

# Facing *the Industry's* Challenges

The PharmaVOICE 100 honorees discuss the challenges facing the pharmaceutical industry, from maintaining innovation to global regulations to reimbursement issues.

**I**nnovation continues to be a challenge in the pharmaceutical industry," says Dominic Behan, Ph.D., chief scientific officer and executive VP of Arena Pharmaceuticals.

"If we are going to address unmet medical needs, we must bring new innovative products to market," he says. "The industry tends to gravitate toward lower risk targets due to the significant investment of bringing products through clinical trials and to approval. This challenge needs to be addressed by using cutting-edge technologies and expertise to access truly unique targets, and by applying innovative strategies early in the clinical trial process to assess likelihood of success. By doing so, we have the opportunity to bring novel treatment options to patients."

The way that companies develop drugs is fundamentally wrong, says Christian Behrenbruch, Ph.D., CEO of ImaginAb.

"We have a huge arsenal of drugs that could be deployed, but we have artificial regulatory and commercial barriers," he says. "Regulations are no longer in tune with the way in which we understand biology and the way in which we tackle medicine — in fact they even induce us to run expensive clinical trials that statistically don't work. Medicine is broken as a consequence of that. We have superb treatments that don't get given to patients because of commercial dynamics around prescription and reimbursement, for example, in the radiopharmaceutical industry, Bexxar. We basically no longer have a healthcare system where we optimize the standard of care relative to the capabilities we have."

The economics around innovation are going to be critical, says Rachel King, president, CEO, and co-founder of GlycoMimetics.

"There is a need to manage the overall cost of the system and, at the same time, support innovation," she says. "It's clear that for companies like ours and other biotech companies, we have to compete with a lot of other investments to get the funds to support programs. We have to have economic incentives in place that are going to continue to make it possible

to invest in innovation, which is expensive, risky, and time intensive."

Jay Udani, M.D., founder and CEO of Medicus Research, says the biopharma industry seems to be driven by fear rather than vision.

"There was a time when things came easy and there was less competition," he says. "In a world of increasing competition and shrinking margins and where all the low-hanging fruit have been taken, the ability to grow and innovate is harder because companies are looking to hold onto what they have rather than take risks."

The need to evolve existing business models is significant, says Ann Mohamadi, managing director, pharmaceuticals and life-sciences for PwC.

"In some companies, the drastic and immediate change has resulted in some people becoming a bit stifled," she says. "There's a certain level of fear and uncertainty. The ability to think more innovatively, out of the box, and in a non-traditional manner is going to be critical. There is a need to innovate and dramatically change current business models, accept change, and respond accordingly."

Innovation on the development side is lagging as well, says Kent Thoeleke, executive VP for scientific and medical affairs at PRA.

"There are some great companies operating in a virtual model that make decisions very quickly," he says. "On the clinical side, we need to figure how to move faster."

Amy Ellis, co-founder and chief strategy and marketing officer at MedAvante, says there is a lack of alignment within large pharma organizations.

"Individuals work in silos defined strictly by their role, and their personal success is defined by departmental objectives that don't add up to the success of the organization's mission," she says. "For the industry to achieve its mission and develop the drug treatments to address the unmet medical needs of the approaching demographic tsunami, all the organization's human resources need to be laser-focused against a clearly defined motivating

mission. Company managers should prioritize the alignment and coordination — across and within functional groups — of their individual employee's incentives to achieve the corporate mission."

## Technology Trends Impacting Pharma

**Accenture has identified six cross-industry technology trends that will influence the life sciences over the next three to five years:**

- 1. Context-based services.** Where you are and what you are doing will drive the next wave of digital services.
- 2. Converging data architectures.** Rebalancing the data architecture portfolio and blending the structured with the unstructured are key to turning data into new streams of value.
- 3. Industrialized data services.** The ability to share data will make it more valuable but organizations will need to rise to the challenge of managing it differently from the past.
- 4. Social-driven IT.** Social will move well beyond a bolt-on marketing channel to being an integral enabler of the next generation of collaboration for life-sciences companies both within their organizations and outside as part of the broader life-sciences ecosystem.
- 5. PaaS-enabled agility.** The maturing platform-as-a-service (PaaS) market will shift the emphasis from cost-cutting to business innovation, supporting rapid evolution for business processes that need continual change.
- 6. Orchestrated analytical security.** Organizations will have to accept that their gates will be breached and begin preparing their second line of defense — data platforms — to mitigate the damage caused by attacks that get through.

Source: Accenture

Tim Davis, co-founder and CEO of Exco InTouch, says the pharma industry tends to put up barriers toward change.

"There is institutionalized processes; organizations tie themselves up in knots applying guidelines and processes that are no longer applicable," he says.

Companies, especially biotech companies, are challenged by the length of time that is required to go from a product concept to an approved drug, says John Mendlein, Ph.D., executive chairman and CEO of aTyr Pharma.

"Biotech companies need to figure out multiple ways of funding their R&D efforts," he says. "One part of the equation is great science translated into meaningful medicine. Another part of the equation is how to finance the different costs of capital, that journey from product concept to product launch."

He says executives at biotech companies spend a lot of time thinking about how to fund that journey at different steps and that becomes a very critical function of what they do.

"There is no recipe for this, in my mind," Dr. Mendlein says. "Therefore, biotech executives spend quite a bit of time thinking about how to arrange the chess pieces and play out the match to create the best benefit, not only for patients, but for shareholders."

John Guarino, executive VP, managed markets and global payer access, at Palio+Ignite, says there is a scarcity of financial resources in the industry.

"The patent cliff has moved billions of dollars from manufacturers to payers and patients," he says. "But innovation is constantly driving newer and more expensive therapies. The conversation is shifting from cost to value; marketers and agencies need to shift their approach. Before it was enough to create a campaign that identified the key differentiators of a product and motivated behavioral change for physicians, now there are many more stakeholders who are trying to influence which products are used, and clinical benefit is only one of the factors they are evaluating. I work on the managed markets side of our business and we have been thinking about this data-driven, informed approach to decision making for some time, but brand-side marketers struggle with this type of decision making. Data, economics, and value are the information that will win the day in the future. Being great at things like comparative effectiveness, data visualization, and value modeling are the new skill sets agencies will need to have."

There is a shift in the healthcare landscape

from volume to value and patient outcomes are in the spotlight, says Jessica Brueggeman, VP, health behavior group, at MicroMass Communications.

"In light of this, helping patients change their behavior to improve disease self-management is critical," she says. "Medical treatment alone cannot achieve the needed outcomes in chronic disease. Medical treatment becomes more effective and efficient when paired with a behavior change solution."

But, Ms. Brueggeman says, solutions within our landscape today are too product-centric and focus on standard marketing and awareness strategies, disseminating information to help provider and patients change behavior.

"Driving lasting changes in health behavior requires more than information alone — it requires building skills and motivation for change," she says. "Pharma and the broader healthcare industry need to look beyond product claims and technology to be relevant in today's landscape."

This shift from being product-centric to patient-centric and focusing on health outcomes will require collaboration with nontraditional business partners, such as technology and consumer- and patient-based organizations to im-

pact those outcomes, says Kim Ramko, Americas advisory life sciences leader at EY.

## Healthcare Trends

The healthcare industry is undergoing many significant changes, from changing reimbursement paradigms to healthcare reform, our honorees say.

The underlying structure of the healthcare system as it exists today is inadequate to the task of providing competent, acute care, access to the most beneficial therapies and interventions, as well as effective, comprehensive preventive care, including continuously advancing diagnostics, says Walter Capone, chief operating officer at The Multiple Myeloma Research Foundation.

The pace of change in healthcare is huge, says Sharon Presnell, chief technology officer of Organovo.

"There have been economical and reimbursement issues for the types of products that were trying to bring forward for patients," she says. "Whether its a drug or a tissue product, there are a lot of changes in the way they will be regulated, the way they will be advanced clinically, and the way they will be reim-

## SOUND BITES



### AMY ELLIS

MedAvante

To achieve its mission and develop the drug treatments to address the unmet medical needs of the approaching demographic tsunami, all organizations' human resources need to be laser-focused against a clearly defined motivating mission.



### JOHN GUARINO

Palio+Ignite

Innovation is driving newer and more expensive therapies. The conversation is shifting from cost to value; marketers and agencies need to shift their approach.



### JAMIE HEYWOOD

PatientsLikeMe

The emergence of new human networks and the reduction in the cost of de-novo discovery technologies combined will redefine health, illness, and treatment at a pace that is unimaginable today.



### RACHEL KING

GlycoMimetics

There is a need to manage the overall cost of the healthcare system and, at the same time, support innovation.



### ANN MOHAMADI

PwC

The ability to think more innovatively and in a nontraditional manner is going to be critical. To drive future value and meet the needs of new stakeholders there is a need to evolve existing business models, accept change, and respond accordingly.



### DARIK VOLPA

Understand.com

Healthcare as we know it will be largely unrecognizable in five to seven years. Speed and agility will become even more important in the years to come.

bursed. I think that's a big challenge for any emerging technology today. There's not a trail forged for many innovative technologies, so the challenge is in how to fit these novel products into the existing and emerging paradigms of healthcare and reimbursement."

### Challenges Facing the Pharma Industry

The PharmaVOICE 100 honorees came up with a list of challenges the industry is facing, including:

- » Patent cliff and generics
- » Changing delivery of healthcare
- » Keeping up with technology
- » Industry's lost sense of purpose
- » A risk-adverse management style
- » A focus on short-term gain instead of longer-term transformation ideas
- » Achieving capital efficiency in the drug development process
- » Increased legislation, including the Sunshine Act and the Affordable Care Act
- » Increased transparency
- » Increased regulatory oversight
- » Impact of increasing costs on developing new life-saving drugs
- » Lowered reimbursement, pricing pressure, and access to medications
- » A shift from a provider-focused business model to a patient-focused business model
- » A negative perception of the industry
- » Lack of innovation and the need for therapies for resistant and more challenging diseases
- » An economic environment that is limiting investment in true innovation and scientific risk-taking
- » A lack of open collaboration and data and resource sharing between public and private organizations
- » Lack of R&D productivity
- » Ineffective processes for discovering and developing new products
- » Recruiting patients for clinical trials
- » Unsustainable cost models
- » Product safety
- » Finding and keeping top talent
- » Patient noncompliance
- » Globalization

Andrea McGonigle, managing director, life-sciences, at Microsoft says the need to lower the cost of healthcare across the board is a challenge facing the industry today.

"For years, each healthcare and life-sciences vertical was able to stay in its own silo and look at issues at a departmental level," she says. "We now need to partner across pharma, providers, plans, health and human services in both commercial and public sector. The only way to look at the problem is to do so through the lens of the patient and look at how we provide high-quality results at a lower costs and have healthier consumers across the board. Patients are demanding this."

Darik Volpa, CEO of Understand.com, says there is so much change in the industry happening quickly.

"Healthcare as we know it will be largely unrecognizable in five to seven years," he says. "Speed and agility will become even more important in the years to come."

One of the biggest challenges in healthcare is reform, says Steven Collis, CEO and president, of AmerisourceBergen.

"The Affordable Care Act is a very complex legislation," he says. "We have to look at how it's going to be implemented as we approach 2014 and consider the impact of new Medicaid patients and the commercial and public exchanges on employers, patients, and our customers," he says. "One of the big challenges for the system will be to set fair and adequate reimbursement for our customers going forward with a even more challenged healthcare expenditure environment. Another area to consider is how specialized programs and more specialized drugs that are unique to a patient's specific tumor type are going to be paid for. In an increasingly global world, how much disparity in pricing should there be on pricing for clinically differentiated products in different markets?"

The Affordable Care Act (ACA) is set to begin enrolling patients in October 2013 with coverage and full implementation of the law beginning in January. When fully implemented, the law will expand coverage to an estimated 27 million previously uninsured Americans and ensure the availability of affordable comprehensive coverage through traditional employer-sponsored insurance and new health insurance marketplaces or exchanges.

According to information from the White House, there are signs that the ACA has started to slow cost increases and improve the quality of care through pay-for-performance programs, strengthened primary care and care

coordination, and pioneering Medicare payment reforms.

For 2014, PwC's Health Research Institute (HRI) projects a medical cost trend of 6.5%, which is lower than what is expected for 2013.

Rick Keefer, president and CEO of Publicis Touchpoint Solutions, says the ACA will impact the market dramatically and in ways we may have not fully anticipated yet.

"Many formerly uninsured patients will be flooding into the healthcare marketplace," he says. "The government is rapidly becoming the largest payer segment in the United States. I think we will see a more segmented healthcare system as Medicaid expands in those states that choose to implement that portion of the ACA."

Denise Duca, senior VP, human resources, at Acorda Therapeutics, says healthcare reform related to the ACA will be challenging for the company and in implementing HR policies.

As a result of the push for greater transparency between pharma and physician collaborations, the industry continues to deal with stricter compliance requirements, regulatory conservatism, and departmental firewalls that make it challenging to effectively promote brands in the context of realistic patient care, says David Rear, president and founder of Advanced Clinical Concepts.

"This paradigm in combination with patent cliffs on blockbuster drugs, a shift toward payers and even patients as decision makers, and the politics of healthcare have put our client companies in a less favorable position as drivers of medical evolution," he says. "Facilitating an ongoing dialogue among all key stakeholders — industry, government, payers, patients, and providers — regarding the shared goal of good patient care would go a long way toward reestablishing pharma as a leader in healthcare in the coming decade and beyond."

One of the biggest efforts to bring transparency to the industry has been the Physician Payment Sunshine Act. This act, a provision of the Affordable Care Act of 2010, requires pharmaceutical and medical device companies to report to CMS payments made to physicians of more than \$10, as well as physician ownership and investments. The first reporting period will be Aug. 1, 2013, to Dec. 31, 2013. The first reports must be submitted to CMS by March 31, 2014. CMS will release the reported data on its public website by Sept. 30, 2014.

DJ Mitsch, president of The Pyramid Resource Group, says a big challenge is the need for healthcare leaders to communicate more fully with their payers, their patients, their



colleagues, their teams, and those who supply products.

"They need to address the incredible chaos facing healthcare and the confusion that impacts us all," she says. "And because of myriad demands on leaders in this space it is difficult for most to find time and pay attention to what is most needed by their people. What we've observed is that learning to lead through change reduces risks, improves quality and safety, and can accelerate care and performance."

### Changing Technologies

Technology is constantly moving forward and is expected to transform the way pharmaceutical companies conduct research and market their products.

A study last year by Accenture predicted that context-based services, i.e. services that combine real-time signals from the physical world with online activities, profile knowledge, social media, location data, and other types of contextual input, will provide customer relevant data, allowing life-sciences companies to provide enhanced health solutions that are relevant, timely, and focused on patient outcomes.

On the R&D side, Accenture predicts that the new generation of wireless sensors will be able to provide more sophisticated, real-time insight. This has the potential to change traditional approaches to R&D and help bring products to market more quickly by extending the ability for trial participants to take part in "in-life trials" from their homes.

On the marketing side, mobile customer-relationship management (CRM) platforms can incorporate contextual information from the sales visit to assist in follow-up actions, reduce the burden of updating call notes, and capture valuable information that the company can use as part of a sales campaign, according to Accenture researchers. By combining contextual information with real-time analytics, companies will be able to further improve sales reps' productivity and the quality of the reps' interactions with healthcare professionals.

Jamie Heywood, co-founder and chairman of PatientsLikeMe, says the industry is entering a new era that will be as big a shift in the life-sciences sector as the computing industry went through when it transitioned from mainframes to personal computers.

"The emergence of new human networks and the reduction in the cost of de-novo dis-

covery technologies combined will redefine health, illness, and treatment at a pace that is unimaginable today," he says. "Who will survive, die, or thrive will depend on knowing how to connect to the new emerging networks that will define health and value in the future."

Matthew West, VP, chief talent officer, at McCann Regan Campbell Ward, a division of McCann Health, says keeping up with technology is an industry challenge.

"The pharmaceutical and healthcare industry has notoriously been slower to adopt and feel comfortable with social media and online communication vehicles," he says. "To survive and remain relevant to patients, the healthcare industry will need to embrace digital media and continue to blaze new trails in exploring its many opportunities."

Mauricha Marcussen, CEO of Auditgraph and Agano Solutions, says there are disparate systems that create silos of critical information.

"We struggle to leverage this information in a positive, productive way because of the complexity of multiple systems and regulatory requirements," she says. "The time is here for new approaches to data consolidation; and to harness intelligence from this data that is useful, pertinent, and up-to-date." **PV**

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