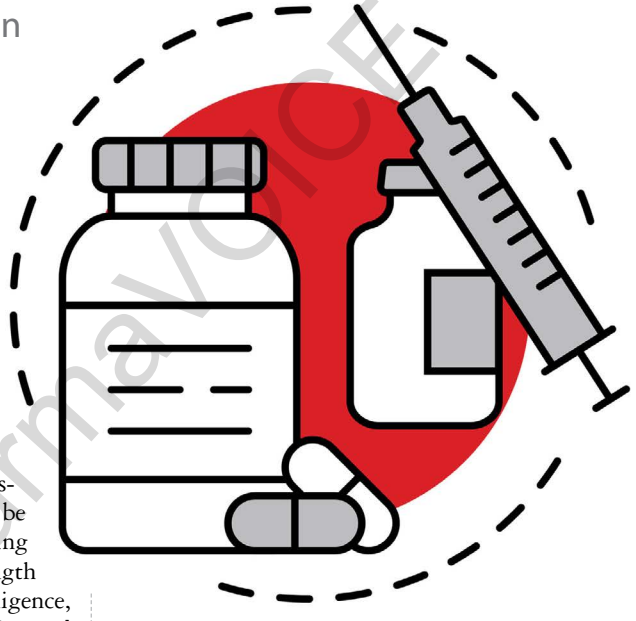
by Denise Myshko

Patient Care: Treatment to Cure

Moving the industry from a focus on treatment to a focus on prevention will require data, new financial incentives, and a change in how healthcare is delivered and paid for.



Today, the U.S. healthcare system is a collection of disconnected components: health plans, hospital systems, pharmaceutical companies, medical device manufacturers, and so on. Healthcare consumers typically interact with the health system only when they are sick or injured. While this approach has led to groundbreaking discoveries and innovations, it fails to account for the influence of nonclinical factors, such as patient lifestyle and socioeconomic status, which can lead to onset of disease.

Many industry leaders say the future of health will be focused on well-being and prevention. Healthcare consultants predict the way healthcare is researched, delivered, and paid for will change in a big way, with patients being at the center. For example, Deloitte researchers expect that in 2040, health will be defined holistically as an overall state of well-being encompassing mental, social, emotional, physical, and spiritual health.

Researchers from Strategy&, PwC's strategy consultancy, say by 2030, healthcare will be centered on patients empowered to prevent diseases rather than seek treatment. Patients will receive personalized health solutions in ways that are integrated seamlessly into their daily lives. All of this will be enabled by data and algorithms and provided within a healthcare system that is organized and regulated in an entirely new way.

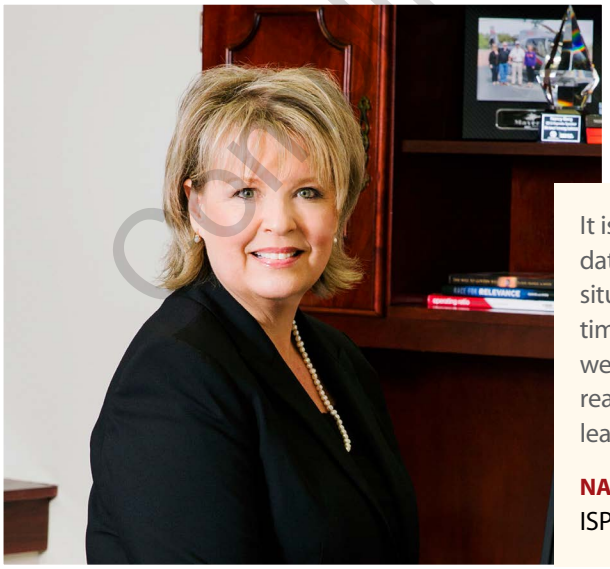
For the biopharmaceutical industry, the shift from treatment to prevention, diagnostics, and cure means companies must pivot from a disease care focus to one of healthcare, says Ben Wiegand, Ph.D., global head, World Without Disease Accelerator, Janssen. "Consumers and health professionals have exciting opportunities to be more proactive and holistic in approaching and maintaining health with the strength of sensors and wearables, artificial intelligence, and data sciences to potentially predict and preempt disease, prior to the manifestation of clinical symptoms," he says. "Also, deeper scientific insights are unlocking novel targets and disease pathways, presenting unimagined solutions, from digital therapeutics, to new OTC, prescription, and diagnostic solutions. At Janssen, we're particularly excited about the potential of disease interception and stopping disease before it starts, a strategy that we are actively pursuing as we look to create a world without disease in the future."

KPMG researchers believe a swing from treatment to prevention, diagnostics, and cure will grow stronger in time, attracting a host of new entrants from within and outside of the pharmaceutical industry.

If pharma stays in the business of product development without expanding to a broader health mandate, the industry risks missing the tectonic consumer and public policy shift to prevention and cure, says David Ormesher, CEO, closerlook. "The industry will get caught in a vise between commoditization on one hand and diminishing demand for chronic therapies on the other as prevention and cure become more effective," he says. "But moving the pharma industry to prevention, diagnostics, and cure must start with reframing the definition and purpose of the industry itself. This is not only an issue of industry scope definition; it also defines the customer relationship. Like many manufacturers, pharma works through 'dealers' and rarely has a direct relationship with patients. This reduces the patient interaction to what is often a price-driven transaction."

Mr. Ormesher says if pharma companies were to expand their mandate to include a broader definition of health, including prevention, diagnostics, and cure they would find purpose and economic drivers to support growth and renewal. And ultimately, they would find a different and more fulfilling relationship with their customers.

In fact, pharma needs to think full circle and urgently reimagine its products and services and expand these to wellness and disease prevention to complement diagnostics and treatment products, says Ric Cavieres, executive VP, strategy, markets and consulting, OZ. "Prevention and wellness is already a $4.2



It is only through integrated data collection, understanding situational defined value, real-time analysis and feedback that we will be able to move from reactive to proactive quality learning healthcare systems.

NANCY BERG
ISPOR

Understanding Disease Through Genomics

DR. ANDRE CHOULIKA
CEO, Cellectis

The best path the industry can take right now is to put less emphasis on commercialized gene therapies that rely on a very complicated and individualized manufacturing process and focusing more on how we can better optimize and streamline these treatments to benefit patients faster.

The autologous treatments, or traditional gene therapies, are made from the patient's own T-cells, requiring the patient's healthcare team to collect and separate T-cells from the patient's other blood cells. This collection process is called leukapheresis and has a lot of logistical complexities and associated costs for resources.

DAN RHODES
Co-Founder and CEO, Strata Oncology

An improved understanding of health and disease through genomics will drive tangible advances in diagnosis, disease-prevention strategies, and the development of targeted therapies. Cancer, a condition of genomic dysregulation, has long been at the vanguard of precision medicine. New models are needed to accelerate progress and ensure more patients with cancer are able to benefit from precision medicine. Large-scale, molecularly informed research that integrates tumor molecular profiling and cutting-edge precision trials will support more informed clinical characterization, prevention, and management of disease.

trillion industry, driven by companies such as Apple, Fitbit, Sonic Boom Wellness, and Virgin Pulse. Pharma companies market share of this $4.2 trillion industry? Zero."

To shift from treatment to prevention, healthcare stakeholders need to fundamentally pivot their mindsets from treating disease to avoiding it, says Kevin Hrusovsky, president, chairman and CEO, Quanterix.

'The industry is making phenomenal strides in conforming treatments to specific individuals, and it's clear that the one-size-fits-all approach is becoming a mindset of the past," he says. "But this is only one part of improving the healthcare system. Doctors have spent years focusing on prevention through nutrition, exercise, and encouraging regular doctor's appointments, and they have the opportunity to do more. The industry should be looking at how doctors can better understand each patient's health at the molecular level and how this type of analysis can become part of routine care. By monitoring patients at this granular level, doctors can better establish a patient's healthy baseline and pinpoint the moment they divert from it."

The Need for Real-World Data

Moving the industry from a focus on treatment to a focus on prevention requires developing a more holistic understanding of patients' lives outside of the clinical setting, says Jean Drouin, M.D., co-founder, CEO, Clarify Health Solutions.

"A major barrier to realizing this vision is the difficulty of integrating disparate types of data across clinical, claims, lab, genomic, and social and behavioral sources, as well as cleaning and formatting this data in a standardized way," he says. "Once we accomplish this at scale, we can build and train reliable predictive models that offer insights to make us healthier, and to make healthcare delivery smarter."

Dr. Drouin says this would enable physicians to predict an individual's likelihood of developing a given disease based on a combination of clinical and nonclinical factors, enabling healthcare providers to recommend preventive measures and potentially avoid downstream costs of care.

"For those conditions that we cannot prevent, we could make use of real-world evidence (RWE) to diagnose patients as early as possible given their risk profiles and then prescribe only those treatments tailored to their unique characteristics," he says. "The industry can use RWE analyses to design smarter trials and find answers to questions that might take multiple years, enhancing our ability to discover cures and expanding the use of existing therapies into new and promising disease areas."

Nancy Berg, CEO and executive director, ISPOR — The Professional Society for Health Economics and Outcomes Research, says RWE is also playing a larger role in moving the healthcare system toward prevention and to optimal health outcomes when treatment is needed. "The number of RWE studies is increasing with the wealth of available data through EHR, claims data, registries, and personal digital devices," she says. "Big data and machine learning supercharge the ability to conduct these studies. It is only through integrated data collection, understanding situational defined value, real-time analysis and feedback, along with aligned incentives, that we will be able to move from reactive to proactive quality learning healthcare systems."

The FDA defines RWE as: "Healthcare information derived from multiple sources outside of typical clinical research settings, in-

The Future of Healthcare

In 2040, the siloed industry segments we have now (such as health systems and clinicians, health plans, biopharmaceutical companies, and medical device manufacturers), will be replaced with new roles, functions, and players. In the future of health, Deloitte researchers expect three broad categories to emerge:

- **Data and platforms.** Data will be collected from multiple sources to enhance research, to help innovators develop analytic tools, and to generate the insights needed for personalized, always-on decision-making.
- **Well-being and care delivery.** Community health hubs, specialty care operators, virtual communities and care-delivery mechanisms, and product developers will partner with one another to drive a tailored promotion of health and well-being.
- **Care enablement.** Financiers and intermediaries will facilitate consumer payment and coordinate supply logistics, respectively, but they could experience decreases in margins and share of profits, driven by advanced analytics and risk assessment.

In this model, biopharmaceutical companies are set to develop hyper-tailored therapies that cure disease rather than treat symptoms. Individual drug prices could rise as therapies become more efficacious and applied in more targeted populations. However, overall drug spending could decrease as the unit volume falls. Advanced early intervention and enhanced adherence could also help ensure the effectiveness of new therapies.

Source: Deloitte

Moving the industry from a focus on treatment to a focus on prevention requires developing a more holistic understanding of patients' lives outside of the clinical setting.

DR. JEAN DROUIN
Clarify Health Solutions

Society as a whole must come to grips with what the true value is of a cure for a disease and how we will pay for that value.

THOMAS NEYARAPALLY
Sema4

cluding EMRs, claims and billing data, product and disease registries, and data gathered by personal devices and health applications." The agency says these data sets can effectively complement the knowledge gained from traditional clinical trials, whose well-known limitations make it difficult to generalize findings to larger, more inclusive populations of patients, providers, and healthcare delivery systems or settings reflective of actual use in practice.

Regulators, in fact, are using RWE to monitor the safety of marketed products through pharmacovigilance tools, as well as digital aids such as the FDA Sentinel Initiative, a postmarket active safety surveillance system. And the 21st Century Cures Act passed in December 2016 establishes public-private partnerships to collect data and improve understanding of diseases, supports patient-focused drug development, and modernizes the design of clinical trials and their review process.

But McKinsey researchers point out there are several barriers to increased use of RWD, including the uneven quality of sources, limits to access, lack of standardization of analytics, and varied public support. McKinsey researchers also say RWE could significantly improve healthcare decisions across the health system and ultimately improve patient care. Expanding its use, however, will require multi-stakeholder action on several priorities, as well as company-specific campaigns.

Financial Incentives Need to Change

To align healthcare systems for early diagnosis, disease prevention, and cure would require substantial disruption of reimbursement models and how healthcare is provided, says Daryl Spinner, Ph.D., managing director, real-world value and strategy at Evidera. "Currently healthcare systems are mostly designed to treat sick patients, and less so to provide early diagnosis/screening, prevention, and cure with most systems being designed based on a fee-for-service model, where payment is based on use of services and products, as opposed to minimizing the need for their use in the first place," he says. "Instead of providers being paid for treating sick patients they would be paid for how long each patient remains healthy. This is very difficult to implement in the current environment where patients mostly visit the clinic only when sick, and patients are not assigned to a specific provider or incentivized to be proactive about maintaining their health."

Dr. Spinner says if financial value was placed on, and industry was compensated for, services and products that maintained health, and for how long a patient remained healthy while using their services and products, there would be a sustainable environment to develop health-preserving treatments.

"Patients and providers would also need to be aligned to ensure compliance with treatments that preserve health for the system to work," he says. "Payers would also need to be willing to pay for services and products that identify risk/early stages and prevention of disease, which would require major changes to what — and the amount — that gets reimbursed. Even in an ideal world where everyone is almost entirely focused around illness prevention and maintaining health, there will always be a need for treatments to aid sick patients, although that need would be greatly reduced."

A survey by Huron of healthcare system executives found respondents believe a shift to value will continue over the next three to five years because of changing regulations. There are roadblocks in the shift to value within the current system, and it's unclear how a system focused on value-based payments will look.

Thomas Neyarapally, chief commercial officer at Sema4, says society as a whole must come to grips with what the true value is of a cure for a disease and how we will pay for that value. "Assessing the value of the prevention of disease is even more difficult, as it involves predicting the likelihood that disease would develop in an individual as well as the projected costs associated with that individual developing the disease," he says. "Beyond establishing viable value models, connecting the appropriate data, analytics, clinical and scientific expertise, industry functions, and mechanisms to deliver insights where they can be acted upon will be critical to move the industry toward the desired outcomes of prevention, diagnostics, and cure."

Mr. Neyarapally says data associated with a patient's journey from well before diagnosis onward must be captured, not just in the instances when a patient is interacting with the health system formally, but in their everyday life through mobile and Bluetooth-enabled devices and other means.

"The meaningful insights about patient treatment must be liberated from the physicians' notes in EMRs," he says. "Data used for disparate purposes such as genomic, EMR, claims, pharmacy, must be combined at the patient level to render a more complete picture of the patient. Data scientists, clinicians, and scientific experts in disease must work in concert to build computational models of disease and wellness from these data."

Geoffrey Gill, president of Shimmer Americas, says the pessimistic view is that we will need to change basic human nature for this focus on prevention to occur.

"Left to their own devices, people are willing to pay almost anything to

The shift from treatment to prevention, diagnostics, and cure means companies must pivot from a disease care focus to one of healthcare.

BEN WIEGAND
Janssen

cure a serious illness," he says. "However, they are willing to pay only a fraction of that cost to diagnose the illness and even less to take a vaccine that would have prevented it from occurring in the first place. However, the current economic and demographic trends are so unsustainable in every country that something drastic needs to happen. That something could be an efficient way of capturing the economic benefits of prevention for those who engage in it. We have not yet seen a system that does that effectively, but we are sure it exists."

The key influencing factor for the shift to prevention and diagnostics would be patient education and awareness, says Vimal Narayanan, founder and CEO, MedTrix Healthcare. "This is especially true for certain diseases such as diabetes where more and more data are available on reversing the disease by being on a fairly reasonable regimen," he says. "The key would be the availability of tools that educate the patients and help them stick to a healthy life style. This could be achieved by lifestyle coaches who are bot-chats and voice assistants. This will ensure that there is a 24/7 support available for the patient and could help with intelligent responses, which could be improved over time."

Mr. Narayanan says with the advent of modern technology, several open source tools are available that can be put into good use to build specific applications for a given purpose/healthcare scenario or a system. "This can be achieved in a fairly quick time with good results," he says. "The key would be the creation of the framework to mobilize these resources and make them readily available for patients."

Thomas Dudnyk, president of VIVO Agency, says health system leaders need to feel financial pain for not measurably improving outcomes. "We need more health-system CEOs who think the way Dr. David Feinberg, now the head of Google Health, thinks about population health," he says. "At Geisinger, Dr. Feinberg reallocated resources to the outpatient environment instead of building hospitals, wings, and towers. He worked to get everyone in his network genetically sequenced, thus identifying the rare diseases many were carrying. In other words, as he demonstrated, we already have many of the tools needed to provide healthcare rather than sick care."

Mr. Dudnyk argues we need today's healthcare leaders to make the same commitment as Dr. Feinberg and begin reallocating significant resources from high acuity, costly in-patient care to low acuity, cheaper outpatient care. "We also need CMS to double readmission penalties, triple the readmission window from 30 to 90 days, and promote hospital scorecards," he says. "Only by making many health system leaders feel financial pain and community shame for not measurably improving outcomes will they find the courage and urgency to act."

Deloitte researchers say building an outcomes-based financial model and data infrastructure to maximize value-based care reimbursement pathways will likely be fundamental to many health systems' sustainable growth. It's expected that one key to prospering in this volume-to-value shift will be business integration and data aggregation — both inside and outside of an organization and across sectors and models of care.

Early Detection Key to Improving Health

JEFF FISCHER
President, Longhorn Vaccines & Diagnostics

Diseases that are detected early, especially before symptoms occur, are often easier to treat, require fewer interventions, and use significantly less resources. For certain medical conditions, simple, accurate in-home testing kits have increased early detection and allowed individuals to self-screen prior to accessing the healthcare system. Insurance companies have sent healthcare professionals into homes for years to provide quick health assessments, draw blood, and collect a urine sample. DNA test kits allow an individual to provide a saliva sample and receive genetic information some of which can inform medical follow up.

Diagnostic tests are continuously being enhanced to detect diseases from influenza to cancer at the subclinical level. For these tests to have the greatest impact, screening will need to be broad-based and frequent.

Sample collection will need to be simple, safe, and minimally invasive to ensure that a gig workforce can be quickly and properly trained to safely collect and transport samples with no special cold chain or pathogen containment equipment to laboratories with current capacity.

A key challenge to implementation will be the payment reimbursement model. Most insurance plans exempt the annual physical from the patient's deductible. As new screening tests become available and demonstrate the ability to detect disease at earlier stages, payers should embrace the tests and the ancillary costs of expanding their uptake.

PETER KEELING
CEO, Diaceutics

The industry needs to stay vigilantly focused on improving patients' lives. This means finding the cures that elude us. In the absence of these cures, the industry's backup plan should be to improve patient access to preventive screening and early and accurate diagnosis. From a companion diagnostics perspective, the focus should be on better testing, better treatment, achievable through optimized patient access to the right diagnostic tests.

A major hurdle preventing patients from accessing the right tests is a lack of adequate funding. Many labs do not have the means to invest in technologies required to run the approved diagnostic tests. Instead, many labs are forced to develop their own versions of diagnostic tests to serve patients, further complicating interpretation and threatening the consistency of test results. The absence of an effective platform to rapidly commercialize and implement new diagnostics within the 2,000-plus labs that serve prescribers is driving this economic hurdle. This broken testing ecosystem is further hampered by non-pharma stakeholders that are not focused on patients and diagnostic companies that are not incentivized to promote better testing at the expense of their own technology, leaving labs fragmented globally. Additionally, many patients do not receive the right tests because they are not sufficiently reimbursed. As a result of these and other testing inefficiencies, patients are underserved and suboptimally treated. For example, one-third of oncology patients are missing out on precision medicine treatments, which is a total loss of more than $16 billion a year. Harmonization of diagnostic tests may address these hurdles, requiring collaboration between stakeholders within the multisided marketplace. Additionally, bold, new thinking is imperative to move us past the commercialization of precision testing 1.0 toward the new industrial solution so urgently required to ensure precision medicines reach the right patients at the right time. PV