentiation, the product patent situation, as well as understanding customer and patient types.

"Essentially, it's all about understanding data to design an optimal model, one that ensures pharma is commercializing its products in a way that maximizes health outcomes, and ultimately the patient experience," she says. "Within this continuum, the model must also recognize the vast number of players involved to transform the model effectively. We can't attack just one aspect. Everything needs to work cohesively together."

Evaluating New Commercial Strategies

Eric Pauwels, senior VP and chief commercial officer, at NPS Pharmaceuticals, says because each stakeholder has its own unique set of needs, structuring a commercial strategy that's as burden-free and as minimally cumbersome as possible for patients and healthcare providers can help enable companies to best meet the needs of their stakeholders.

"For payers, it's important to characterize the burden of the disease and value that the product offers to the healthcare system from a direct cost and a societal perspective," he says. "For physicians, communication channels need to be in place to make sure the feedback loop continually goes from patients to physicians. Feedback is a key component of knowing if the product is meeting expectations and if patients are seeing benefits with treatment. For patients, care coordinator and reimbursement support services can be implemented to help ensure proper use of pharmaceutical products and manage ongoing access challenges and expectations."

Ms. Gratz agrees how data are communicated is key to the success of a Pharma 3.0 model.

"While only about 10% of the U.S. population is above the age of 65, they consume approximately 35% of total U.S. personal health care expenses," she says. "Therefore, the industry can't alienate such an important segment by only relying on digital communication channels. Rather, new forms of communication via mobile devices, apps, and interactive websites must be effectively integrated with traditional media channels to reach all patients.

"We keep hearing about mobile and digital technologies, but at the end of the day, it's still all about effectively communicating and supporting customers, wherever they are," Ms. Gratz continues. "The market continues to evolve, as does the customer base. As a result, the number of channels available is increasing and we need to identify the consumer of information, how they want to receive it, where they want to receive it, and how to make that information useful for them. The dialogue has become multi-faceted, and clearly our approach to commercialization must support that."

KIRK GALLION ▪ *Octagon Research Solutions*

"Companies that understand the value of metadata and how to leverage it across disciplines and throughout cross-functional processes will continue to leapfrog the companies that struggle to access global information or that still view content and metadata as regional assets."

Jim Walker, director of emerging trends, Cadient Group, says there are several areas where social networks and social insights can be leveraged for greatest impact, in terms of both patient outcomes and overall business results.

"The most obvious impact area is patient compliance," he says. "Contrary to popular understanding, compliance does not begin when patients first get their script. This is because patients have already been searching for information about their condition before getting a script and have formed preconceived notions about the importance, or lack thereof, of being compliant. Thus, as the industry moves toward a more patient-centric model, the importance of 'using the product as prescribed' becomes paramount. Tactics to influence compliant behavior should be woven into core online brand messaging, carried into patient-physician educational materials, and then reinforced via intuitive digital reminders that can be received through a variety of channels. Not only does this make good business sense for both pharmaceutical companies and payers, but, more importantly, this approach makes for improved outcomes."

Mr. Walker says a patient-centric approach not only sustains the patient's brand attention downstream, after the script is written; this approach can also expand patients' brand engagement upstream — with patient insights helping to inform product decisions very early in the drug development process.

"While patient insights can still be gathered in traditional focus groups, the range and breadth of social networking sites now make them a powerful resource to help inform a

GADI SAARONY ▪ *Parexel*

"Biopharmaceutical companies need to address commercialization goals as early as possible to develop products and acquire the right data to receive reimbursement approval in the most efficient way."

firm's product development and packaging and its understanding of which indications are sought," he says. "The commercial insights gleaned from social resources can have tremendous impact on the overall market share of a product once it gets to market."

Mr. Pauwels says for orphan drug companies, in particular, collaborations in the area of health outcomes will continue to be important given the higher costs of these therapies.

"Because clinical trials for orphan drugs are small, traditional pharmacoeconomic data are often challenging to generate," he explains. "Companies can collaborate with healthcare providers and scientists in centers of excellence to conduct natural history studies to characterize the burden of illness before orphan drug launches, and then compare the data in a registry database postlaunch. Generating patient-reported outcome data pre- and postlaunch helps drive the value proposition and demonstrate to physicians and payers that the drug can make a profound impact on the quality of patients' lives."

Collaborating with patient advocacy groups will also continue to be important for companies such as NPS Pharmaceuticals that focus on developing orphan products for rare disorders.

These advocacy groups help educate and provide information in an unbiased manner to the patients, caregivers, and their families who desperately need treatments.

"As is the case with any collaboration or partnership, the objectives and deliverables need to be well-defined and each party has to be committed to robust communication and mutual respect," Mr. Pauwels says.

Although there has been significant focus on moving to an outcomes-based approach to improve healthcare and demonstrate value, the reality is very challenging," Ms. Anderson says.

"Establishing a fair and measurable approach to demonstrating outcomes and aligning those outcomes to the perceived value across customer segments represents a significant effort," she says. "The opportunity lies in establishing the operational elements to make outcomes measurement defined in the context of how care is delivered and how healthcare funders and payers measure value. Philosophically, there is alignment but when it comes to designing and executing a performance-based approach to the market the details of implementation often sidetrack the effort. The more effort placed on market collaboration across segments and addressing the practical issues such as alignment of incentives and sharing of data, the more likely this will become a reality." PV

USE YOUR QR CODE READER OR GO TO bit.ly/PV0312-Pharma3

EXPERTS

KARLA ANDERSON. Partner, Advisory Pharmaceutical and Life Sciences Practice, PwC, which provides industry-focused assurance, tax and advisory services to build public trust and enhance value for its clients and their stakeholders. For more information, visit pwc.com/us/pharma.

KIRK GALLION. President, Octagon Research Solutions Inc., which specializes in transforming clinical R&D through an integrated suite of regulatory, clinical, process and technology solutions. For more information, visit octagonresearch.com.

KELLY GRATZ. President, inVentiv Health Commercial Solutions, inVentiv Health, a provider of clinical, commercial, and consulting services to healthcare clients worldwide. For more information, visit inventivhealth.com.

LIZ KAY. VP, Business Development, Healthcare, Cramer, which specializes in developing and delivering innovative marketing solutions. For more information, visit crameronline.com.

NEIL MACALLISTER. Chief Business Officer, INC Research, a global CRO providing the full range of Phase I to IV clinical development services, and President, AVOS Consulting. For more information, visit incresearch.com.

ERIC PAUWELS. Senior VP and Chief Commercial Officer, NPS Pharmaceuticals, a specialty pharmaceutical company. For more information, visit npsp.com.

GADI SAARONY. Corporate VP and Worldwide Head, Parexel, Consulting and Medical Communications Services, a global bio/pharmaceutical organization providing a broad range of contract research, consulting, and medical communications services to the pharmaceutical, biotechnology, and medical-device industries. For more information, visit parexel.com.

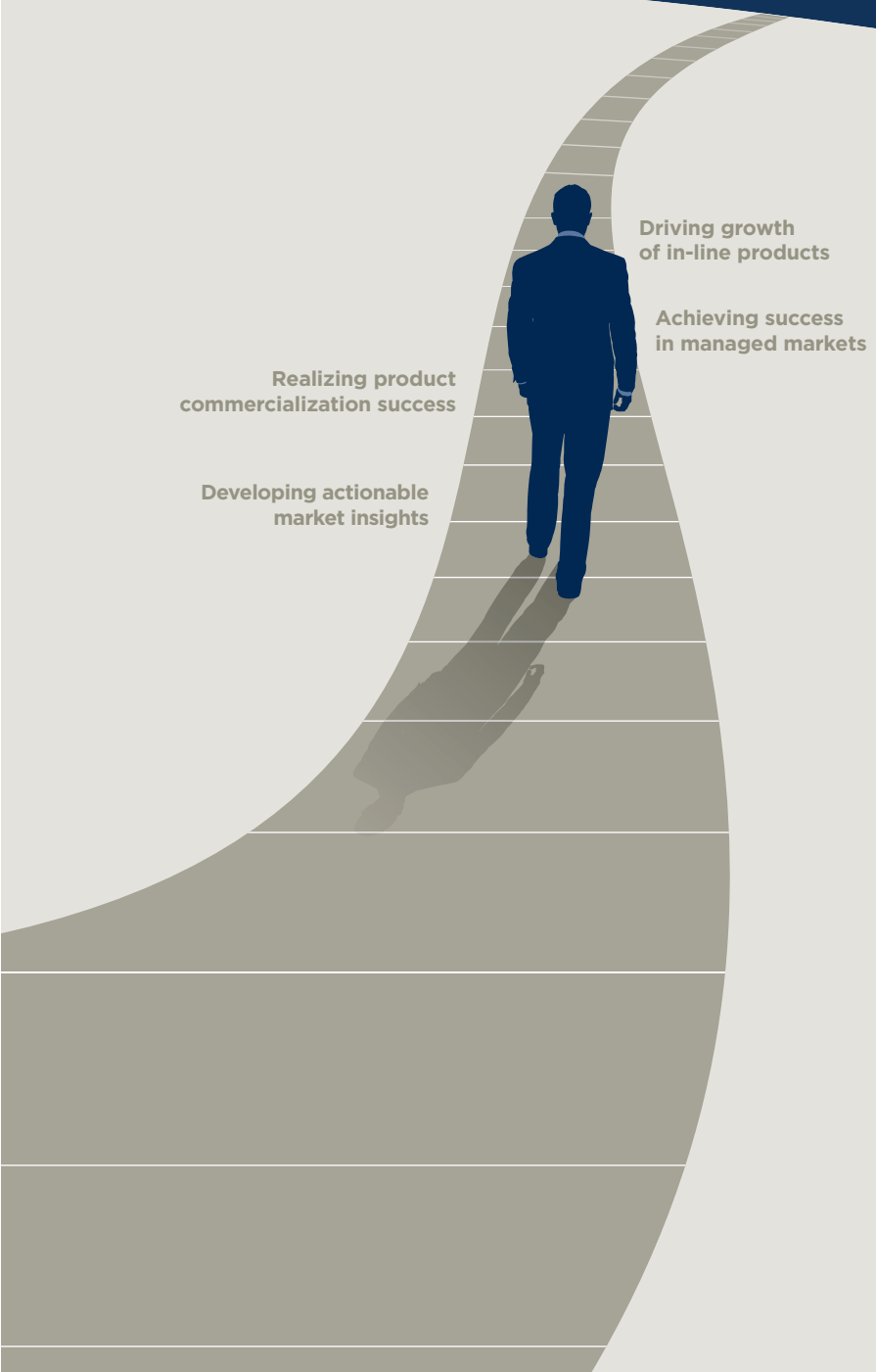
MARTHA SLOBODA. Business Manager, ARx LLC, a wholly owned subsidiary of Adhesives Research Inc., which develops and manufactures pharmaceutical products with a focus on unique technologies in oral, topical, and transdermal drug delivery. For more information, visit arxllc.com.

NAGARAJA SRIVATSAN. Senior VP, Head of Life Sciences, North America, Cognizant, a global provider of information technology, consulting, and business process outsourcing services. For more information, visit cognizant.com.

JIM WALKER. Director of Emerging Trends, Cadient Group, a digital healthcare marketing agency serving a diverse range of industry markets and stakeholders, including pharmaceuticals, biotechnology, medical devices, hospital healthcare systems, institutions, and associations. For more information, visit cadient.com.

A CONSULTING FIRM

IN STEP WITH YOUR NEEDS



Promidian is a management consulting firm that is focused on the pharmaceutical and biotechnology industries. We combine deep industry and functional area knowledge with specialized expertise in market assessment, analytics, and strategy development—to assist life sciences executives in addressing their most pressing business challenges.

For more information on Promidian, please contact Kevin Barnett at 646-571-2414 or kbarnett@promidianconsulting.com.

www.promidianconsulting.com

PROMIDIAN

Market Insight › Strategy › Results

An Access Group Company

PHARMA 3.0: A Manufacturer's Perspective

Ryan Saadi, M.D., World Wide VP, Health Economics, Reimbursement, and Strategic Pricing, Cordis Corp., provides his insights on the complex topic of Pharma 3.0.


Dr. Ryan Saadi

Despite Pharma 3.0's complexity, it is extremely critical that manufacturers communicate in a manner that will resonate and foster required changes.

The perspective of Ryan Saadi, M.D., world wide VP, health economics, reimbursement, and strategic pricing, at Cordis Corp., is that of a medical device manufacturer, and with an emphasis on the realigned customer-base and ensuing new evidence requirements.

Although occurring more recently, the challenges and required solutions for devices mirror what has been ongoing with pharmaceuticals. Changes in both sectors are being driven by the need for governments across major markets to control unsustainable, rising healthcare costs. For devices, evidence and experience indicate that much like pharmaceuticals, companies will need to reinvent their business models to operate more efficiently in a changed marketplace. Essentially, the key ongoing challenge will be to identify and communicate product value in a manner that is meaningful and compliant with evidence needs of customers who are increasingly striving to balance the optimization of population health with affordability.

Historically, a healthcare product primarily faced regulatory hurdles, for example, demonstration of efficacy and safety, to achieving market access. Both the pharmaceutical and medical device industry generated success based on the principle of creating innovative, safe and effective products and marketing them to physicians that would generate demand among prescribers, patients, health plans, and hospitals. However, a growing demand for reducing healthcare expenditures has resulted in new hurdles to product adoption and market success. Now, healthcare payers have taken a central role in cost containment and act as gatekeepers of access to approved products. For pharmaceuticals, payers control product access through product formulary rules, for example, product exclusion, restriction, or tiering. For devices, budget reductions by payers translate into hospitals limiting the number of products available to physicians. A recent global survey of medical device and diagnostic companies revealed that more than 40% of executives no longer view physicians as the primary customer; rather, other customers — hospital procurement, public and private payers, patients — are increasingly becoming more important. It is therefore essential that manufacturers understand these new customers and the metrics they are using to assess product value.

Identifying what constitutes value to these new customers and distinguishing a product based on that definition of value is integral to market success. A critical component of value assessment is that it is comparative. Key questions relevant to a healthcare payer for instance, may include: is the product better than current treatment; is the higher price justified by the comparative clinical benefit; and is the new product affordable given the target population and price?

To generate positive answers to these questions for new products, the manufacturer needs to understand the unmet value need, generate the required evidence, align price with value, and then communicate that value to decision-makers. Unmet need includes clinical gaps in care, as well as humanistic requirements. Reimbursement by payers across regions globally has become less dependent on regulatory approval but increasingly requires evidence beyond efficacy and safety, such as resource efficiency, patient health outcomes, and improvement in physician decision-making. Furthermore, a substantial need exists for comparative effectiveness data. The highly competitive nature of device markets limit the conduct of randomized trials that include all relevant comparators; therefore, demonstration of a product's incremental benefit requires alternative methods, such as database analysis, indirect treatment comparisons, and modeling. Aligning price and value requires an understanding of value-for-money, which addresses whether a product is worth the added cost. This is an integral value concept that involves new and evolving metrics and evidence requirements. Finally, as a result of expanding evidence requirements and budgetary constraints, the complexity of the decision-making process has increased. For medical de-

13th Annual

IMMUNOGENICITY for Biotherapeutics

The largest and longest-running event devoted to designing reliable assays and safer molecules, and setting industry-leading strategies to ensure the safety of follow-on biologics

APRIL 17-19, 2012 • HYATT REGENCY BALTIMORE • MD

Insights from leading minds in Immunogenicity:

AMY ROSENBERG, PhD
FDA

Michel Awwad, PhD
PFIZER

Harald Kropshofer, PhD
F. Hoffman La ROCHE AG

Xiao-Yan Cai, PhD
MERCK

All new themed sessions focusing on:

- Predicting immunogenicity through a better understanding of its underlying causes
- Clinical assay design, implementation, and troubleshooting
- Preventing immunogenicity through advances in protein engineering and tolerance induction
- Breakthroughs in immunogenicity considerations for biosimilars and biobetters

INTERACTIVE UPDATE Panel on FDA regulatory guidelines:

Do you have questions about the regulatory criteria for cell-based NAb testing, or the expected methods of following-up after positive immunogenic results?

Pre-registrants will have the opportunity to submit their questions in advance!

Moderator: Darshana Jani, PhD, **BIOGEN IDEC**
Panelists: Susan Kirshner, PhD, **FDA**
Laura Salazar-Fontana, PhD, **FDA**

Register using discount code **P1738PVAD** for a special **25% discount!**

www.immunogenicityevent.com

RADICAL INNOVATION

Industry experts provide their insights on what radical innovation means to the industry.

KARLA ANDERSON is Partner, Advisory Pharmaceutical and Life Sciences Practice, PwC, which provides industry-focused assurance, tax and advisory services to build public trust and enhance value for its clients and their stakeholders. For more information, visit pwc.com/us/pharma.

"In some parts of the business, radical innovation is required to impact growth; however, in other areas more incremental, sustainable innovation may help transform the business. The real challenge from PwC's perspective is that since so many aspects of the business need to change simultaneously, the amount of change collectively feels radical. If business transformation only needed to happen in a few areas it would not be nearly as daunting as it is. Because change needs to happen so broadly across organizations and the overall business is more challenging than ever, the most difficult element is the ability to drive meaningful, sustainable change in a reasonable time period and simultaneously run a successful business."

NEIL MACALLISTER is Chief Business Officer, INC Research, a global CRO providing the full range of Phase I to IV clinical development services across six continents, and President, AVOS Consulting. For more information, visit incresearch.com.

"Existing players have aligned their business models and strategies to the historically fragmented or siloed approaches and structural features of the healthcare environment. In this context, change and especially dramatic change is both difficult and costly for these players. The challenge is that each step of the value chain is tied to a different structure. This has to be addressed, otherwise advancements are just small steps in improving segmented systems. Absent a big change in the overall healthcare structure it may be too much to overcome. Payers will have to drive the move to Pharma 3.0, shifting the economic incentives to track patients over the longer term and becoming more invested in their health as opposed to just their treatment. Product innovation alone will not get us there, it will require changes to the structure of the healthcare industry itself."

AUDREY SLOOFMAN is a Consultant with Insigniam Performance, a global management consulting firm with a proprietary methodology for enterprise performance transformation and catalyzing breakthrough results. For more information, visit insigniam.com.

"Einstein famously said, 'We can't solve problems by using the same kind of thinking we used when we created them.' The model that built a successful pharmaceutical industry is insufficient to resolve the problems and challenges it is confronted with today. Radical innovation is necessary when faced with corporate gravity — that vital, defining, invisible force that prevents employees from venturing too far beyond the company's current business model. Corporate gravity hinders innovative thrust, that natural desire for discovery and invention that human beings naturally possess. Today's most successful pharmaceutical businesses are held in place by corporate gravity — limited by current realities, networks of conversation, deeply held beliefs, and unexamined assumptions that masquerade as facts. Add those forces into the enterprise immune system of internal corporate systems and procedures that protect the business model from any real or perceived threat presented by the forces of change and you have a mandate for disrupting business as usual. The model that got you here will not get you there. Only radical innovation will provide the opening for imaginative, new solutions, the unthinkable. Radical innovation begins with the human factor. Technology, capital, processes, and other hard assets have a significant impact on business success and failure, but unless the people in the organization think and act differently none of these can successfully lead to innovation.

All performance comes down to the effectiveness of individuals and groups. The access organizations have to radical innovation is through impacting the performance of the individuals and groups. Radical innovation requires a fundamental shift in thinking and approach. It requires a commitment to producing specific, measurable, and unprecedented results, results that defy historical trends and industry norms, and are

vices, hospitals have adopted several systems to control escalating costs, such as technology assessment committees (TACs) or value analysis committees (VACs) to consolidate and standardize purchasing decisions. Such measures are comparable on some level to the ever-expanding use of health technology assessments (HTAs) to inform pharmaceutical reimbursement. In essence, for device and pharmaceutical manufacturers alike, marketing needs have shifted from acquiring physician interest to understanding and generating the entire value proposition for a product and communicating it effectively to all relevant audiences.

A New Reality

Given this new reality, market success may be threatened if company strategies and processes are not adapted to meet these changing demands. Accordingly, manufacturers must understand the perspectives of their new customers and adapt to their requirements in order to achieve product adoption. This includes consideration of the needs of patients, an increasingly knowledgeable group of consumers that bear a direct impact on decision-making on a variety of levels. At the same time, manufacturers must maintain the required level of product awareness among physicians, who are now typically considering economic data in addition to effectiveness and safety. Given the changed demands across the customer base, manufacturers need to build structures that foster innovative thinking and synergistic outputs. Specialized skill-sets must be acquired to generate, articulate, and communicate evidence-based clinical and economic value within health economics and outcomes research functions. Strategic pricing needs to be involved in translation of such evidence into "right price." If the relationship between price and benefit is appropriate, not only will reimbursement be ensured, the common mistake of under pricing and related financial loss will be avoided. Therefore, the functions of health economics, strategic pricing, and reimbursement groups cannot be contemplated as separate entities. Rather, they must collectively fall under a single umbrella with the purpose of achieving the key goal of successful market access. PV

Editor's Note: A more detailed discussion surrounding the evolution of the medical device industry, the challenges to market success, and the recommended strategies and solutions for manufacturers to thrive in this new environment will be available shortly in an upcoming book entitled "The Science of Commerce: Succeeding in the Changed Medical Device Market" written by Dr. Ryan Saadi with colleagues D. Grima and N. Ferko. The focus of this book is the identification and communication of product value in an environment where achieving such is essential to market access success.

unfettered by current resources or circumstances. Radical innovation requires breakthrough thinking that includes upfront commitments and can be achieved in a sustainable manner without sacrificing quality, integrity, safety, or well-being.

What does it take to create this radical innovation that leads to extraordinary, unprecedented results? Many of the pharma businesses operating on the cutting edge are implementing a powerful methodology that disrupts their current thinking and provides the innovative thrust needed to shatter the corporate gravity that challenges them. This methodology is composed of four basic stages: reveal, unhook, invent, and implement. In the reveal stage, individuals and groups identify beliefs and assumptions that shape the way people in the organization think, act, interact, approach problems, and produce results. These prevailing beliefs and assumptions are influential until they are recognized as just one possible viewpoint among many. Once these limitations are revealed then the individuals and groups can disengage or unhook from them and are freed up to invent new ways of thinking and acting. This increased ability to discern the facts allows people to see new opportunities for action, to invent, and to drive those actions to achieve the desired results. In this stage, people change their actions from being circumstantially based to being commitment-based.

Finally these innovative opportunities are implemented. In the implement stage people design and execute appropriate structures, ways of operating, and practices that deliver results that had been considered unlikely or even impossible."

JENNIFER ZIMMER is a Consultant with Insigniam Performance, a global management consulting firm with a proprietary methodology for enterprise performance transformation and catalyzing breakthrough results. For more information, visit insigniam.com.

"One pharmaceutical company was challenged by a slow, linear approach to its Phase III development process. It was costly on all levels. This group of dedicated and talented employees was constrained by their corporate gravity and was unable to generate radical new solutions. They were introduced to an innovative methodology that challenged their deeply held beliefs and unexamined assumptions, and unleashed their innovative capacity. They recognized that the conversations they were engaged in as an organization had to be altered if they were to open their minds to new solutions. They began to recognize that the thinking and conversations about what might be possible — or not — had to be questioned with a new mindset. These individuals loosened their grip on all they held sacred. They learned and applied a set of unique skills and tools that enhanced their creativity individually and as a team.

Questioning the practices and processes they had always counted on, they began to generate and institutionalize drastically innovative approaches. Using the breakthrough methodology of reveal, unhook, invent, and implement, this group was able to question the established internal corporate systems and procedures that were designed to protect the corporate immune system. Their corporate immune system had to be disrupted if they were to invent a radical new approach.

During this process those involved began to recognize the self-limiting thinking and behaviors that were harnessing their capacity to think differently. Once they were able to question what they had as rock-solid reality, these individuals easily let go of their attachment to the familiar ways of doing things, and experienced a renewed freedom to explore new, creative approaches that were not based in the past, but created as an inspiring possibility. The passion for their new, innovative approach released a freedom to take risks leading to a dramatic acceleration of new drug development from last patient visit to NDA submission. This human performance methodology has been successful in various phases of drug development. One pharmaceutical company discovered how to achieve FDA drug approval 20% earlier than it had predicted possible. Another pharmaceutical group captured 57% of the U.S. market, beating the analysts' global forecasts by 12% to 30%.
This group had been attempting to launch a new product effectively against a competitor's product launched two years earlier in the United States. They were at a loss about how to catch up to and beat the competition. Once the breakthrough methodology was applied, solutions flowed, passion drove committed actions and unencumbered thinking and communications generated new, innovative practices and procedures."