Health Research Institute
Spotlight

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Patient engagement: Pharma's strategy for success in the New Health Economy

Pharmaceutical companies are facing new demands from consumers, regulators, insurers and independent groups. Constructive engagement with patients and consumers can form a crucial link between these stakeholders, providing better outcomes and value for pharmaceutical companies.

Shifting reimbursement and regulatory environments and increasingly engaged patients are forcing pharmaceutical companies to change the way they develop, test, market and sell their products.

Consumers are taking charge of their health and asking to be more involved in decisions related to their care. Regulators are tailoring regulatory approvals to patients' tolerance for risk and desire for benefits. The healthcare system at large, and insurers in particular, are asking pharmaceutical companies for more evidence that products produce favorable outcomes.

The health industry also is in the midst of a fundamental restructuring. The traditional healthcare delivery model continues to evolve into a health ecosystem of collaborators focused on paying for the value of outcomes, and not the volume of care.[1]

While the pharmaceutical industry has always interacted with patients, in particular through clinical trials and marketing efforts, these types of engagement may no longer be sufficient for some companies as industry and regulatory changes take hold. What is needed is proactive patient engagement that anticipates and meets the evolving needs and wants of consumers.

Pharmaceutical companies can reap new value from these new types of patient engagement but it will not be simple. Consumers lack trust in the pharmaceutical industry. Regulatory hurdles may create roadblocks, too, requiring companies to explore new ways of engaging patients. Companies will need to start connecting with patients more often, with the help of partners and technology, and earlier in the research and development process.

Companies that succeed in their engagement efforts can increase their chances of regulatory and commercial success by learning more about the day-to-day experiences of patients living with particular diseases, those patients' values and needs, and their willingness to assume risks in return for access to new treatments.

Three forces driving new patient engagement

As the healthcare ecosystem continues to evolve, new trends are emerging and existing players are adapting. These changes, and three in particular, are creating a need to engage with patients and consumers in new ways. These forces—the emergence of consumerism, the shift from volume to value, and regulatory interest in patient perspectives—increase the importance for pharmaceutical companies to participate in patient engagement in appropriate ways.

The emergence of consumerism: More consumers are rejecting the healthcare industry's once-paternalistic relationship with them. Instead, consumers increasingly want to take charge of their care, and communicate their needs, desires and concerns to healthcare companies.[3,4]

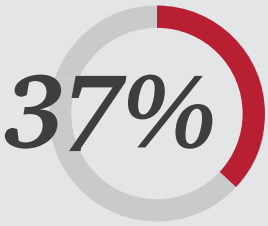
More than ever, patients and consumers are able to find information about their diseases, connect with one another on social media networks, track and access their health data, and locate complex information about drugs under development. New technologies like wearables and mobile apps are making it easier for patients to track and use their own data to help make healthcare decisions. Twenty-four percent of consumers have used Facebook for healthcare purposes.[5,6] Thirty-seven percent have sought healthcare information on at least one social media network.[7]

As patients increasingly take charge of their health, they need access to information to make informed decisions. Finding information quickly and in an easy-to-understand format is not always simple though.

Historically, the pharmaceutical industry has focused on obtaining regulatory approvals and marketing products, requiring them to engage with doctors and regulators more than patients. Instead, companies will now need to consider what types of information patients want access to, how they want to access it, where they want to access it, and other needs that they might have. Caregivers, including families and friends, may need access to these same types of information.

The information patients want access to will depend on their degree of health. Some patients may want to know specific

patient engagement:
Interactions between healthcare companies and patients in the hopes of providing more positive experiences that result in higher standards of care for patients with improved satisfaction and outcomes.[2]



of consumers have used social media to find or share healthcare information.[7]

information like how to find and enroll in a clinical trial. Others, such as patients with terminal illnesses, may want to know more about accessing experimental therapies and information on how to participate in expanded access programs.[8]

The shift from volume to value: Insurers, government payers and pharmacy benefit managers are looking for ways to control health costs. Insurers and drugmakers are striking novel outcomes-based contracts that peg reimbursement rates to a drug's effect on patients in real-world settings outside of clinical trials. Independent, third-party value assessment groups like the Institute for Clinical and Economic Review (ICER), the National Comprehensive Cancer Network (NCCN) and the American Society for Clinical Oncology (ASCO) are beginning to publicize their own judgments about drug value using formulas that take into account clinical performance, outcomes and patient perspectives.[9]

This emphasis on value is creating new pressures and complexities for pharmaceutical companies, which already are grappling with increasing research and development costs and the difficulties of obtaining regulatory approvals to market their products. It now costs the pharmaceutical industry more than $1 billion in research-and-development spending on average to successfully develop one drug. In the 1960s, more than 10 drugs were developed each year, on average, per billion dollars spent.[10] As the costs of development swell, the need for companies to price their products appropriately—balancing the needs of their shareholders and stakeholders—grows as well.

Companies should find ways to measure real-world outcomes in pre-market trials. Factors important to patients, including those that affect adherence, may be especially important as pharmaceutical companies enter into outcomes-based contracts. A drug that patients consider easy to take, for example, may be more valuable if more patients take it as prescribed, improving their outcomes. Insurers and pharmacy benefit managers, including Cigna, Harvard Pilgrim Health Care and Express Scripts, have started to implement agreements that base payments for drugs on whether they work as intended.[11] Pharmaceutical companies may be setting themselves up for failure if their financial success depends on patient outcomes but they do not understand how those outcomes are affected by patient preferences regarding ease of use or side effects.[12]

Regulatory interest in patients: The FDA is becoming more involved with patients as never before. As part of the *Food and Drug Administration Safety and Innovation Act* of 2012, the FDA set up a Patient-Focused Drug Development program to better engage with patients.[13] So far, the FDA has held 21 disease-specific meetings in which they ask patients for perspectives on their diseases, treatments, willingness to participate in clinical research and tolerance for risk. The meetings focused on well-known diseases and conditions such as HIV and breast cancer, and less-well-known conditions such as female sexual dysfunction and Chagas disease. Regulators have shown consistent interest in certain questions and are using the meetings to guide regulatory decision-making on whether to approve new drugs (see Figure 1).[14,15]

This approach is likely to expand in the near future. As part of the FDA and pharmaceutical industry's proposed revisions to the Prescription Drug User Fee Act (PDUFA), the FDA will be releasing several policies intended to further integrate patients into the regulatory process (see Figure 2).[16] Already, the FDA has proposed allowing independent groups, such as patient advocacy organizations, to conduct Patient-Focused Drug Development meetings, potentially accelerating and spreading their patient-engagement efforts.[17]

In part, this increased focus on patients is due to changes in the types of drugs the agency is regulating. The agency is receiving an increased number of applications for approval of "orphan" drugs—products intended to treat diseases or conditions with fewer than 200,000 US patients (see Figure 3).[18] Products granted Orphan Drug Designation are recognized by the FDA for targeting rare diseases and, if approved,

Figure 1: What is the FDA asking consumers about their diseases?

Selected questions based on an analysis of 63 types of questions asked at 21 of the FDA's Patient-Focused Drug Development meetings

Questions about symptoms	**Percentage of meetings where question asked**
Of all the symptoms that you experience because of your condition, which one to three symptoms have the most significant impact on your life?	90%
Are there specific activities that are important to you but that you cannot do at all or as fully as you would like because of your condition?	85%
How do your symptoms and their negative impacts affect your daily life on the best days? On the worst days?	52%
Questions about current treatments	
What are the most significant downsides to your current treatments, and how do they affect your daily life?	90%
Assuming there is no complete cure for your condition, what specific things would you look for in an ideal treatment for your condition?	81%
Questions about perceptions of risk	
What factors do you take into account when making decisions about selecting a course of treatment?	14%
What information on the potential benefits of these treatments factors most into your decision?	14%
How do you weigh the potential benefits of these treatments versus the common side effects of the treatments?	14%

Source: HRI analysis of Federal Register notices for 21 patient-focused drug development meetings

are eligible for special incentives. With drug companies looking to bring drugs to market for smaller groups of patients, regulators have expressed interest in learning more about these uncommon diseases and the experiences of the people who endure them.

Other regulatory shifts are under way. The FDA has opened some of its troves of regulatory information on adverse events and drug information in the form of its openFDA database. Companies such as Iodine Inc., Social Health Insights and Advera Health Analytics Inc., are turning these data into searchable insights.[19] This information can help patients come to their own conclusions about the safety and efficacy of products. The FDA also is working with its European counterpart, the European Medicines Agency, on patient engagement, indicating that its approaches may influence regulators in other parts of the world as well.[20]

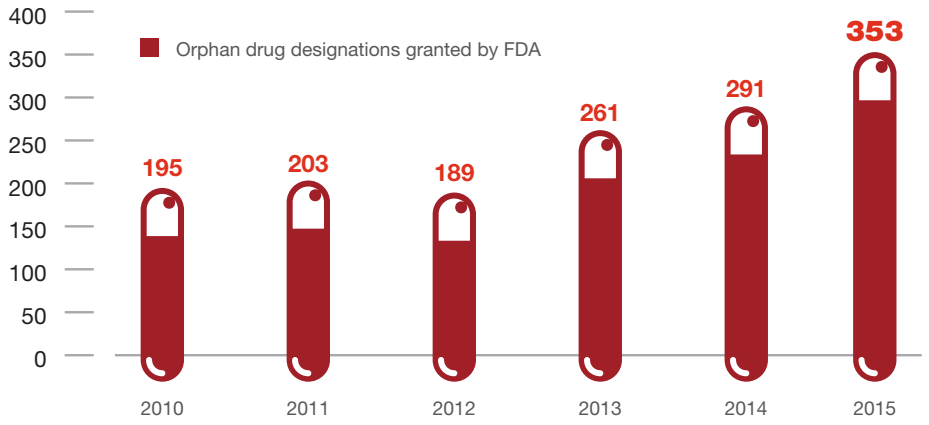
Patient advocacy groups are also increasingly active in the regulatory space. Parent Project Muscular Dystrophy, for example, developed a guidance document intended to help companies develop drugs for Duchenne Muscular Dystrophy. It was later modified and adopted by the FDA for use by companies developing drugs for the disease. "This example of collaboration between engaged stakeholders and FDA highlights how input from patients and caregivers can contribute to drug development," the FDA said in a statement.[21]

Figure 2: Patient engagement proposals included in the Prescription Drug User Fee Act VI

Proposed change by FDA	Action expected
Hire additional staff focused on engaging with patients and facilitating the development and use of patient-focused drug development methods	2017-2021
Draft guidance describing approaches to collecting patient and caregiver input	2018
Draft guidance describing how companies can collect information from patients, and how that information can be used in the drug development and regulatory decision-making process	2019
Draft guidance describing how meaningful patient perspectives and information can be collected in clinical trials	2020
Draft guidance on patient-reported outcome measures to replace the one released in 2009	2021

Source: FDA's PDUFA reauthorization proposal

Figure 3: Interest in orphan drug development is increasing



Source: HRI analysis of the FDA's Orphan Drug Designations database

Barriers to patient engagement

While the pharmaceutical industry stands to benefit from greater patient engagement, there are challenges—trust between patients and pharmaceutical companies, access to relevant information, and regulatory compliance hurdles—to overcome before those benefits can be realized.

American consumers have a complex relationship with pharmaceutical companies when it comes to trusting them with their data and other information. HRI research has shown that many US consumers say they are unwilling to share certain health care data directly with pharmaceutical companies, even when the stated purpose is altruistic. While 88% of consumers would share their healthcare data with their doctors to help them discover new treatments for diseases, just 53% would share that information with a drug company (see Figure 4).[22] As most doctors and hospitals typically are not involved in the pharmaceutical research and development process, this may require drug companies to partner with both groups in order to access patient data they otherwise might not have access to.

However, not all data are created equal. When asked if they would be willing to share answers to some specific questions with pharmaceutical companies or regulators, patients were significantly more likely to say yes (see Figure 5).[23] Patients may be willing to share their thoughts about their diseases with pharmaceutical companies, even if they're not willing to share all of their medical data and records.

Communication is another barrier to fruitful engagement with patients. Many of the most common concerns cited by patients about the clinical trials process have to do with not knowing, or not being able to find, information. For example, 25% of consumers polled by the Memorial Sloan Kettering Cancer Center said they had no idea how a clinical trial works—a concern that might make them reluctant to participate in trials.[24] For consumers, information about clinical trials—how to enroll, what the companies are testing, how the trials work—needs to be easy to find, explained in plain language and answer key questions.

Some companies are taking the lead in this area. For example, Eli Lilly's Lilly Trial Guide and the Michael J. Fox Foundation's Fox Trial Finder were built to help patients navigate the often-confusing clinical trials process. For example, Eli Lilly's site has a simple explanation of what a clinical trial is and tells patients what they should expect while participating in one.[25] By making this process easier to navigate, companies can attract more patients to trials, and better manage expectations once they are enrolled. Bayer US, for example, is working with patient groups such as Friends of Cancer Research to ensure that patient perspectives are reflected in the design of their clinical trials.[26]

Companies should be prepared to listen and offer solutions. Some patients may need assistance or tools to manage their own health or participate in research. A company concerned about the ability of their patients to travel to a clinical trial might partner with

a ride-sharing service to transport them to the trial site, while a company concerned about the ability of their patients to remember to take an infrequently-dosed drug might develop an app to help.[27]

The pharmaceutical industry also must be wary of regulatory hurdles to engagement. Greater patient engagement raises the risk of patients sharing details that a company may not want to receive or have shared, such as information about a patient's participation in a clinical trial, which risks unblinding the trial to other participants and affecting its outcome. An online support forum for patients, for example, could cause adverse event information to be shared publicly, which the company would be obligated to report.[28] Data shared by patients with a company must be kept private, and companies will need to keep data secure and design processes to ensure that primary and secondary uses of data are appropriate.

What this means for your business

Systematic engagement can set companies up for R&D and commercial success. Early engagement with patients allows companies to better understand their needs and wants, enabling companies to better design their products and set up cohesive support systems for users of their treatments. Understanding those needs is crucial in a value-based environment, where patients, payers and healthcare providers focus on quality and costs.

Companies should begin these discussions during the research and development phase to ensure patient perspectives can be taken into account. Engagement can be a market differentiator, positioning pharmaceutical companies to capture added value in the reimbursement process. As risk-sharing agreements take hold, patient engagement may become even more important as companies will develop vested interests in making sure promised outcomes are realized.

Companies should think about research and development as the development of a suite of products and supports, including wearables and mobile applications, to enhance the products' use by consumers. The integration of these technologies into the research and development process can allow companies to test them in clinical settings, generating evidence that may help increase patient adherence during the trial and lead to prescribing by physicians.

Companies will need to make sure to secure important clinical information—such as data from a mobile app that may be accessible to the developer of that application—so that they are not leaked or compromised. However, the inclusion of these consumer-friendly technologies may increase the upfront costs of a clinical trial, added expenses that may not be financially feasible for some small companies.

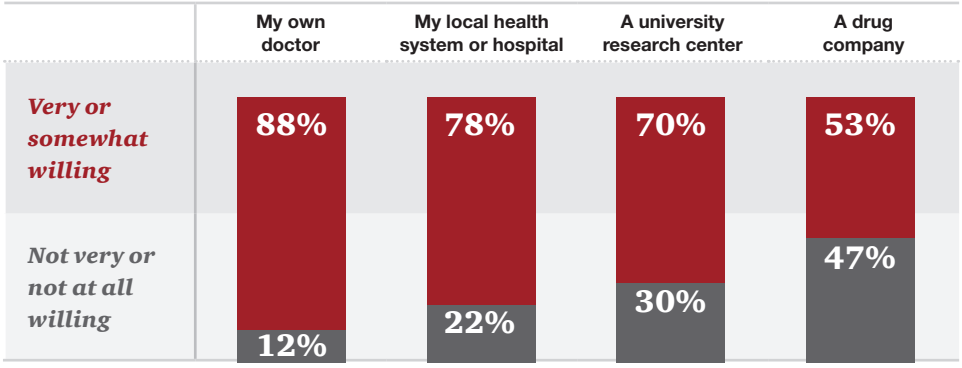
Engagement can improve a company's chances of regulatory success. Patient perspectives can shape the regulatory approval discussion. While patient input is unlikely to improve the approval chances of a drug lacking solid efficacy and safety data, regulators may be more willing to work with companies that are developing a product in close concert with engaged or especially ill patient populations.

Instead of outright rejecting certain drugs, regulators might instead offer restrictive approvals, giving access to only the most seriously ill patients. This especially is true if these patients have shown they are willing to assume greater risks in return for the possibility, however slim, of benefit. In explaining his vote in favor of a controversial drug in 2015, FDA advisory committee member Dr. Tobias Gerhard said, "The unmet need seems to be so strong that even for a drug with rather modest benefit, I think approving the product with strong limitations seems to be the right step at this point."[29] The drug was eventually approved by the FDA—with safety restrictions—despite its concerns.[30]

Even a drug judged to be inferior to the current standard of care in safety and efficacy might be granted approval if it is shown to be desirable to patients, such as a drug which can be swallowed or inhaled instead of needing to be injected. Rather than engage directly with patients,

Figure 4: Patients far less likely to share their data with pharmaceutical companies than doctors, hospitals or researchers

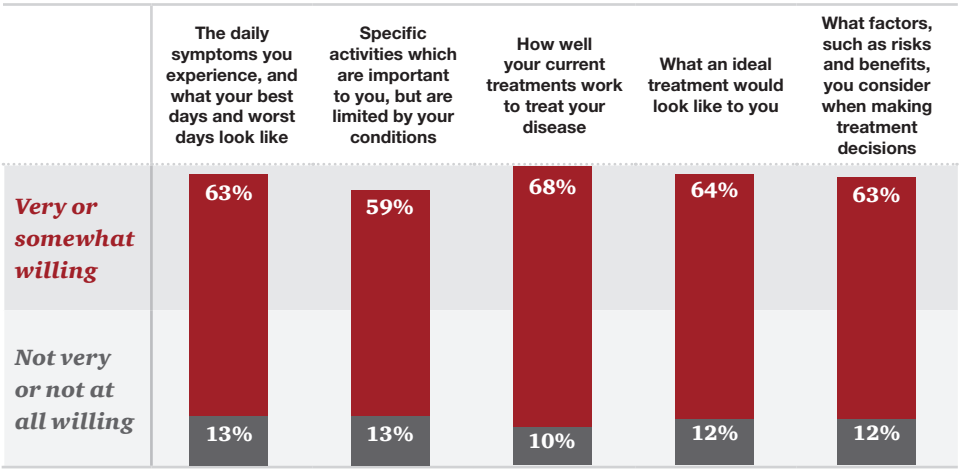
How willing are consumers to provide the following groups with their personal health data to help discover new treatments?



Source: 2016 HRI Consumer Survey

Figure 5: Consumers are willing to share certain health data with pharmaceutical companies and regulators

How likely are consumers to share the following personal information with regulators and pharmaceutical companies in order to help them improve their care?



Source: 2016 HRI Consumer Survey

companies may wish to partner with other groups, such as patient advocacy groups, to obtain data to avoid the appearance of conflicts of interest.

Invest in partnerships and capabilities to collect and use data efficiently. Only 53% of consumers say they are willing to share information with drug companies (see Figure 4).[31] Information related to patient preferences and patient needs is a valuable input to companies' research and development decisions. Pharmaceutical companies will need to partner effectively in order to access data that may only be collected by organizations such as hospitals, doctors and patient advocacy groups.

Intermediaries that collect information from patients on behalf of companies may help to increase trust and engagement. Patient advocacy groups may be especially important in this regard. Such groups regularly collect detailed information from patients, and collaborations can yield important information about their preferences, needs, and even targets for potential drug development.[32,33] However, it is critical that companies have controls in place to ensure that these partnerships are compliant with regulations like HIPAA, are transparent to patients, and increase trust and engagement with the healthcare community.

Companies should think about how they can collect data, measure engagement and develop standards to track and gauge the success of engagement activities. These measurements should be developed with the help of patients to ensure engagement is meaningful. Companies should have analytical capabilities to understand the quality and importance of data being collected and use them appropriately. Failure to engage with patients may bring its own risks.

Frustrated patients can demand change and organize support against a company if their requests are not met. In 2014, a pharmaceutical company CEO resigned after initially declining to allow a dying child access to an experimental therapy, sparking an outcry on traditional and social media.[34]

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About this Research

This report is based on an analysis of the state of patient engagement, including an analysis of 21 patient-engagement meetings and data from the FDA's Orphan Drug Designations database. HRI also surveyed consumers—once in 2015, and again in 2016—to determine their willingness to engage with the pharmaceutical industry, regulators and other entities in the healthcare industry.

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PwC Health Research Institute

Kelly Barnes
US Health Industries and Global Health Industries Consulting Leader
kelly.a.barnes@pwc.com

Benjamin Isgur
Health Research Institute Leader
benjamin.isgur@pwc.com

Sarah Haflett
Director
sarah.e.haflett@pwc.com

Trine Tsouderos
Director
trine.k.tsouderos@pwc.com

Benjamin Comer
Senior Manager
benjamin.comer@pwc.com

Matthew DoBias
Senior Manager, Regulatory
matthew.r.dobias@pwc.com

Alexander Gaffney
Senior Manager, Regulatory
alexander.r.gaffney@pwc.com

Laura McLaughlin
Senior Manager
laura.r.mclaughlin@pwc.com

Laura Sieger
Analyst
laura.m.sieger@pwc.com

Contributors

Karla Anderson, Omar Chane, Peter Claude, Sierra Hawthorne, Erinn Hutchinson, Ankush Khona, Erin McInerney-Prichard, Tim Pantello, Oneil Rego, Jeffrey Rieske

To have deeper conversations about how this subject may affect your business, please contact

Kelly Barnes
US Health Industries and Global Health Industries Consulting Leader
(214) 754 5172
kelly.a.barnes@pwc.com

Ben Gill
PwC Health Advisory Services
Principal
(617) 283-2638
ben.gill@pwc.com

Sean Rooney
PwC Health Advisory Services
Principal
(215) 694-8241
sean.o.rooney@pwc.com

Benjamin Isgur
Health Research Institute Leader
(214) 754 5091
benjamin.isgur@pwc.com

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