

# INNOVATION IN A PATIENT-CENTRIC WORLD

The PharmaVOICE 100 honorees offer their view on the innovations and breakthroughs that will have the biggest impact on the industry and on healthcare.

From healthcare reform to the push for value in medicines to personalized healthcare, the patient is now at the center of, well, everything. This means that pharmaceutical companies are now required to create a new paradigm, with the patient at the center.

An initiative that began last year within the U.S. Congress — the 21st Century Cures — is aiming to understand how to advance innovative medical research and to accelerate the development of safe, effective medical treatments and cures, particularly for patients with unmet medical needs.

The effort brought together patients, innovators, providers, regulators, consumers, and researchers to talk about how to bridge the gap

between advances in science and medicine and how to regulate those therapies.

In May, leaders from the Energy and Commerce Committee released a discussion draft in the 21st Century Cures initiative. The bipartisan initiative began in April 2014 to look at ways to accelerate the pace of medical breakthroughs in the United States. In July, the initiative passed unanimously through the House.

In the last 100 years life expectancy has almost doubled, and most of this can be attributed to advances in medicine, says Boris Kushkuley, Ph.D., executive VP of Intouch Solutions.

“A lot of deadly diseases were irradiated or became manageable chronic conditions,” he

says. “As in many other areas, the progress in medicine continues to accelerate and we can expect dramatic breakthroughs in treatments of many rare diseases, including the treatment of cancer. Most of it comes from our ability to leverage advances in technology, including genetic mapping, bio-engineering, and big data analytics.”

The pharmaceutical industry, he says, is redefining its role with more focus on overall treatment outcomes. Medications become just

## Fostering Innovation

The PharmaVOICE 100 honorees have highlighted the important factors that foster innovation within companies.

- ▶ Ability to anticipate challenges and opportunities
- ▶ Commitment to excellence
- ▶ Continuous improvement
- ▶ Cross-functional collaboration and teamwork
- ▶ Culture of ideation
- ▶ Disrupting the status quo
- ▶ Diversity of opinion
- ▶ Empowered employees who are open-minded
- ▶ Entrepreneurial culture
- ▶ Faith
- ▶ Focus on long-term goals
- ▶ Hiring talented, driven, curious people
- ▶ Incentivizing employees
- ▶ Interrogative environment
- ▶ Persistence
- ▶ Risk taking
- ▶ Strong leadership
- ▶ Willingness to accept failure and learn from mistakes



The convergence of technology — from wearable devices to mobile apps — is the next big thing in healthcare; wearable devices have the power to transform the healthcare field.

**ALAN ONG**  
INC Research



Wearables will become one of the biggest breakthroughs in healthcare management and disease prevention.

**KEITH STENLUND**  
AbelsonTaylor

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The biggest breakthrough will be the seamless integration of all mHealth solutions across all sectors; this will change how we deliver healthcare.

**CHERYL LUBBERT**  
Health Perspectives Group



A company full of somewhat innovative employees will outperform any company with a few very innovative rock stars.

**RICHIE ETWARU**  
IMS Health



I would love to live to see the day when cancer is treated as a chronic disease and not a death sentence.

**DR. ANDREW ZUPNICK**  
Novella Clinical

a component of broader, comprehensive approach to treating diseases. Changing patient behaviors to prevent or better treat their conditions moves to the forefront.

“We will see better use of customer insights, clinical data, and real-time behaviors in creating truly customer-centric service model,” Dr. Kushkuley says.

Bruce Alan Feinberg, DO, VP, clinical affairs and chief medical officer, at Cardinal Health Specialty Solutions, says there will be a confluence of medical breakthroughs due to genomics, proteomics, pattern recognition supercomputing, and interoperability that will likely transform healthcare.

“At the same time, we will continue to struggle with how to make the innovations affordable and with the challenges posed by a society that has become increasingly obese and sedentary,” he says “In the quarter century after World War II, life expectancy increased by one-third with improved health. A similar extension of age with good health will be possible in the coming years if we use resources wisely and responsibly.”

The industry has been working to harness new technologies and new discoveries while at the same time reassessing both its business model and the culture to allow for innovation to develop.

For example, MedImmune aims to create an environment where innovation can thrive.

“As such, we empower our employees to look beyond standard expectations and push the boundaries of what’s possible in an effort to advance science and the development of

life-changing medicines to improve public health and help fight and cure disease,” says Rakesh Dixit, VP, research and development, and global head, biologics safety assessment, MedImmune. “Our employees are united by this sense of purpose and by their passion to make a difference in the lives of people worldwide. It is important to create a culture that encourages and rewards innovation — and characteristics that lend themselves to innovation, such as curiosity and persistence.”

Richie Etwaru, chief digital officer at IMS Health, says innovation is a collective orchestra rather than a solo performance.

“A company full of somewhat innovative employees will outperform any company with a few very innovative rock stars,” he says. “As a result, it is my mission to work with every employee to be more innovative in every aspect of our business, so that as an aggregate, we win for the benefit of our customers.”

Mr. Etwaru says healthcare is somewhat behind operationally and digitally when compared with other industries, such as financial services, because there was a period of stagnation during the times of high margins.

“Stagnation is not good for any single industry,” he says. “I welcome the accelerating

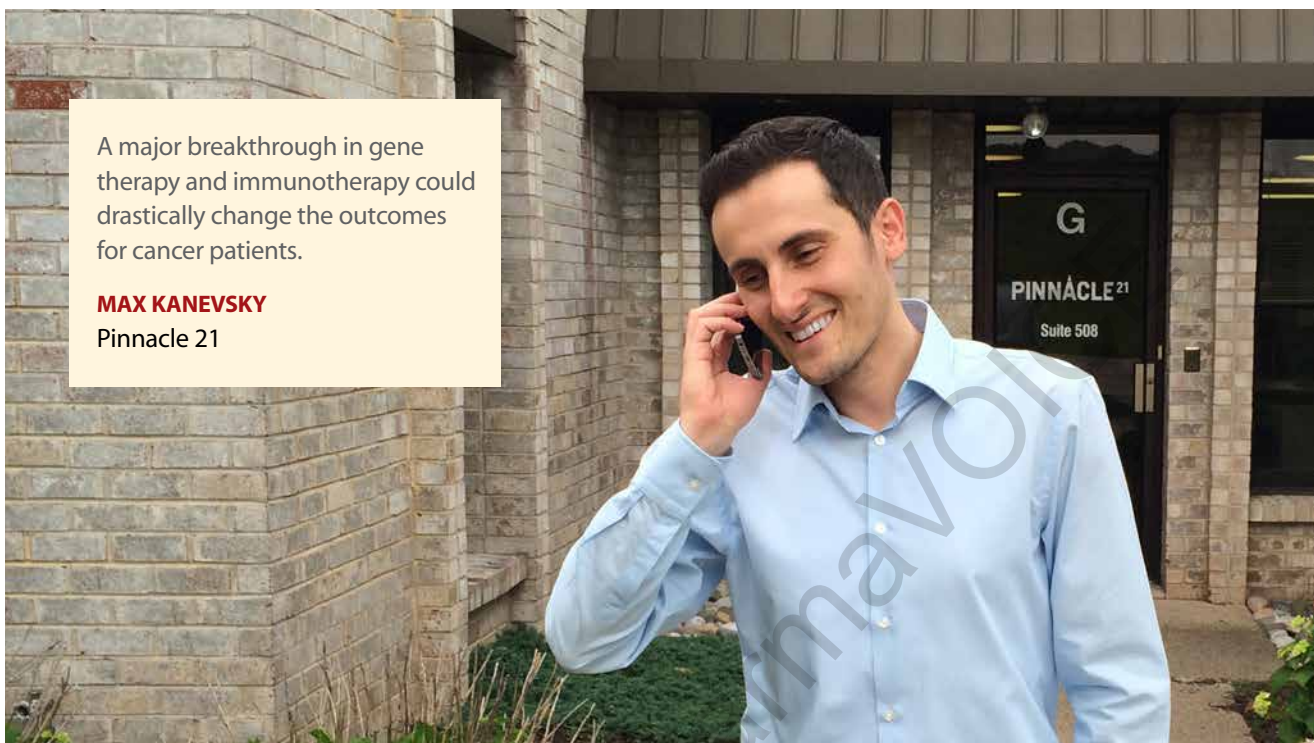
The fact is, while our industry as a whole has been quite adept at communicating on an intellectual level — through the use of positioning and messaging — we have been far less sophisticated in reaching beyond the intellect to affect the emotions through the use of brand personality.

**NICOLE HYLAND**  
Natrel



A major breakthrough in gene therapy and immunotherapy could drastically change the outcomes for cancer patients.

**MAX KANEVSKY**  
Pinnacle 21



We will see a large uptick in at-home diagnostic testing, which, coupled with the changing role of patients and physicians, is going to create a lot of interesting challenges and questions.

**JEANINE O'KANE**  
Biosector 2

### Personalized Medicine

Many of the PharmaVOICE 100 honorees named personalized and precision medicine as the biggest breakthrough in healthcare.

A recent report from EY found that personalized medicine will come of age in the next five years. With the price of personal genome sequencing falling significantly, manufacturers are increasingly focused on personalized medicine approaches. The high price of targeted therapeutics is poised to exacerbate the pressure on payers, while the anticipated increase in genomic data will create new opportunities, and challenges, for companies looking to gain access to, and make sense of, this information. The personalized medicine diagnostics market, for example, is expected to grow with a double-digit CAGR for the period of 2013 to 2018.

Additionally, EY finds the availability of genetic and genomic information — pharmacogenetics and pharmacogenomics — is helping to bring in sweeping changes in the development of new therapies. Genes and gene products thought to be involved in specific disease mechanisms represent new targets for intervention, driving promising new drug discovery programs. These techniques will make major improvements in the identification of new drug candidates.

Patrick Hughes, chief commercial officer of CluePoints, says the advancements in personalized medicine and genome sequencing are incredibly exciting and represent transfor-

change that is upon us and intend to continue to champion it for our customers.”

Willie Muehlhausen, D.V.M., head of innovation at ICON, says the company deployed Spark late last year to manage challenges and ideas within ICON and will open this up to external partners.

The ideas management solution, managed by the ICON innovation team and branded Spark, enables all employees to have their voice heard in overcoming particular challenges. The system also facilitates cross-department collaboration and gives employees access and a communication channel with all departments enabling cross-pollination of ideas.

“Everyone in ICON can put forward challenges to invite colleagues to bring ideas and comments to the challenge,” Dr. Muehlhausen, says. “I am a strong believer in crowd

sourcing and Spark brings all of us together to collectively address issues and develop solutions and visions for future challenges. We are also collaborating with academia, partners — suppliers and clients — and actively participate and manage industry consortia.”

At EY, the company aims to encourage innovation by taking the organizational fear out of failure and providing a safety net, says Ric Cavieres, principal, advisory life sciences commercial practice leader, EY.

“Innovation, by its definition, is to do things differently and that means taking risks. If people are afraid of the consequences of failure they will not innovate. For instance, the ability to innovate is directly tied to EY’s cultural and organizational mindset to be entrepreneurial and take calculated risks. At EY innovation is rewarded. The status quo is not.”



The days of the blockbuster may be past; in the future we may be more selective in treating only those for whom the treatment is likely to work based on various predictive factors including genetics.

**STELLA BLACKBURN**  
Quintiles

mative approaches to healthcare that everyone will benefit from.

“My hope is that this type of patient-driven care will be widely available in the next five to 10 years,” he says.

Stella Blackburn, VP, global head of risk management, real world and late phase research, Quintiles, says this effort started in oncology where tumors are genotyped and treatment is based on the individual markers and mutations.

“I think that the days of the blockbuster may be past; in the future we may be more selective in treating only those in whom the treatment is likely to work based on various predictive factors including genetics,” she says.

Sandra Lottes, VP, global clinical development and operations, United BioSource Corp. (UBC) says we will be able to identify more and more actionable mutations in treating various cancers.

“We’re able to identify aberrations in a genomic sequence — something we once thought was impossible,” she says. “That process is ancient history now, but we cannot always act on this breakthrough, until highly sensitive assays continue to be developed. Ever improving technology will allow clinicians to potentially impact our findings to the level of

## Innovation In CNS and Biosimilars

### CNS

There continues to be a significant global burden particularly of central nervous system (CNS) diseases, says Thomas Hospodar, head, global office of strategic planning, Sunovion Pharmaceuticals. In fact, the global economic burden for psychiatric illness is estimated by the WHO at \$1 trillion per year. He says over the last decade, 40 NMEs were approved for CNS disorders, out of a total of 304 NME approvals in all therapeutic areas.

“This is not commensurate with the disease burden that these illnesses present to society, so it is my hope that we can address these public health issues as an industry, and with other stakeholders,” he says. “While innovative drug development in CNS is certainly impossible, and research in academia and NIH continues to increase our understanding of basic neurobiology, it is challenging and difficult to translate these advances into new medicines.”

Sunovion is working in partnership to use a new neurobiology phenotypic approach to drug discovery, which has historically yielded many of the most important CNS drugs, in order to rapidly drive chemistry optimization efforts and yield drug-like molecules with novel pharmacology.

“We also believe in partnerships and pre-competitive consortiums to help drive innovation,” Mr. Hospodar says. “For example, we have been a key leader in the Massachusetts Neuroscience Consortium of the Massachusetts Life Science Center. This is a new model that can help to accelerate early-stage research and enable collaboration among various stakeholders for the benefit of patients and the healthcare system, and the model is being expanded across the United States. Pharmaceutical companies, academia, and others have come together through the consortium in a no-strings attached approach to support research by the most deserving

researchers and labs in the areas of neurodegeneration and pain. This underscores the role the biopharma industry can play by working collaboratively with government, academic institutions, and other organizations and stakeholders toward common goals.”

Mr. Hospodar says working together will encourage more funding and government investment across the R&D value chain to maintain a sustained innovation pipeline and meaningful results for current and future generations will drive big breakthroughs.

“We see this advancing economic competitiveness, the future pipeline for innovators and innovation and seeding next-generation technologies, and importantly, providing access for patients to new therapies that have a positive impact on the healthcare system,” he says.

### BIOSIMILARS

Lisa Jenkins, Ph.D., VP, regulatory strategy and content development, Virtual Regulatory Solutions, says the generics industry revolutionized healthcare and biosimilars are the next wave in that revolution.

“Biosimilars have the potential to continue to drive costs down and make symptomatic and disease-modifying treatments affordable to more patients than ever before,” she says. “I predict that process improvements will trigger innovation in other areas of pharma.”

Marc Kikuchi, senior VP, global sourcing and procurement officer, AmerisourceBergen, agrees that the introduction of biosimilars will be a big breakthrough for the industry.

“I’m reminded of the Hatch-Waxman act of the 1980s,” he says. “Generics were questioned back then, but now they make up 80% of all prescriptions filled. I think biosimilars will be more accepted, as these products make healthcare more affordable to a broader audience.”



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**DR. BORIS KUSHKULEY**  
Intouch Solutions



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**DR. BRUCE FEINBERG**  
Cardinal Health Specialty Solutions



Innovation, by its definition, is doing things differently and that means taking risks. If people are afraid of the consequences of failure they will not innovate.

**RIC CAVIERES**  
EY

a cure. I think more personalized medications in many more diseases and disorders will be developed and technology eventually will allow us to take greater action to help larger numbers of patients in earlier stages of their disease.”

Personalized medicines, along with immunoncology, are already starting to have an impact, says Andrew Zupnick, Ph.D., senior director, oncology division at Novella Clinical, a Quintiles company.

“I would love to live to see the day when cancer is treated as a chronic disease and not a death sentence,” he says. “Imagine a time when a person can walk into a cancer hospital, give a blood sample for genomic sequencing, and walk out with a combination of low-toxicity chemotherapies, biomarker-defined kinase inhibitors and antibodies, and immunotherapies customized to keep their specific cancer at bay so they can continue living a healthy and active lifestyle.”

Gene therapy also will have a huge impact on cancer, says Max Kanevsky, founder and CEO of Pinnacle 21.

“A major breakthrough in gene therapy and immunotherapy could drastically change the outcomes for cancer patients,” he says. “In healthcare as a whole, I’m really excited about personalized medicine. I hope this field can overcome its challenges and become a reality.”

### Technology Trends

The future of healthcare is digitization, says Sanjit Singh Lamba, Ph.D., managing director, Eisai Pharmaceuticals India.

“The healthcare industry is on the cusp of a third wave of IT adoption, and now is the time for everything to go all in on digital strategies,” he says. “Understanding what patients want can help pave the way. Digitizing the health system to reengineer the way we collect, store, and use health information will achieve the kind of efficiency gains that technology has produced in most other aspects of our lives.”

Innovation is the result of surround sound insight, adapted meaningfully, says Nicole Hyland, chief marketing officer at Natrel.

“We are an industry driven by data; it’s everywhere,” she says. “But the challenge is to filter the data in a way that’s actionable. Suddenly the analytics are focused, relevant and meaningful in the right segments. It’s all about creating potential, both in people and in this case data.

“In addition, bilateral thinking is a key component of innovation,” she continues. “The fact is, while our industry as a whole has been quite adept at communicating on an intellectual level — through the use of positioning and messaging — we have been far less sophisticated in reaching beyond the intellect

to affect the emotions through the use of brand personality. This is a serious oversight when you consider that emotion is at least equal to reason as a driver in the decision-making process, and personality makes an immediate impression, long before the audience has a chance to consider the message. By focusing equal attention, discipline, and analysis on both the intellectual and emotional aspects of branding, we can effectively double the impact while ensuring that the brand is differentiated well beyond what data and claims alone might achieve.”

Big data is also expected to have a big impact on the pharmaceutical industry, PV 100 honorees say.

Michelle Keefe, president and CEO of Publicis Touchpoint Solutions, says big data is going to provide us with greater opportunity to impact healthcare at a macro level.

“And, of course, healthcare apps are progressing and will go a long way toward helping to create a more educated and informed consumer,” she says.

Andy Pyfer, co-founder and managing partner, Fingerpaint, says pharma marketers will get even better at harnessing big data, enabling much more precision in their promotional outreach.

“We’re seeing it today with data from EMR companies and mobile-enabled geo-spe-

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## In Pursuit of Innovation: A CEO Checklist

- ▶ **Approach:** Breakthrough innovation requires an experimental, iterative approach. Teams responsible for implementing an innovation strategy should follow a nonlinear path, but in a disciplined way that is guided by protocols, phases, and methods.
- ▶ **Organization:** Breakthrough innovation is a balancing act between separating from and collaborating with existing business units. The three levers of the organization component are senior leadership, governance, and collaboration.
- ▶ **Resources & Competencies:** Breakthrough innovation requires resources comprised of the individuals who perform the work, the skills, tools, and training. The three levers are funding, talent management, and innovation tools.
- ▶ **Metrics and Incentives:** Breakthrough innovation should require a mixture of leading indicators and lagging indicators tied to individual and collective incentives. The three levers include financial and nonfinancial rewards, innovation metrics, and external attraction.

Source: Deloitte Center for Health Solutions

We empower our employees to look beyond standard expectations and push the boundaries of what's possible in an effort to advance science and the development of life-changing medicines to improve public health, and help fight and cure disease.

**RAKESH DIXIT**  
MedImmune



Once the access barrier is lowered, there will be really smart and out-of-the-box thinkers and doers who will surprise us in unimagined ways. We have started to see this already, for example, PatientsLikeMe.

**DR. LIHUA YU**  
H3 Biomedicine

cific targeting tools — and things will only get better,” he says.

The McKinsey Global Institute estimates that applying big-data strategies to better inform decision-making could generate up to \$100 billion in value annually across the U.S. healthcare system, by optimizing innovation, improving the efficiency of research and clinical trials, and building new tools for physicians, consumers, insurers, and regulators to meet the promise of more individualized approaches.

Lihua Yu, Ph.D., VP, data science and information technology, H3 Biomedicine, says the knowledge barriers, the technology access barriers, and financial barriers are still very high.

“This means only people who are insid-

ers, insiders in renowned academic institutions, insiders in well-funded biotechnology or pharmaceutical companies etc, can work on some of the problems by accessing the data, technology, and other resources,” Dr. Yu says. “My hope is that technology advancement will greatly lower access barriers to data just like the Internet lowered barriers for many of the successful companies started in the last 15 to 20 years that took advantage of the information flow and connectivity provided by technology. Once the access barrier is lowered, there will be really smart and out-of-the-box thinkers and doers who will surprise us in unimagined ways. We have started to see this already, for example PatientsLikeMe.”

Mr. Hughes of CluePoints says in clinical technology, innovation around mobile health

will change the face of how patient data is collected and used within trials and the wider healthcare market.

“Additionally, risk-based monitoring and data quality oversight will improve patient safety, data quality, and significantly reduce costs of drug development in the next few years,” he says. “I’m very excited to be at the forefront of what I am sure will be revolutionary change. The introduction of digital health, including wearable health technology, will change the way that healthcare is delivered around the globe.”

Jeanine O’Kane, managing director, Biosector 2, part of inVentiv Health, says the most pervasive change will be how technology empowers patients to take control of their healthcare.



More personalized medications in many more diseases and disorders will be developed and technology eventually will allow us to take greater action to help larger numbers of patients in earlier stages of their disease.

**SANDRA LOTTES**  
UBC

“At-home healthcare and self-care will grow dramatically,” she says. “We will see a large uptick in at-home diagnostic testing which, coupled with the changing role of patients and physicians, is going to create a lot of interesting challenges and questions.

ICON’s Dr. Muehlhausen says capturing data directly from patients via sensors will be the new standard and communicating with avatars and robots on a daily basis will be commonplace.

“In my sector BYOD will be acceptable and will be a major breakthrough in distributing questionnaires to patients globally,” he says.

Alan Ong, executive VP, Asia Pacific of INC Research, says the convergence of technology — from wearable devices to mobile apps — is the next big thing in healthcare.

“Wearable devices have the power to transform the healthcare field,” he says. “It is an exciting time. This is all leading to more patient empowerment throughout healthcare.”

Keith Stenlund, chief financial officer at

The healthcare industry is on the cusp of a third wave of IT adoption, and now is the time for everything to go all in on digital strategies.

**DR. SANJIT SINGH LAMBA**  
Eisai Pharmaceuticals India



AbelsonTaylor, says wearables will become one of the biggest breakthroughs in healthcare management and disease prevention.

“I’ve been using a fitness and sleep tracker and I’ve been impressed with the amount of information it can collect about my habits,” he says. “It actually helps nudge me to do a little better each time. So if it can help push me to be better, imagine what it can do to a larger number of people. And it’s only a matter of time before these wearables can aggregate data to predict outcomes.”

Dan Diaz, VP, business development/global feasibility, SPRI Clinical Trials, says he is excited about the new tools that are now available that will allow patients to be monitored remotely and that have the ability to upload data electronically via Bluetooth and other devices.

“For patients in remote areas of Eastern Europe, Asia, and the United States, we will be able to participate in trials that they may not have been able to be involved in before,” Mr. Diaz says.

The global wearables market is expected

to grow at a compound annual rate of 35% over the next five years, reaching 148 million units shipped annually in 2019, up from 33 million units shipped this year, according to BI Intelligence.

Fitness bands, because of their appeal to niche audiences interested in health and exercise, will see their share of the wearable device market contract to a 20% share in 2019, down from 36% this year. There will be some blurring between fitness bands and smartwatches.

Cheryl Lubbert, president and CEO of Health Perspectives Group, says technology in healthcare is like the Wild West right now.

“There has been a lot of innovation but the innovation is siloed,” she says. “We have apps. We have EMRs. We have pharmacy systems. We have industry-sponsored support programs. But this innovation is not integrated in a way that really allows us to impact healthcare costs, improve outcomes and meet patient needs. I think the biggest breakthrough will be the seamless integration of all of these solutions across all sectors. It will change how we deliver healthcare.” **PV**

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