Meeting the Industry's Challenges

The PharmaVOICE 100 honorees discuss the challenges facing the pharmaceutical industry, from maintaining innovation and the cost of development to changing regulatory and payer environments to the challenges of the industry's business model.

When asked about the challenges pharmaceutical companies face, many of the PharmaVOICE 100 honorees mention the need to find new approaches to business models, marketing, research and development, and just about every aspect of the industry. While many point to the need for innovation in the pharma industry, some leaders say the industry continues to be stuck with traditional processes that create silos and legacy systems. The new science and advances in the understanding of biology have not led to as many new drugs on the market as fast as many predicted.

The industry is currently in a very dynamic state, with challenges on all fronts, pushing it to break all conventional barriers and move toward new horizons, says Chitra Lele, Ph.D., chief scientific officer at Sciformix.

"Electronic health records, social media, and big data are forcing a revolution that the industry has to embrace," she says. "With new operating and partnership models emerging across product development and lifecycle maintenance, new cross-functional and technology-based innovative offerings are the need of the hour."

Rapid change is everywhere, points out Angela Tenuta, executive VP at Intouch Solutions.

"With the Affordable Care Act, EMRs, and rep call-time decreasing, customers are expecting personalized interactions through a hundred channels; data are exploding without context in confluence with new technologies such as programmatic media, automated marketing, NPP platforms, and wearables," she says. "No aspect of this industry looks the way it did three years ago. As a pharma company or an agency, it's impossible to know if you are doing the right thing. And those who aren't confident, scramble like lost ants."

But for all the talk of finding new ways to do things, our industry seems to simply be looking for a new way to repackage what we've always done, says Kenneth VanLuvanee, president and CEO at Virtual Regulatory Solutions.

"The challenges are different from 20 years ago, but we're still largely approaching them with the same tools," he says. "We need to rethink from the ground up, figuratively throw away everything, and start over. Especially since the entrepreneurial portion of my career, I've had a strong preference for working with smaller biopharma companies. I see them becoming an increasingly larger and more stable portion of the life-sciences industry. These companies are where the innovation and entrepreneurialism are happening."

Jean Pierre Wery, Ph.D., president, of Crown Bioscience, says if you analyze the rate of introduction of novel medicine to the market for the past 50 years, there has been virtually no change.

"Despite many, much-hyped, technological advances, we are not discovering drugs today faster or more efficiently than we did 50 years ago," he says. "The industry has made great progress in creating very exciting drug candidates preclinically. But these promising molecules often fail when they are tested in a clinical setting. Translational approaches will address these problems and increase the rate of success in the clinic for promising drug candidates. We have and will continue to develop preclinical models that are very predictive of clinical results."

There seems to be a lot of talk about challenges facing the industry, but many of these same challenges present opportunities, which may be a more productive way to look at it, says Susan Perlbachs, executive VP, executive creative director, at GSW Worldwide.

"For example, the Affordable Care Act is putting greater time constraints and pressures on primary-care physicians, nurses, and healthcare professionals than ever before," she says. "Additionally, there's more and more pressure to keep drug costs low and demonstrate value. But this presents an opportunity more than anything. The pharmaceutical industry has the chance to step forward and demonstrate tremendous value through educational efforts and adherence/compliance programs."

Things for Pharma to Consider

- Incorporate value-based outcomes into R&D design. Whether they are just entering a competitive market or are experienced players with proven products, drug makers will be under pressure from purchasers to demonstrate the true value and appropriateness of their goods. Additionally, risk-based providers will start to tap into pharmacy management using value-based outcomes data to extract additional savings.
- Understand the impact of increased cost-sharing on consumers. Employers are raising insurance co-pays and converting to coinsurance. Tighter restrictions from insurers and employers may have consumers looking to manufacturers for financial assistance, or they may forgo treatment altogether.
- Risk-based relationships. Providers that are under risk-based contracts are hungry for new cost-cutting strategies. Determining specific clinical impact and costs per patient are becoming necessary elements in drug evaluation. Pharma companies should proactively prepare and promote solutions that incorporate comparative effectiveness, price, and utilization.
- Partner with disease associations. Drug makers can partner early on with disease associations and patient groups to develop treatment protocols and programs to assist patients in exploring therapy regimens and payment options for new treatments.

Source: PwC Health Research Institute

LEADERSHIP CHALLENGES

The PharmaVOICE 100 honorees discuss the personal and leadership challenges they face.

JEFFREY BERG, PH.D.

AbelsonTaylor

Balancing the needs of the agency and the needs of the staff is a challenge of mine.

MATTHEW D'AMBROSIO

Sunovion Pharmaceuticals

One of my biggest challenges is striking the right balance in the organization between rules and freedom — that is a balance between the company's policies and procedures and our innovation and entrepreneurship.

JENNIE FISCHETTE

Concentric Health Experience

My biggest challenge is time. I believe in being present and a true partner with my teams. The struggle of running a business and being present is one I face more often than I would like.

TARA FITZGERALD

INC Research

Engaging with employees on a global level is a big challenge for me. We can have the best processes and practices in the industry, but if we do not take the time to recognize our internal talent, place recognition where recognition is due, and build consistent, trusting teams, we will continue to struggle at inefficiency.

TIMOTHY FRANK

Triple Threat Communications

Finding the right people who fit our model and trying to get the industry to realize that it needs to change are challenges.

RICHARD GAMS, M.D.

Novella Clinical

Ensuring the integrity of the drug discovery process is a priority for me.

DANIEL GHINN

Creation Healthcare

Despite many opportunities to innovate, I am constantly aware that to succeed, I must be very focused on areas where I can make the greatest difference.

SHANNON HARTLEY

Rosetta

Continuing to grow and stay relevant in the marketplace is a challenge for me, and many leaders, today.

CHITRA LELE, PH.D.

Sciformix

My biggest challenge today is to help chart a course, keeping both the short-term and long-term organizational objectives in mind, and prioritize implementation of initiatives that will fulfill the current and the future need of the industry, in alignment with the identity that we have built over the years of our existence.

FREDA LEWIS-HALL, M.D.

Pfizer

My challenges are increasing the speed and value of innovation, building trust in our industry, and helping colleagues connect themselves to the important role they have in better health, everywhere.

JULES MITCHEL, PH.D.

Target Health

My challenge is growing key employees for the long term and keeping motivated people motivated and employed. With mergers and automation, we need to be even smarter in order to maintain long-term relationships with customers and employees.

JAN ELLEN NIELSEN

Sonexus Health

My biggest challenge as a leader is one that many leaders face: to stay focused on the end goal and to not deviate from that focus. I also want to stay focused on creating and delivering the best care possible for patients.

MICHELLE ROHRER, PH.D.

Genentech

My challenge is the constant need to keep up with the evolving policy landscape and investing time to build new relationships.

NANCY MARIE RUIZ, M.D.

Meda Pharmaceuticals

My challenge is maintaining focus of teams in the face of uncertainty.

RAMAN SINGH

Mundipharma

We need to keep every part of the development process enthused as people face increasing demand, complexity, and regulation. We also need to balance the expectations of the regulators, patients, stakeholders, and shareholders.

MARK WHEELDON

Formedix

My challenge is managing supplier, customer, and internal politics.

CORBIN WOOD

Snow Companies

My challenge is continuing to innovate our business model and finding new strategies to reach and engage patients.

Ms. Perlbachs says taking this position serves both the interests of patients and overall public health. "There are some great examples of this out there already, with Lilly arguably leading the charge, particularly with its diabetes work," she says. "This patient-centric, value-added approach is something I believe more and more drug makers will be adopting."

The industry is constantly evolving, but we manage through these changes by putting patients at the very the center, says John Glasspool, global head of emerging therapies and market development in Baxter BioScience.

"This helps to center our attention and motivate us every day," he says.

Innovation requires change, says Tara Fitzgerald, executive VP, biometrics, at INC Research.

"That means that the roles and responsibilities as we have known them to be will be different," she says. "Most people are adverse to change, but the reality is that in order to succeed at moving great drugs to market faster and at a lower cost, the roles need change. This will be our greatest test."

In big pharma, there is a realization that the old way of looking at drug development will no longer work, and competitive pressures and patent expiries will radically change the way companies conduct and/or fund trials, says Mark Wheeldon, CEO of Formedix.

"This has led to the rise in outsourcing to CROs and will continue to do so," he says.

Sydney Rubin, chief communications officer inVentiv Health, says organizational silos — rigid structure, hierarchical decision making, and a lack of cross-functional collaboration — are antithetical to innovation, efficiency, and productivity.

"In some ways, the transformation taking place in the life-sciences industry has made my job easier because the type of strategic partnerships pharmaceutical companies need for development and commercialization of products are exactly what we are uniquely positioned to provide," she says.

Development Challenges

The ability to innovate is critical. While the United States is currently the world leader in innovative biopharmaceutical R&D and

The Challenges

The PharmaVOICE 100 named the following challenges facing the healthcare industry.

- Academic research funding
- Access to healthcare/medications
- Adoption of digital technologies
- Antibiotic resistance
- Compliance
- Creating and sustaining growth
- Data mining and data sharing
- Emerging dominance of payers
- Evolving media
- Evolving regulations
- Globalization of healthcare
- Globalization of clinical development
- Healthcare provider shortage
- Healthcare reform
- Increasing focus on efficiency
- Industry reputation
- Mergers and acquisitions
- Maintaining innovation
- More complicated science
- More complicated clinical landscape
- Organizational silos
- Patient adherence
- Patient engagement
- Patient recruitment
- Patient-physician communications
- Productivity
- Rare disease research
- Recruiting and retaining employees
- Rising costs of development
- Rising costs of healthcare
- Social media engagement
- Uncertainty that comes with change
- Women's health

manufacturing, industry executives interviewed for a report by Battelle and the Pharmaceutical Research and Manufacturers of America expressed concern that U.S. leadership cannot be taken for granted. Global trends suggest that U.S. leadership will be challenged as emerging economies implement more favorable policies to attract R&D investment and spur growth in their own innovative capacity in biopharmaceutical manufacturing to meet domestic demand.

The Battelle report finds three policy factors as most critical for enabling innovation: coverage and payment policies that support and encourage medical innovation; a well-functioning, science-based regulatory system; and strong IP protections.

The industry is experiencing dramatic changes in all areas of drug development and success — whether as an individual, project team, or company — is dependent on quickly adapting to the changes. Recent advances in data and technology have fundamentally changed the clinical trial environment. Industry leaders say these advances bring significant challenges, specifically the ability to fully integrate data and technology as an end-to-end clinical trial solution and the relatively short life-span of a new technology.

Drug development strategies once primarily focused on obtaining regulatory approval to market a new product; now, drug development strategies must simultaneously focus on marketing approval and reimbursement strategies, says Michael Brooks, VP, clinical development services (site intelligence and activation) at PPD.

"Reconciliation of the marketing and reimbursement strategies, particularly on a global scale, is a complex challenge facing drug development companies and their service providers," he says.

The high failure rates of new drug discovery are unsustainable, says James Powers, CEO of HemoShear.

"Mergers and cost cutting are not the answers," he says. "Strategies to outsource innovation are not the answers either. The industry needs fundamental advancements in new, human-predictive science to understand disease biology and assess drug candidates in a human-relevant context. Although we are in an increasingly tight spending environment, I think many in the industry are beginning to realize the importance of new, predictive science."

As Anna Protopapas, president of Millennium: The Takeda Oncology Company, points out, we are in the midst of an explosion in biology as we understand more fully the far-reaching impact of genetics and the relationship of science to diseases.

"Harnessing this knowledge and turning it into drugs that can help patients is still the goal," she says. "But we need to innovate in a way that is cost-effective and allows drug makers to bring medicines to patients of all economic strata."

Michelle Rohrer, Ph.D., VP, U.S. regulatory, at Genentech, says the development cycle is too long.

"Ten years-plus years is too long a development time for major new pharmaceutical advances; patients are waiting and need innovation now," she says. "Ultimately, what used to be strictly pharmaceutical advances will be partnered with diagnostic and technology advances as a whole curative package for patients."

Advancing science itself, while providing an unprecedented wealth of knowledge, has made new compounds highly optimized — and this complexity brings new challenges, says Stephan de la Motte, M.D., chief medical advisor at SynteractHCR.

"I see the current era, where one could improve medicine with a single compound acting on a single biochemical pathway, coming toward an end," he says. "Most simple pathways seem to have been identified. Compared with the time when I started in the industry 21 years ago, today new compounds when reaching the stage of clinical trials are already so highly optimized, that it's very difficult for any follow-up compound to surpass the achieved standard. I think that the future will bring much more complex treatment schemes, involving different compounds, devices, and strategies in smart combinations."

Ms. Fitzgerald says the industry is getting better at collaboration and communication, developing ways to standardize processes globally and implement new innovation to expedite the processes is a huge advantage.

These challenges will require better ways of working together says, Chris Trizna, president of CSSi.

"Too many companies are looking to get the biggest piece of pie and lose sight of the goal: finding cures for the future," he says. "If more companies figured out ways to work together, we all would be more successful and get more business."

Freda Lewis-Hall, M.D., executive VP and chief medical officer at Pfizer, says companies have to transcend rigid thinking about what constitutes collaboration and raise collaboration among all members of the R&D ecosystem to a new level.

Clinical development is a global enterprise and has been for some time, and we have much to do to ensure that people, process, and systems are integrated and the communication flows appropriately across global teams, says Susan Seroskie, executive VP, strategic resourcing, at Advanced Clinical.

"Globalization, technical advances, timeline compression, and stringent regulatory requirements all contribute to the challenges of aligning talent with opportunity," she says. "However, these demands do create a path forward; they help us more clearly identify the right team and help us to establish a cogent agenda for training and development."

Dr. Lele says many more companies, not just the large global ones, are open to working with partners in a globally distributed manner and are willing to consider many areas that were previously taboo for outsourcing.

"Some of the large companies that have years of experience in working with offshore partners are re-evaluating their strategy based on their experience and are getting into deep relationships with large full-service CROs or want a stronger onshore presence of the vendor but at the same time, there are some who want to move to a two-vendor strategy and are interested in the second vendor being more specialized," she says.

Mr. Brooks says patient recruitment for clinical trials can be challenging for numerous reasons.

While personalized medicine is leading to significant breakthroughs in the treatment of a patient's disease or condition, it has also created significant challenges for developing an investigational product in a reasonable period of time and budget.

"For instance, once common disease indications, such as lung cancer, have been reduced into tens of sub-indications that are much more difficult to enroll and retain subjects," Mr. Brooks says. "Essentially, many common diseases have been transformed into a series of rare diseases in terms of clinical trial conduct. Ultimately, these targeted investigational therapies are a significant benefit to clinical trial subjects and it is critical that drug development teams continue to adapt to this environment starting with protocol designs and continuing through all parts of the clinical trial process."

Patient recruitment is especially challenging in oncology.

"During my time leading PPD's global hematology/oncology therapeutic area, one of the biggest frustrations was the generally low participation of oncology patients in clinical trials (e.g., many publications have cited clinical trial participation for U.S. cancer patients at between 3% and 8%)," Mr. Brooks says. "Research indicates a variety of reasons, ranging from general patient mistrust of the biopharmaceutical industry to limited participation of oncology centers in clinical trials. Regardless, access to potential patients and a willingness of patients to participate in a clinical trial continues to be a significant threat to the drug development industry."

Mr. Trizna says new technologies, especially in patient recruitment, are making an impact.

"Technology has made the biggest impact on how we are able to identify and contact people for studies that are most appropriate for them," he says. "We all provide information about ourselves through our Facebook pages, Google searches, and even at the grocery store; it has become easier to get our clinical trial messaging to the right people. Technology has also provided more efficient ways to keep patients compliant and decreasing the number of no-shows. These used to be tasks the study coordinator had to do which took up valuable time, now there are systems in place to do the work for the study coordinator."

Aaron Fleishman, social innovation and strategic consultation, at BBK Worldwide, says while the industry has been slow to adopt tech innovations, especially in the area of social media, that's starting to change.

"Our clients are keen to innovate but understand that the one-size approach does not fit all," he says. "They have come to realize that one small step can make a really big difference. It's more about finding your comfort zone within innovation and piloting small initiatives to see what works and what doesn't."

The trial model is broken, says Graham Wylie, MB.BS., CEO of Medical Research Network.

"Investigator sites are a bottleneck rather than a gateway to patients and this needs to be changed," he says. "Without addressing how we get patients into trials and how to keep them there, by making the experience more about them and less about their physician or the industry, the harder trials are going to get. The more the physicians and the industry give to the patient, the more they will get back from the patient. "

And while many within the industry advocate the use of social media for reaching patients, Dr. Wylie believes the Internet and social media is going to drive the dis-intermediation of investigator sites in trials.

"It makes patients more the master of their own destiny in participation in research as they do not need to rely on the interest in the trial by their physician to get access to the trial," he says. "This has altered in a permanent and yet-to-fully-develop way the ownership by patients of their medical data, the physicians they want to consult, how they consult with them, how they participate in research, etc. The genie is out of the bottle, and research will never be the same again."

Dr. Wyle asks: "If patients can record, track, and graph their own data on Internet sites and they run algorithms over them to predict if they are on active therapy or not, what does that do to blinding and controls? If they can share that data with each other what does that do to random nature of responses?

"I am no statistician, but it seems to me the basis of much of our testing of probability is under threat," he continues. "Will the meta analysis become the de facto standard of determination of effect of a compound? Today the randomized controlled clinical trial is the gold standard, and for good reason. Meta analysis is possibly going to become the new standard, yet it is inherently less rigorous. It can ask questions and raise new hypotheses, but it is not a good way to test a hypothesis, although there is a risk it will be seen as such."

The need to do more with less is a result of increased peri- and post-approval evidence requirements and fewer research dollars, says Krista Payne, executive director and principal scientific consultant at United BioSource Corporation (UBC).

"In many markets, data in support of risks and benefits are necessary even after market access to demonstrate effectiveness, safety, and value relative to the standard of care," she says. "While the burgeoning of the CRO industry and the promise of big data have resulted in an abundance of potential solutions, research sponsors nowadays are easily overwhelmed and confused by the goods and services put before them. Integrated cost and time-efficient solutions that solve data and information gaps across a program of studies are seldom obvious."

Ms. Payne says solutions providers from across the industry need to offer more transparency and leadership with respect to agnostic recommendations for evidence gathering strategy.

"We have to help our sponsors focus on the 'must-have' versus the 'nice-to-have' data sourced from within, or even outside of, our own research organizations," she says. "Though many of us represent end to end solutions providers, gaps will inevitably emerge and we must be client-centered and strategy driven enough to refer business to other providers if it's in their best interest.

Marketing Challenges

The current agency/client model is broken, says Timothy Frank, managing partner at Triple Threat Communications.

"We the agencies need to be more focused on our clients' best interests instead of our own," he says. "Just look at the recent failure of the Publicis and Omnicom merger. By their own admission, it failed because of their egos and self-interest. Never once in the press did I ever hear them talk about how the merger would help clients, or the customer's need for a larger network."

Mr. Frank points out that the pharma market is becoming more specialized, yet the agencies that are supposed to serve the pharma market are still based on the old blockbuster, primary care model.

"The days of having a huge organization that still supports the churn-and-burn mentality should be gone," he says. "We need to be more flexible and nimble to meet the ever-changing client market and its needs. The networks have not changed with the market and I don't think they can; it is not in their DNA."

Jeffrey Berg, Ph.D., senior VP, director of client services, at AbelsonTaylor, says the biggest challenge facing the advertising industry is the devaluation and commoditization of agency services.

"I believe agencies provide enormous value to clients and in order to continue to do so we need to retain and recruit top talent," he says. "A race to the bottom in terms of pricing and compensation benefits no one in the long run.

Dr. Berg says the Internet has changed the balance of knowledge.

"Customers have access to information that was once the sole realm of the expert," he says. "Increased knowledge has enabled the brand to speak to the customer in much more engaging ways."

Physician access continues to be a challenge, says Diane Iler-Smith, executive VP, chief creative officer, at Ogilvy Healthworld, part of Ogilvy CommonHealth Worldwide.

"Memorial Sloan Kettering just joined a growing list of institutions banning access to pharmaceutical sales representations," she says. "Our industry needs to be innovative in reaching these physicians, exploring digital channels as well as promotional medical education channels."

There is definitely a shift in clients with an appetite for digital-first thinking and an appreciation for data analytics and measurement, says Leerom Segal, co-founder and CEO of Klick Health.

"Whereas historically digital used to be an adjunct, it's now the primary driver of marketing programs," he says. "We believe this trend will only continue as it aligns with the push for stronger financial accountability. But as far as we've come in the area of data-driven marketing, there's still much work to be done. Digital is still seen as a tactic rather than a fundamental piece of the strategic planning approach. The industry needs to elevate its digital proficiency, starting in the planning stage, to unleash its full potential."

Shannon Hartley, managing partner, healthcare industry leader, at Rosetta, says the continuously changing regulatory landscape is one of the biggest challenges for the healthcare industry today.

"Regulations change in real-time, causing the need for companies and agencies to have a depth of understanding in compliance and regulatory changes," she says. "As brands and sales reps have less access to physicians, they need to be better armed and have flexibility. This has created the challenge and opportunity for us to help clients understand how customer engagement is the future of marketing."

The regulatory environment is a constantly evolving challenge that requires savvy marketers and account management teams with greater depth of experiences, says Corbin Wood, COO, Snow Companies.

"As we have moved away from the blockbuster model to one of more personalized medicine and products for niche/orphan indications, being able to find and work with these small patient groups means less of the traditional DTC, mass market activities, and more patient focused tactics," he says. "In short, we have to shift from a volume mentality to value."

A challenge will remain the need to do less with more, says Michelle Marlborough, VP, product strategy at Medidata Solutions.

"This challenge will only increase as payers become more demanding when it comes to showing clear, statistical value in new drugs," she says. "Regulators and payers are now very interested in understanding a drug's overall value — not only whether a drug is safe and effective, but whether it also significantly improve the quality of life and reduce the burden of disease in comparison to available therapies. It's up to the industry to be agile enough to adopt new technology and new processes to reshape the way it does development. "

Challenges for Patients and Physicians

Several of the PharmaVOICE 100 honorees mentioned rising healthcare costs and access to healthcare services and providers as a challenge that patients and consumers face.

"Over the past decade healthcare costs have risen 131% while wages have only increased 38% during that same timeframe, according to the Kaiser Family Foundation and the Health Research and Educational Trust," says Jennie Fischette, executive VP, director of client and strategic planning services, Concentric Health Experience.

"Being in the healthcare field, we can help translate the best choice for the patient," she continues. "No one in healthcare today puts profits before patients. It's our responsibility to ensure that we take the guess work out of the discussion so that price can be a discussion that balances the best welfare of the patient and the price of the medication before them. The price of drugs is only one cost. For most it's the immediate cost. The increase in health costs is a compilation of both short and long term decisions."

PwC's Health Research Institute (HRI) projects a medical cost trend for 2015 of 6.8%. Taking into account likely adjustments to benefit design such as higher deductibles, HRI anticipates a net growth rate of 4.8%. PwC says four factors are likely to inflate spending: an economic upswing; specialty drugs, physician employment, and information technology investments.

Although total U.S. health spending will likely increase as more people gain insurance under the Affordable Care Act (ACA), it may have little effect on employer health spending. The increase in utilization under the ACA will likely drive up total national health expenditures without changing prices for those with employer coverage.

The popularity of high-deductible health plans continues to rise as employers attempt to manage their benefit costs. According to PwC's 2014 Touchstone Survey, 44% of employers across all industries are considering high-deductible plans as the only insurance option for their employees during the next three years.

According to a recent study, families in consumer-directed plans used fewer brand-name drugs, had fewer visits to specialists, and were hospitalized less.

Andrea McGonigle, managing director, life sciences, at Microsoft, says partnerships need to happen across pharma, providers, plans, health and human services in both commercial and public sector.

"The only way to look at the problem of higher overall healthcare costs 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," she says. "The patients are demanding it."

Ms. Fischette says when communicating to patients, payers, or healthcare professionals, the industry needs to provide a balanced approach so that all parties can have an educated discussion.

"Price matters," she says. "If one is going to pay the price for a medication that can enhance life or even save their life all parties need to have the facts before them and be able to understand both the short and long-term consequences to be considered. This is a challenge we all face and is one that is the new reality."

The majority of payers in the United States and Europe believe that drug adherence solutions and data that pharma companies possess are vital to lowering healthcare costs and improving outcomes. But lingering mistrust of the pharma industry is likely to stymie efforts by pharma companies to engage with payers in these areas without a fundamental change from current approaches. These are findings of EY's Progressions report. Most payers do not think that pharma companies developing beyond-the-pill services can be unbiased between their products and those of competitors, with only 15% of respondents even somewhat agreeing with that statement.

Jan Nielsen, division president, access and patient support, at Sonexus Health, a Cardinal Health Specialty Solutions Company, says incentives across stakeholders have been aligned incorrectly.

"In general, we are a fee-for-service business, and that means we make more revenue by providing more service, not by providing quality," she says. "While there is some interest in moving toward quality-based care, we need to see some real meaningful steps in this area. The focus should be simple: on the best treatment for the patient."

Primary Attributes for Advancing a More Favorable Business Operating Environment

- Coverage and payment policies that value innovative medicines
- Strong, science-based regulatory system
- Robust intellectual property (IP) rights and enforcement in the U.S. and abroad
- Competitive corporate tax rate
- Access and robustness of private funding of R&D in early stage and emerging biopharmaceutical companies in the U.S.
- Robust government basic R&D funding and favorable technology transfer environment
- Strong R&D and STEM workforce
- Favorable trade policy environment for U.S. biopharmaceutical products
- Robust manufacturing workforce in the U.S.
- Competitive state-level incentives for innovation

Source: Battelle

Patient adherence is one of greatest challenges faced by our industry today, says Michelle Keefe, chief operating officer, at Publicis Touchpoint Solutions.

"As the Affordable Care Act (ACA) shifts the focus in healthcare from disease treatment to prevention and toward improving health outcomes, we will see even greater emphasis on patient adherence," she says. "Touchpoint's most recent (2014-2015) What Physicians Want! Survey shows that this issue is critically important to physicians as well. The physicians surveyed were interested in receiving help with educating and supporting their patients, as well as assisting patients with access to the medications that they need."

The healthcare landscape is becoming increasingly more complicated and continues to put added business pressure on physicians, says Heather Gervais, VP, commercial operations, athenahealth.

"ACO adoption is growing faster than expected and the majority of physicians are now employed by or closely affiliated with large health systems, which means they have more pressure to comply with protocols of care, not determined by them, more pressure to understand and track the cost of care and less time to spend on providing care," she says.

Ms. Gervais says all of this change impacting physicians is challenging the traditional business models for pharmaceutical manufacturers.

"Most are faced with re-thinking how they can continue to invest in developing drug therapies that help save/improve lives, while still making a profit," she says. "But this also creates an opportunity for us. With physicians having less time and less control, it is hard to find measurable ways to reach physicians when they are most open and receptive to treatment decisions, but we are fortunate enough to have a highly engaged physician network turning to us for treatment decisions in the moments of care."

Business Model Challenges

Ann Aerts, M.D., head of the Novartis Foundation for Sustainable Development, Novartis, says one of the greatest challenges facing the healthcare industry today is the ability to create measurable and replicable solutions to global health challenges that exist throughout the world.

"Not only do we have to measure and document everything in our programs to build the evidence that the initiatives we support are successful, but we also have to make sure that the solutions we support can become scalable, included in health policy, and available for hand-over to other local organizations based in the countries we are working in, whether these are private or governmental, for-profit or not-for-profit," she says.

Joe Doyle, director of digital strategy, at HCB Health, says the business model is becoming a riddle.

"How do pharma and medical device companies get paid when it takes billions of dollars to get a product to market in a time with decreasing payer options?" he asks. "The Affordable Care Act has caused large medical device clients to squeeze marketing budgets in an effort to pay for the 'device tax'. We see this trickle down to new digital ideas that are usually well received, but often hard to fund. Change has to occur for industry leaders to keep producing."

Dr. Aerts says business models used in developed countries do not work in countries where health services are weak (or nonexistent), because making drugs available does not mean that they will be used in the proper way and lead to better outcomes for the patients.

"To make sure drugs deliver the desired patient outcomes, quality healthcare needs to be delivered too," she says. "Additionally, the healthcare industry may need to bridge the gap between 'the best possible care for every patient' and 'the optimal care for the largest possible portion of the population' in an innovative way."

Daniel Ghinn, CEO of Creation Healthcare, says the globalization of health information is a challenge and opportunity that will continue to change the environment for the pharmaceutical industry.

"Global pharmaceutical companies operate within national and regional regulatory frameworks, yet their customers and stakeholders including patients and healthcare professionals operate in an increasingly connected world," he says. "Thanks to the Internet, health information is largely without boundaries, yet most pharmaceutical companies are limited in their current ability to plan, measure, and respond in a globally coordinated manner to real-time events."

Mr. Ghinn points out that the way that healthcare professionals interact with pharmaceutical companies and each other is changing.

"One way in which this is happening is via social media," he says. "Healthcare professionals are increasingly using social media to learn from peers, collaborate with each other, and mobilize action. At the same time, the life-sciences industry has an increasing appetite for openness, which aligns with the openness of healthcare professionals in public social media."

How people communicate within the organization also is changing.

"We see big challenges relating to data and sharing of data across multiple departments," says Neil Gleghorn, CEO of Kallik. "Historically companies have built up 'point' solutions that are specific to a part of the process but don't add value or connect downstream. I see much more connected working practices across multiple departments."

Life-sciences organizations are being somewhat devalued right now, primarily because they're struggling to adapt to change and keep pace with the changing healthcare landscape, says Dan Goldsmith, general manager, Europe, Veeva Systems.

"Across life sciences, organizations must quickly acclimate to global expansion, increasing competition, more multifaceted customer networks, and greater customer expectations for speed and access," he says. "But it's been difficult for pharma to respond quickly and effectively, largely because companies have been stuck using non-integrated, outdated legacy systems in critical business areas across the enterprise…from commercial to R&D. Pharma needs to reinvent itself and embrace a more interconnected and real-time environment, making wholesale shifts to new technologies that can enable higher efficiency, faster time-to-market, and improved customer engagement from molecule to market."

George Savage, M.D., co-founder and chief medical officer, at Proteus Digital Health, says the opportunity exists to redefine the pharma business model into one based on data and services and outcomes, rather than prescriptions and patents. PV