The FDA and industry:
A recipe for collaborating in the New Health Economy

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At a glance

Pharmaceutical and life sciences executives face increasing pressure to deliver innovative, high-value products in the New Health Economy.

pwc

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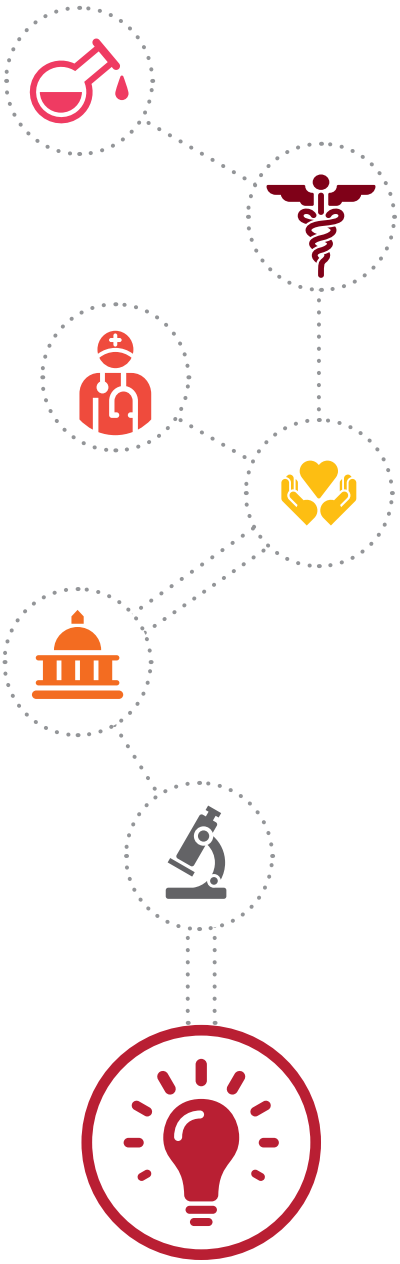
Heart of the matter

The New Health Economy requires that pharmaceutical and life sciences companies and their chief regulator—the Food and Drug Administration—collaborate to meet 21st century demands. A new framework is needed to ensure America's perch as a global leader in medical innovation and to stimulate the next generation of treatments and cures.



Executive summary

Drug and device manufacturers face mounting pressures from an evolving health industry that places a premium on speedy access to breakthrough, cost-effective and safe medical products.

The $347 billion-a-year industry answers to a new class of consumers who shoulder more of their treatment costs and who demand a greater role in product development.[1] Companies working to invent novel therapies and win regulatory approval face the added pressure of demonstrating the value those products bring.

These trends force the pharmaceutical and life sciences industry to reexamine interactions with its most important stakeholders: the Food and Drug Administration (FDA) and consumers.

In summer 2014, PwC's Health Research Institute (HRI) surveyed senior executives from a cross-section of pharmaceutical and life sciences companies on their views about the industry's relationship with the FDA. HRI also surveyed consumers on their attitudes about the industry, the FDA and how well they work together to provide individuals with clinically- and cost-effective treatments.

Most company executives indicate that their relationship with the FDA has improved over the past two years. They recognize investments made by the FDA to improve its relationship with manufacturers; in particular, becoming a more open and communicative partner.

Yet the industry leaders question whether aging regulatory processes may be hindering industry's ability to work productively with the agency to bring about major breakthroughs in drugs and devices. Executives are turning their focus away from user fee programs meant to simply expedite the FDA's processes. They desire a more collaborative relationship, one marked by greater flexibility in product development and review.

The onus isn't just on the FDA. Industry appears willing to do its part to achieve this goal. Executives may be open to additional oversight as part of a more expedient, predictive process that spans the innovation life cycle from clinical development to post-market surveillance.

Pharmaceutical leaders, recognizing the rapid transformation sweeping across the entire health sector, told HRI they are more willing than in the past to have their products judged based on value. This includes both clinical and economic value.

In many instances, consumers' definition of value differs greatly from those of regulators or industry. Next generation healthcare consumers want more than a seat at the table. They want to provide input into developing therapies and know that the information they offer is being utilized.

Frustrated by the lack of progress, consumers are taking matters into their own hands and assuming responsibilities that have historically resided with the FDA or industry—such as developing guidance, creating incentive programs and funding Research and Development (R&D) directly.[2]

Key findings and considerations

- **Executives say that the FDA has become a more communicative and open partner.** Seventy-eight percent said that the FDA has improved the quality and frequency of its communications in the past two years. Seventy-six percent think that the agency provided actionable feedback and 70% think it offered more applicable guidance, rules and regulations.

  Executives and regulators should seize upon this momentum to ***build closer relationships*** and facilitate more meaningful communications around product development and review. A greater reliance on public-private partnerships could also provide a forum for the exchange of ideas. For instance, the Medical Device Innovation Consortium coordinates efforts of industry and regulators to develop new tools, methods and technologies.

- **Executives understand that balancing innovation and risk requires tradeoffs.** To improve access to new treatments, the industry is willing to consider regulatory reforms such as stricter post-market safety requirements and restrictions on promotional activities. Seventy-one percent agreed that accelerated approval programs should be balanced by stricter post-market surveillance.

  Additional protections once a drug goes to market may help ***allay fears that patients could be placed at risk*** by the acceleration of the drug review process.

- **Executives' attitudes are shifting when it comes to determinations of value.** Forty-three percent support the idea of the FDA evaluating a drug based on both clinical and economic effectiveness. In 2010, only 14% of executives supported this concept.

  Manufacturers will need to ***demonstrate value over existing therapies*** as both purchasers and consumers look for products that meet their medical and financial needs.

- **Consumers want more engagement from both the FDA and industry.** A little more than one-third of consumers (39%) believe the FDA incorporates their views in the agency's review process. Similarly, 38% say that drug and device manufacturers adequately consider consumer views. With the emergence of a New Health Economy, ***now is the time to prioritize consumer input.*** Companies should seek out consumers' views, diligently incorporate their input at every stage and share this information with the FDA.

The relationship between pharmaceutical and life sciences companies, the FDA and consumers has been one of continuous evolution. It must evolve yet again in the face of 21st century demands. A closer, more collaborative bond among all stakeholders may create a more efficient development and regulatory process that leads to the next generation of treatments and cures.

Since 1995, as part of its *Improving America's Health* series, PwC has periodically surveyed industry executives on their relationship with the FDA and how the collaborative process is changing to reflect recent trends. For the sixth installment of this report, PwC's Health Research Institute worked with Biocom to poll 100 senior executives on issues such as the current regulatory environment, the challenges of medical product development, and how companies engage with consumers. For the first time in this report's history, 1000 adult consumers from across the country were also polled about their views on the FDA and the pharmaceutical and life sciences industry.

To read previous reports go to:
www.pwc.com/us/hripharmalifesciencesfda

An in-depth discussion

As science and the practice of medicine have evolved, so has the regulatory paradigm for drugs and devices. Yet many industry executives believe that these processes have not advanced enough to spur continued innovation.

The current regulatory paradigm vs. 21st century R&D

Achieving a 21st century research and development (R&D) apparatus for pharmaceuticals and devices will require a more modern partnership between manufacturers and the FDA.

A New Health Economy has emerged that is putting greater pressure on companies to rethink the way they compete.[3] Device and drugmakers must develop products that are not only safe and effective, but also deliver value, as defined by numerous purchasers.

The FDA plays a significant role in determinations of value to consumers and to the larger healthcare system. Charged with evaluating the safety and effectiveness of medical products, the agency controls which products can compete in the US marketplace and which cannot. Understanding regulator's actions and decision making process are paramount concerns for industry.

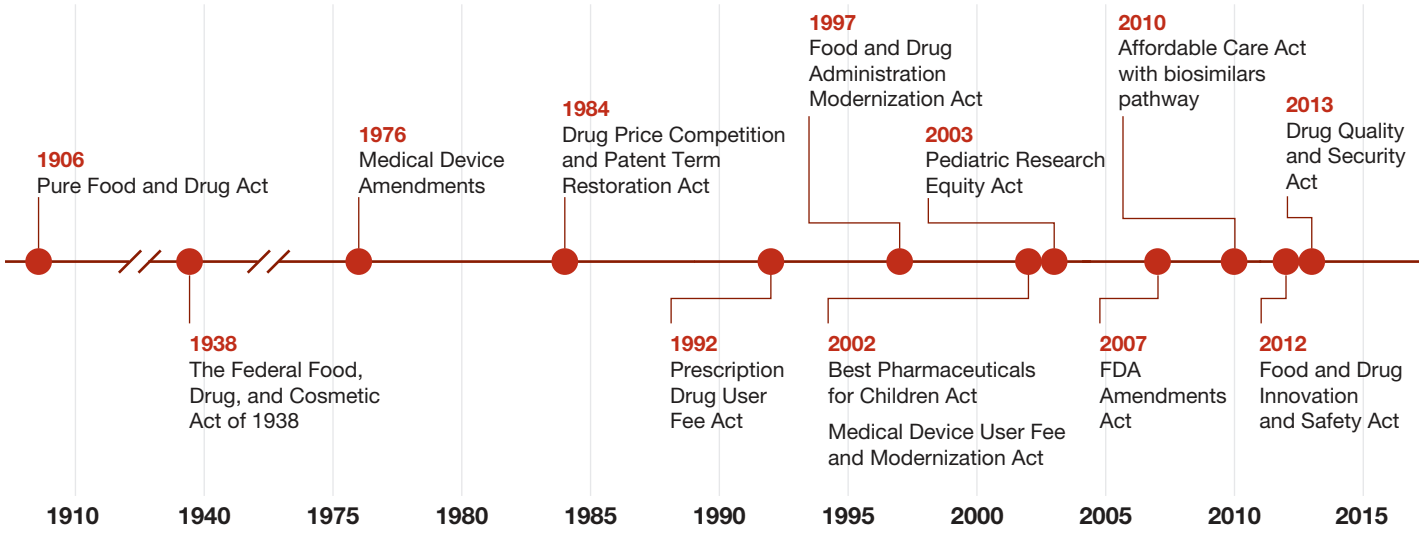
In the latest survey, a majority of executives (78%) cited improved frequency and quality of communications as the most important things the FDA has done to improve its relationship with industry.[4] Better quality and more frequent communications with the FDA help executives anticipate the agency's expectations and satisfy regulatory requirements.

Improved communications can lead to a more predictable process, but not necessarily a shorter one. Executives remain focused on how long it takes for a product to enter the market. A key part of that is the FDA review period, which has been heavily subsidized by industry in the form of user fees to help reduce that timeline.

The fees industry has agreed to pay have risen steadily since the first program was created in 1992 and account for a growing share of the agency's overall budget. (See figure 3.) Drugmakers' paid $23.1 million in fees when the program first started.[14] In 2015, pharmaceutical companies are expected to pay $718 million to the FDA.[15]

Similarly, the amount of fees device makers have paid has increased from $11.1 million in 2003 to approximately $128 million in 2015.[16, 17]

Figure 1: Major FDA-related legislative events



Source: FDA: Significant Dates in US Food and Drug Law History

Size makes a difference when sizing up the FDA

The size of a company can greatly influence the way pharmaceutical and device executives interact with the FDA and their overall view of the agency and its programs.[5] (See figure 2.)

For instance, industry leaders question how effective user fees are at advancing innovation, though support for the program is greater among large manufacturers. Forty percent of executives from larger companies said they think user fees help accelerate innovation. Comparatively, 32% of executives from small companies share the same view.[6]

More than half (52%) of executives from large companies said their organization directly benefited from the user fee program.[7] Only 20% of executives from small firms thought their companies benefited.[8] Part of this divide may be explained by how frequently companies take advantage of some of the benefits offered under the user fee programs such as meetings with agency officials during the development and review process.

Meeting with the FDA can help clarify regulatory requirements and improve the quality of an application prior to its submission. Executives across all company sizes agree on this point. Yet large companies reported they were more likely to take advantage of meetings with the FDA and incorporate feedback.

Forty-two percent of executives from large companies said they always met with FDA at key juncture points during clinical development or prior to submitting an application.[9]

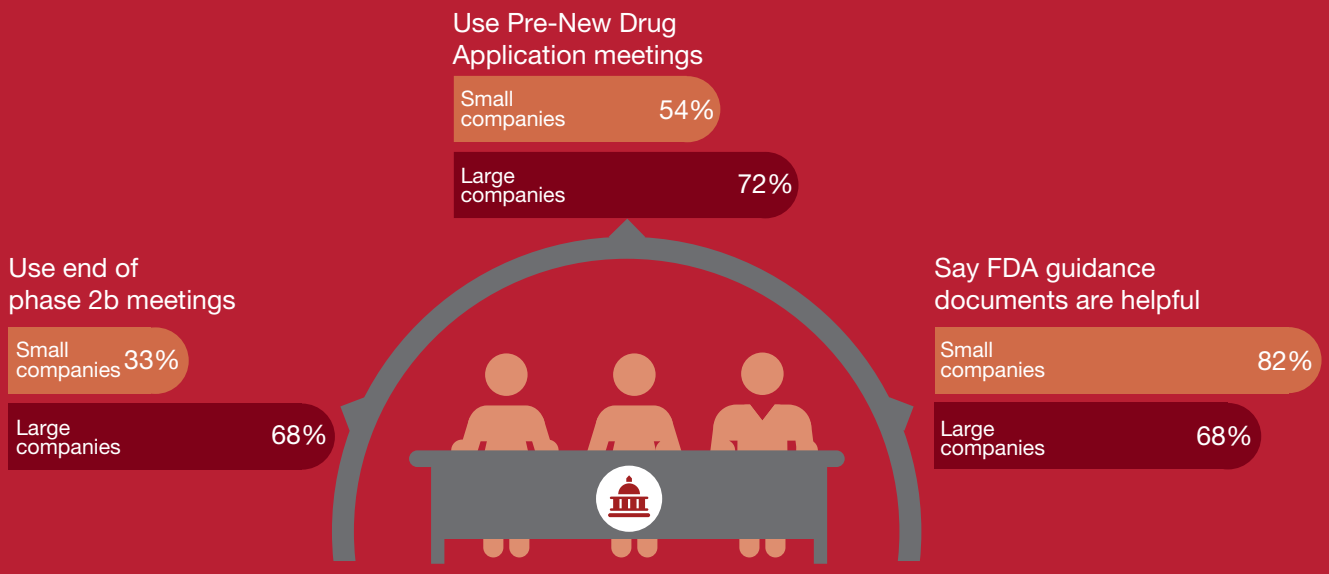
But smaller companies don't take advantage of the same opportunities to confer with agency officials. In the latest HRI survey, only 23% of executives from small companies always participated in meetings and 40% said they rarely participated—a trend similar to previous surveys.[10]

"A smaller company may not have the resources or in-house regulatory expertise to take advantage of these meetings," said Kim Oleson, senior vice president of clinical affairs for Sunshine Heart—an early-stage medical device company with less than 50 employees.[11]

Smaller companies may also have the view that engaging with the FDA will result in more work and require additional resources that they don't have. But limiting interactions with regulators may actually work against these smaller firms. Dr. Susan Alpert, who consults with small and large companies and previously served as both a FDA official and senior executive at Medtronic said, "For newer companies, the reluctance to meet with the FDA is that it may foster other questions about their product. But my opinion is not taking advantage of FDA meetings is shortsighted on the part of a company."

Indeed, more frequent interaction with the FDA can be the building blocks to a better working relationship. Seventy percent of executives that always took advantage of meetings with the FDA said their relationship with the agency improved over the previous two years.[12] Only 38% of companies that rarely met with the FDA said their relationship improved over the same time period.[13]

Figure 2: Smaller companies rely more on the FDA's guidance materials than formal meetings with the agency.



Source: 2014 HRI Pharmaceutical and Life Sciences Executive Survey

Executives question the value they get from user fees and the impact the levies have on improving access to novel therapies. Just 32% thought the fees they paid have resulted in shorter review times and only 34% think the fees help accelerate innovation.[18]

In spite of the significant growth in fees paid by industry, executives are concerned that the FDA does not have the resources to keep pace with the scientific and technical breakthroughs revolutionizing the drug discovery and development process today.

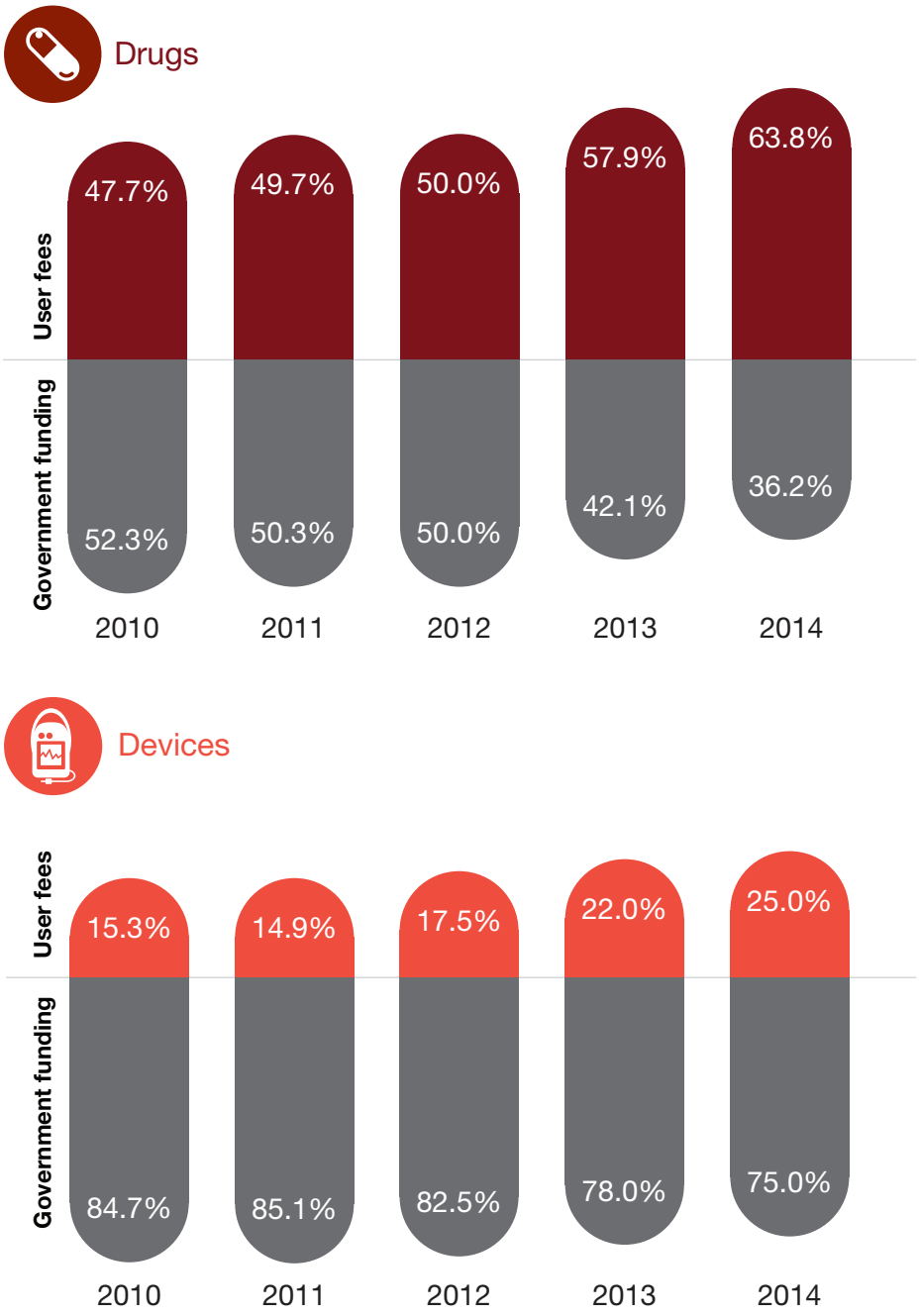
"Science is advancing so quickly, it's difficult for any single organization to stay on top of everything," said Stacy Holdsworth, senior advisor of US regulatory policy and strategy at Eli Lilly & Company. "We need a system in the 21st century that allows regulators to access the scientific expertise they need, both internally and externally, in a timely manner."

Yet the problem is larger than just resources. There is growing sentiment within industry that a more expedient and predictable regulatory process can no longer be obtained simply by increasing fees. Industry leaders want the regulatory process reevaluated from start to finish with an eye toward advancing innovation.

"You have to recognize that the user fee program is only addressing the review cycle and that's not the issue," said former FDA commissioner Andrew von Eschenbach. "Review is only one piece. You need a much broader view. The issue is the process from the very beginning of development to the post-market. And the FDA influences that entire process."

Figure 3: Where does the FDA's funding come from?

*In 2013, **user fees surpassed government funding** for the Center for Drug Evaluation and Research.*

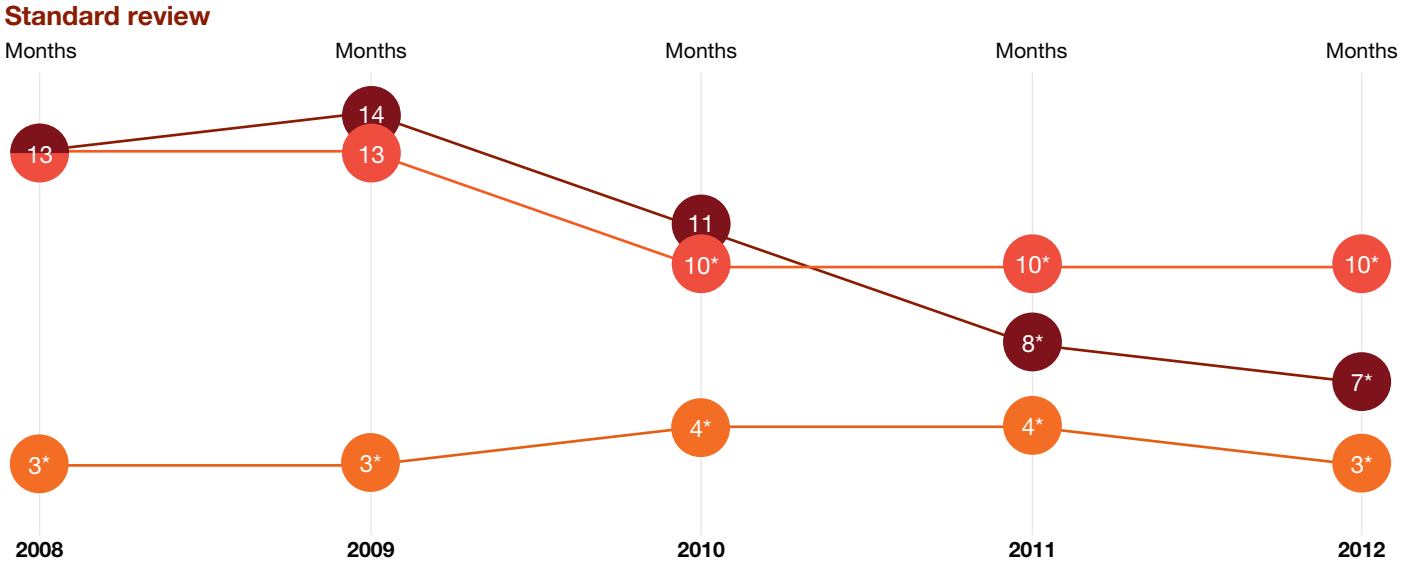


Note: Total budget authority appropriations and user fees are collected specifically for the Center for Drug Evaluation and the Center for Devices and Radiological Health at the FDA

Source: Health and Human Services Justification of Estimates for Appropriations Committees

Figure 4: The FDA's standard review speed has improved, especially for devices

The chart below shows the change in review times for drugs and devices measured in months over a five year period.



*Estimate as cohort is still open for review

**Drugs includes applications for new drugs and biologics

‡Premarket Notification (also known as 510(k) clearance), initiates FDA review to determine if a new device is substantially equivalent to a device already approved. In contrast, Premarket Approval (PMA) is a stricter form of review intended for more complex devices or for devices with no existing equivalent.

Note: Figures represent median review times in months

Source: FY13 FDA PDUFA Performance Report and FY12 FDA MDUFA Performance Report

Ensuring the industry's continued success will greatly depend on having a 21st century regulator to advance medical innovation, which industry leaders say may require a mindset shift.

"The FDA needs to be part of the innovation engine," said Fred Hassan, former CEO of Schering-Plough who now serves as a managing director at Warburg Pincus. "I don't think they currently see that as a primary role."

Changes may be afoot. The FDA has been working with Congress and other stakeholders to map out potential improvements to the regulatory process. And the agency has recently implemented two new programs to help speed review of novel therapies: the innovation pathway for devices and the breakthrough therapies pathway for drugs.

But it appears executives don't know enough about how these programs work to fully capitalize on them. Only 24% of survey respondents said they were familiar with the breakthrough pathway. Not surprisingly, industry leaders were more familiar with the FDA's expedited review programs that are well-established such as fast-track, priority review and accelerated approval.[19]

Those who are familiar with the breakthrough pathway and its success are wondering whether the resource intensive strategy could be applied more broadly. Dr. Mark McClellan, a former FDA commissioner who is now a senior fellow and director of the Health Care Innovation and Value Initiative at the Brookings Institution explained, "It does seem to be changing the way the agency is doing things. If this is a promising direction, we need to ask what else needs to change along with it. The breakthrough process is focused on drug review and approval but there are other things that need to get done at the same time such as review of good manufacturing processes."

Benefits in breakthrough therapies

The FDA's new expedited regulatory review provides a shortcut to market for products targeting serious or life-threatening diseases that have demonstrated "substantial improvement over existing therapies" in early clinical studies.[20] The breakthrough therapy designation, enacted as part of the Food and Drug Administration Safety and Innovation Act (FDASIA) in 2012, aims to provide drug sponsors with another expedited development and FDA review pathway for new, clinically urgent products.

Companies receiving this designation for a new product can expect to have frequent meetings with the FDA to collaborate on clinical trial design and data collection. Last summer, the FDA released a policy manual detailing the agency's approach to managing products designated as breakthrough therapies, including staff roles, processes and best practices.[21] And the agency may look to further standardize the process this year.[22]

The breakthrough therapies pathway has proven popular with those that have used it.

"It is increasingly clear that everyone benefits from early and continuing engagement of FDA with researchers and product developers," said the FDA Commissioner Margaret Hamburg, at a National Organization for Rare Diseases (NORD) meeting last fall.[23]

"Not surprisingly, one of the most important features of our new breakthrough designation is the intensive guidance developers receive, potentially as early as when the [investigational new drug application] is first submitted, offering timely advice and interactive communications to help the sponsor design and conduct a drug development program as efficiently as possible."[24]

As of December 2014, the FDA had received 260 requests for breakthrough therapy designation, and had granted 74.

The agency had approved 17 of those applications as breakthrough therapies ready to be used by patients.[25]

In November 2013, California-based Pharmacyclics, Inc. was among the first pharmaceutical companies to receive the FDA's breakthrough drug designation for its product IMBRUVICA®.

The drug, co-developed and co-commercialized with Janssen Biotech, Inc., received accelerated approval for its first indication for the drug to treat patients with mantle cell lymphoma, a rare form of blood cancer, who had received at least one prior therapy. From the first clinical trials in humans to commercial approval, the process took just four and a half years—warp speed compared with many decade-long drug development programs.

IMBRUVICA® has received two additional breakthrough designations, one for chronic lymphocytic leukemia (CLL) and another for Waldenstrom's macroglobulinemia (WM), a rare B-cell lymphoma; the product was approved for CLL in 2014, but has not yet been approved for WM.

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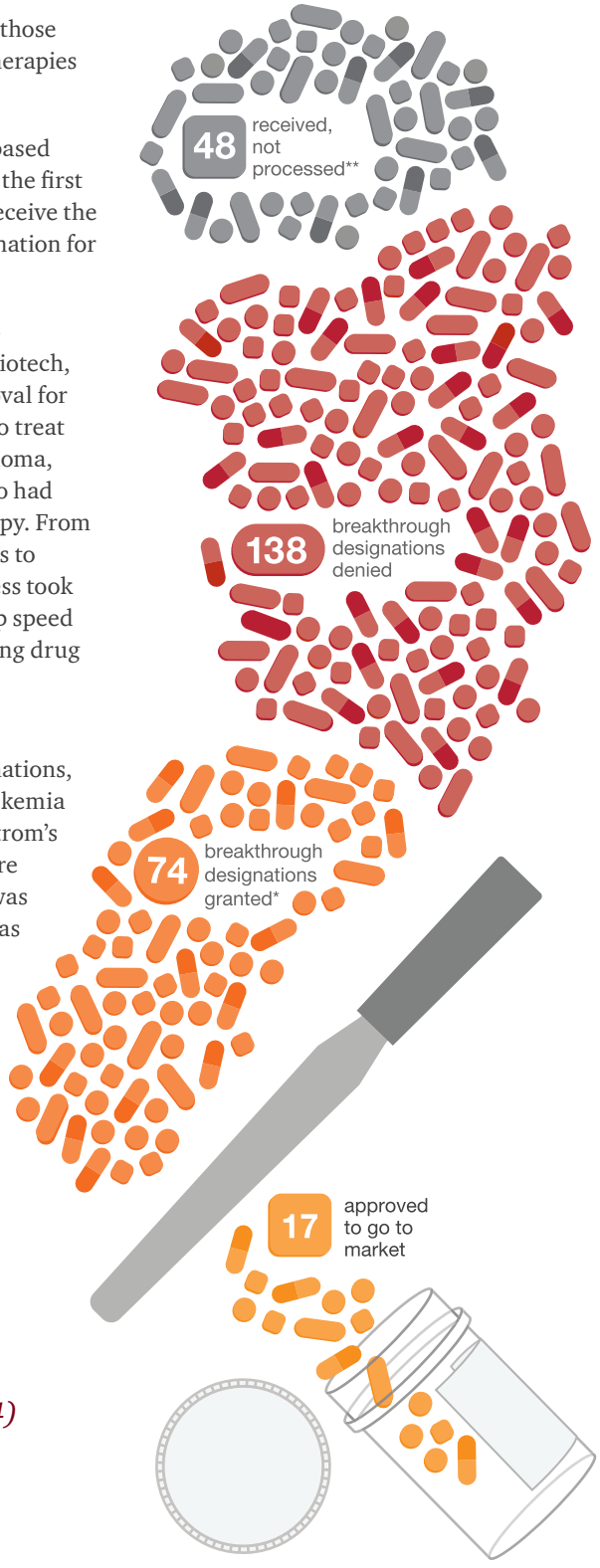


260

breakthrough therapy designations have been received since 2012 (as of December 26, 2014)

*2 of the applications granted were subsequently withdrawn

**There is insufficient public information to determine the status of 48 breakthrough requests

Source: Figures represent CDER and CBER data http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdcact/significantamendmentstothefdcact/fdasia/ucm341027.htm

The drug is the first and only product to receive three different breakthrough designations.

"We are talking to the FDA very regularly" about IMBRUVICA®, said Urte Gayko, PhD, senior vice president of global regulatory affairs at Pharmacyclics. "My experience with the FDA has been overwhelmingly positive. That doesn't mean questions or issues never arise during our discussions with the agency, but I'm happy because my expectation is that we can work through those issues and get them resolved collaboratively, before they become larger issues, which we've been able to do successfully."

Gayko offered two suggestions to Congress on improving the breakthrough therapy process during a briefing organized by Friends of Cancer in May 2014.[26] First, she asked that the FDA provide informal target dates for review to help companies work out manufacturing capabilities needed to make the product available to patients as quickly as possible.

Gayko also suggested that some of the formal meetings required under the Prescription Drug User Fee Act may be unnecessary for breakthrough therapy designees, since the breakthrough process itself incorporates a great deal of agency engagement. She suggested making those meetings optional for the FDA's review of breakthrough therapy marketing applications.

The breakthrough therapies regulatory pathway is an important route for industry and the FDA to get innovative new products to patients sooner. However most new products don't qualify for breakthrough status, which limits the industry's ability to capitalize on the program's benefits. Expanding the resource-intensive program to include more products without additional resources could place new strains on the agency.

Rebalancing innovation and risk

In the past, the FDA has sought to balance its primary goal of protecting the public health with the secondary goal of expediting the availability of breakthrough therapies. But 21st century demands may be evening the scales.

Potential breakthrough drugs are more anticipated in this era of rapid scientific and biotechnical discovery. Consumers believe they have a right to try an unapproved, potentially risky medication, if there's a possibility it could be a cure. Seventy-five percent of consumers said they agreed that patients with life-threatening or serious conditions should have greater access to experimental treatments if they are willing to accept the risk.[27]

Consumers use social media to publicize their demands for access to developing therapies, targeting not only the FDA but also manufacturers directly. Yet the risks remain and many patients have suffered harmful, even fatal effects from taking unproven and underdeveloped drugs.[28] Meanwhile, another factor is rising in importance: value.

Everyone agrees that consumers should have access to novel, safe and effective therapies. But views diverge on how to achieve that goal. Industry executives say that enabling the FDA to speed access to innovative products may require departures from the existing regulatory framework.

Executives, seeking predictability and speed in the review process, are open to new regulatory approaches.

"We're looking at outcomes data and how it should influence regulatory decisions," said Lilly's Holdsworth. Other pharmaceutical companies such as Merck are maintaining global, long-term clinical outcomes databases to support the future success of their brands in a changing marketplace.[29]

The emergence of digitized and accessible patient data could also improve access to novel therapies. Regulators may provide conditional approval of products while using enhanced post-marketing surveillance programs to evaluate the safety and efficacy of a product on patients.

Seventy-five percent of consumers said they agreed that patients with life-threatening or serious conditions should have greater access to experimental treatments if they are willing to accept the risk.

In Europe, for example, the European Medicines Agency (EMA) recently launched an "adaptive licensing" program that will provide new drugs to restricted patient populations, followed by an evidence gathering period focused on patient outcomes.[30] This evidence will be used to expand the label to a broader patient population if a medicine proves safe and effective.

Indeed 71%, of executives told HRI that expedited approval programs should be balanced by stricter post-market surveillance programs to determine how well patients respond to new therapies.[31]

The FDA's expanded access or "compassionate use" program, which makes promising drugs and devices available to patients with serious or immediately life-threatening diseases, such as cancer and more recently, Ebola, has been in place for 27 years. Yet consumers are using social media campaigns to highlight their desire for greater access to experimental therapies.

Some states are responding by enacting "right to try" laws that would make investigational medicines that have not been approved by the FDA more readily available to terminally-ill patients. In November 2014, Arizona became the fifth state to enact such a law and was the first one to do so by referendum.[33] And a proposal was introduced in Congress late last year to increase transparency of drugmakers' compassionate use programs so consumers could access them more readily.[34]

Industry executives overwhelmingly agree (77%) that patients willing to assume greater risks should be able to access new medical products.[35] But that sentiment must be weighed against the capability and willingness of industry to manufacture small amounts of an experimental drug prior to market approval. Industry is also concerned about jeopardizing the FDA's review process if patients experience adverse events during compassionate use of an experimental drug that may trigger red flags for product reviewers.

FDA officials have sought to assuage industry fears about making drugs available through these programs. At a National Organization for Rare Disease meeting last October, two FDA officials[36]—told an industry audience that patient adverse events reported as a requirement of compassionate use programs had not affected product approval during their tenures at the agency.[37]

The continued movement in healthcare from fee-for-service payment to a value-based model is placing new demands on pharma and life sciences companies to demonstrate value and justify their costs.

"Quickness to market is clearly a basic principle," said Dr. Ray Woosley, president emeritus of the Critical Path Institute and founder of CredibleMeds—an organization focused on safe medication use. "With that comes an even greater need for post-market surveillance."

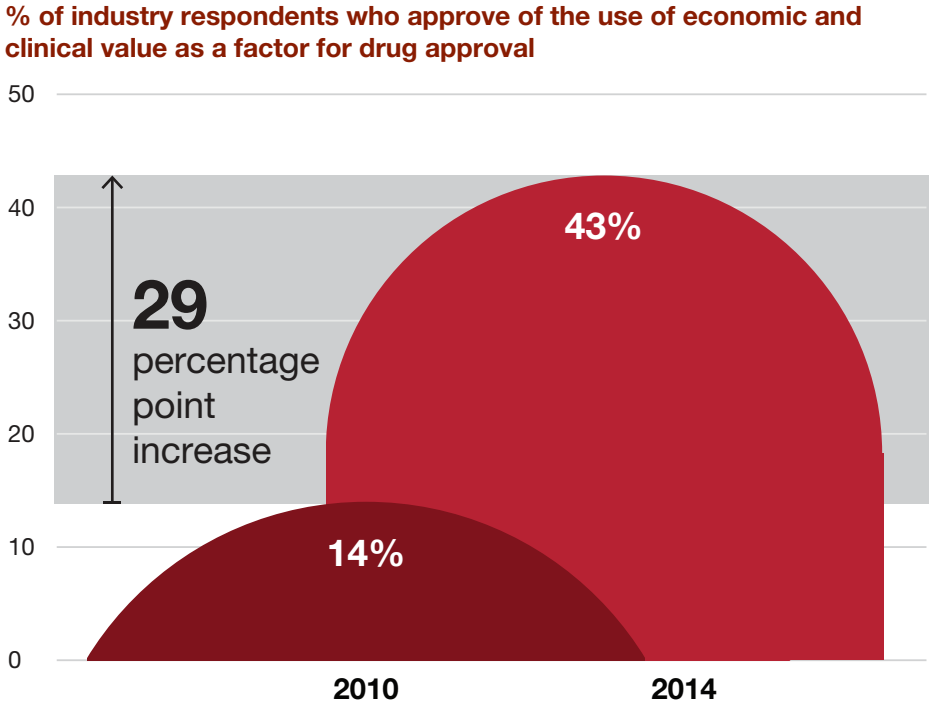
Bill Murray, president and CEO of the Medical Device Innovation Consortium, a nonprofit industry group that partners with the FDA, agreed more post-market data will be needed for the agency to release medical devices to patients faster.[32] Structures that make it easier for patients to report such data would also be needed.

The value factor

In the New Health Economy, success is no longer measured strictly by who is the most innovative or who can get to market fastest. Who can demonstrate the most value for the buck is equally important. The debate about value and innovation go hand in hand.

The continued movement in healthcare from fee-for-service payment to a value-based model is placing new demands on pharma and life sciences companies to demonstrate value and justify their costs. Rising concerns about the price of new therapies reinforces this push.

Figure 5: Industry views are shifting on demonstrating economic value



Source: 2014 HRI Pharmaceutical and Life Sciences Executive Survey

"We don't want to squelch innovation," Dr. Scott Josephs, national medical officer at Cigna Corp., said at an Advanced Medical Technology Association meeting in October 2014. "But tell me what I'm getting for my healthcare costs. Show me that these new technologies are superior."[38]

In PwC's 2010 *Improving America's Health* survey, 68% of executives were opposed to giving the FDA the authority to use economic data as a factor for approving or denying a new drug.[39] This year, opposition to such economic considerations, once considered anathema by pharmaceutical companies launching products in the US, fell to 45%. (See figure 5.)

Nadine Cohen, senior vice president regulatory affairs and R&D compliance at Biogen Idec, says it's unlikely that the FDA will begin to integrate cost of therapy into the review process anytime soon.[40] But the shift in executive's attitudes suggests an acknowledgment of cost as a key product component.

In addition, multinational pharmaceutical companies have grown accustomed to drug submissions that require a broad health technology assessment, which considers the social, economic and ethical issues of launching a new health product. In European markets, cost can be a deciding factor in the availability and reimbursement of new medicines. In Germany, for example, several pharmaceutical companies have withdrawn products from regulatory review over disagreements about the price of the drugs.[41, 42]

Since most new drugs approved for use in the US are submitted for approval in global markets, executives have learned to think about cost as a factor to be considered besides efficacy and safety.

Most executives (67 %) support a closer alignment of US and international regulatory standards, indicating that harmonization of regulatory requirements would make it easier, and faster, to bring a new drug to market worldwide.[43]

"The lack of agreement on endpoints across geographies is a difficult problem," said Cohen. "The more requirements you have, the more difficult it is for companies."

"We don't want to squelch innovation. But tell me what I'm getting for my healthcare costs. Show me that these new technologies are superior."

—Dr. Scott Josephs, national medical officer at Cigna Corp

Costs are not something the FDA considers when reviewing a drug or device, but many consumers think that should change.

According to a previous HRI study, 60% of insurers strongly agree that pharma must demonstrate a significant clinical benefit compared to current branded and generic treatments to be considered for formulary placement.[44] Similarly, consumers are concerned about the financial side effects of shouldering more costs via the rise of high-deductible health plans and larger cost-sharing requirements.[45]

Although 39% of consumers said they have delayed purchasing a drug due to its cost, consumers are willing to pay for products that they perceive to provide value.[46] Nearly half (49%) of consumers surveyed said they would pay more for personalized therapies that use their genetic information or other health data to treat their specific medical needs.[47]

Costs are not something the FDA considers when reviewing a drug or device, but many consumers think that should change. Fifty-one percent indicated that the FDA should take into account the expected cost of a drug or medical device when considering whether it should be marketed in the US.[48]

Healthcare providers are also increasingly cognizant of the impact cost has on their patients. In 2012, the Memorial Sloan-Kettering Cancer Center in New York City announced that it would not prescribe Sanofi's cancer drug Zaltrap due to price, and publicized its decision with an op-ed in *The New York Times*.[49]

The authors—three physicians from the cancer center—said their decision was a simple one: "The drug, Zaltrap, has proved to be no better than a similar medicine we already have for advanced colorectal cancer"—Avastin—"while its price, at $11,063 on average for a month of treatment, is more than twice as high."[50]

The physicians concluded that "when choosing treatments for a patient, we have to consider the financial strains they may cause alongside the benefits they might deliver."[51] In response, Sanofi subsequently reduced the net cost of Zaltrap across the U.S.

According to a recent HRI survey of 1,000 clinicians, only 1% of doctors did not consider the cost of a drug when prescribing it.[52] Fifty-four percent of physicians said they considered cost to a significant degree.[53] This matters to consumers, who rank a physician's recommendation as the most important factor that influences their treatment decisions, followed by their own out-of-pocket costs.[54]

Drug safety and effectiveness is a prerequisite for discussions about value. Currently, the FDA approves new products based solely on safety and efficacy, before anyone knows how much they will cost; that discussion begins once the drug hits the market with a price tag. Willingness to pay depends a great deal on the treatments already available for a given disease, and whether a new product represents an improvement over existing therapies.

This is exemplified by the recent FDA decision to approve Harvoni—a new combination product for the treatment of hepatitis C by Gilead Sciences, which can cost more than $90,000.

In a statement on the drug's approval, Edward Cox, director of FDA's Office of Antimicrobial Products, emphasized the benefit for patients: "Until last year, the only available treatments for the hepatitis C virus required administration with interferon and ribavirin. Now, patients and healthcare professionals have multiple treatment options, including a combination pill to help simplify treatment regimens."[55]

Proponents of the new drug argue that the treatment is cost-effective, because the medicines cure more patients in less time than older therapies and saves the health system money from higher-cost complications, such as liver transplants.[56] But state governments and private insurers have limited budgets and will need strong evidence to support total cost savings for patients at different progressions of the disease.

Bringing in the consumer

Individuals have new tools at their fingertips that can help make them more discerning healthcare consumers. Web sites such as Iodine and Treato can inform decisions about treatment regimens by providing information on price, side effects and patient testimonials.

Armed with information from these sites, consumers are becoming more engaged in determining their own treatments; working with providers to select which products best meets their clinical and financial needs.

"Today's consumers make decisions in conjunction with medical authority, not because of a medical authority," said Ido Hadari, CEO of Treato, in an interview with HRI.

As consumers exert greater control over their health, drug and device companies need to master the complexities of consumer behavior. Consumers are willing to offer feedback that informs companies who they are, how they behave and how existing biases impact their behavior—potent information for drugmakers hungry for real world results.[57]

Regulators also must invest in understanding consumers better. Some improvements already are underway. The FDA has initiated a five-year Patient Focused Drug Development Program, which will include 20 meetings with patients to learn about disease severity, risk tolerance and unmet medical need. And late last year, the agency began seeking feedback on how to better incorporate consumer views during the medical product development process and regulatory discussions.[58]

Consumers taking charge: Kids V Cancer

The drug development process can stretch for over a decade, though many important decisions occur before any clinical development or company investments occur. Here at the start is when consumers are exerting greater influence.

"The question isn't how to get a drug approved. The question is how you get a private company to make the drug in the first place," says Nancy Goodman, founder and executive director of Kids V Cancer, a patient organization that promotes pediatric cancer research.

The group was instrumental in advocating for the 2012 Creating Hope Act, which encourages manufacturers to develop new drugs for children with rare diseases. Under the law, a company that develops a drug for a pediatric rare disease receives a voucher when the drug is approved by the FDA. The voucher can be used to obtain priority review by the FDA for any new drug application, which can shave months off of a product's review time. The voucher can be sold or transferred from one holder to another without limitation.[59]

In July 2014, the first priority review voucher was sold by BioMarin Pharmaceutical Inc. for $67.5 million. The company received the voucher for a drug it developed to treat Morquio A Syndrome, a rare inherited disease that occurs in 1 out of every 200,000 births.[60] BioMarin sold the voucher to Sanofi and Regeneron, which used it to obtain priority review from the FDA for a new cardiovascular drug—a market which is fiercely competitive. BioMarin CEO Jean-Jacques Bienaimé said the company will use the proceeds from the sale to reinvest in developing products to treat rare diseases.[61]

According to Goodman, the program is correcting market failures that keep pharmaceutical companies from developing certain drugs. "Large pharmaceutical companies have a responsibility to their shareholders," she told HRI. "Part of their mission is to maximize financial wealth. There's nothing wrong with that. It's the system we've created. But the way you maximize profits is by having the biggest hit. That's never going to be [a drug for] kids with cancer the same way it's with a drug like Lipitor."

It may be too soon to tell how successful the program will be in generating more research, treatments and cures. But the outlook appears good. A second voucher was sold to Gilead Sciences for $125 million by Knight Therapeutics in November 2014.[62] And some in Congress are looking to expand the use of vouchers for other diseases and conditions. Lawmakers recently added Ebola to the list of tropical diseases that could qualify a manufacturer for a priority review voucher if they develop a vaccine or treatment.

However, consumers increasingly want to know how the information is being put to use. "Having a seat at the table is important, but how do you make sure the patient perspective can be turned into data points that can inform and influence the review process," asked Cecilia Arradaza, executive director of the Milken Institute, which includes FasterCures—an organization focused on speeding medical innovation. "We're talking about quickly moving from a lofty goal of making patients part of the system to a very technical conversation about how to make it happen."

Industry also needs to move faster to involve consumers in the drug development process. Traditionally, companies have collected consumer views through focus groups during the marketing of a drug or worked with advocacy organizations when a FDA Advisory Committee meeting is being scheduled. But these methods may be too late for increasingly engaged consumers.

Companies are beginning to recognize that there is a business imperative for engaging with consumers throughout a product's life-cycle, including the early stages. Sanofi recently created the position of chief patient officer and hired a former official from the Patient Centered Outcomes Research Institute to lead it.[63] Social media, within regulatory parameters, represents new opportunities to solicit and collect consumer input along every step—from clinical trial development to post-market surveillance.

"I've told industry that patients can contribute to the conversation," said Diane Dorman, vice president of public policy for the National Organization for Rare Disorders. "That the patient voice is important earlier in the process, such as how clinical trials are designed."

Dorman recalled one instance while attending a FDA patient-focused meeting for the narcolepsy community.

"I learned that these patients are impacted by seasons. During fall and winter the days are shorter, so these patients may have greater difficulty coping with narcolepsy," she said. "When that was mentioned, I think it was a real revelation for some industry representatives in the room who worked for companies possibly preparing to conduct clinical trials to treat the condition. Considering when to conduct trials became just as important as how they were conducted. The patient voice was heard. That was further evidence to me that the patient voice is important early in the process."

Consumer groups are not waiting on regulators or industry to address their concerns. Pat Furlong, founding president and CEO of Parent Project Muscular Dystrophy, explained how her group created the first patient-centered guidance document on clinical trial design. "No patient community has ever done this and it sets the stage for new partnerships with the FDA," she told HRI. But, what's still unclear is how the FDA will use the document.

Patient groups also are at the forefront of developing new methods to finance research and development of innovative cures or treatments. In some cases they are partnering directly with industry, which gives consumers a greater say in the drug development process and the chance to raise revenue that can be reinvested into research.

The Cystic Fibrosis Foundation recently earned $3.3 billion from its alliance with Vertex Pharmaceuticals to develop the drug Kalydeco.[64] In addition to a $150 million investment from the foundation, the partnership gave Vertex access to leading scientists, clinical trial participants and rich patient information.[65]

In other cases, consumers are working with regulators and policymakers to create incentives for manufacturers to develop products.

"I've told industry that patients can contribute to the conversation. That the patient voice is important earlier in the process, such as how clinical trials are designed."

—Diane Dorman, vice president of public policy for the National Organization for Rare Disorders

Considerations for the future

Skilled at utilizing the latest in science and technology to develop breakthrough therapies, pharmaceutical and life sciences companies will need to deploy new techniques to strengthen their relationships with the FDA and consumers. A closer, more collaborative bond among all stakeholders may create a more efficient development and regulatory process that leads to the next generation of treatments and cures.

Enrich the dialogue

Communicate more often and effectively with the FDA. Doing so will allow companies to build stronger relationships with agency officials, including the reviewers tracking their products. These interactions can help companies understand the agency's thinking and compile stronger applications to avoid multiple review rounds.

Survey data and interviews with executives indicate that increased communication between industry and the FDA led to actionable results. Yet not all companies take advantage of these opportunities, particularly smaller firms that may be unfamiliar and wary of the FDA review process. Greater outreach from regulators to smaller firms may help assuage fears.

New entrants to healthcare also may benefit from closer and more frequent contact with the agency.[66] Companies wading into healthcare's murky regulatory waters for the first time, such as tech firms, may be unfamiliar with the FDA's processes, making it important that they avail themselves of the agency's communication channels.

Prioritize consumer input

Companies should incorporate consumer views into product R&D, and share the information with the FDA. Many companies are acting on insights gleaned from social media and other online patient conversations, but a systematic process or model for incorporating these insights into product development remains in the early stages.

Regulators and policymakers may look for new ways to embed consumer views into the product review process. Negotiations prior to the reauthorization of the user fee programs in September 2017 may further codify consumer input as criteria for product approval. Consumers will want details on how the information they provide is being utilized in product review, which may necessitate new methods for data collection and reporting metrics.

Pursue new opportunities to minimize risk and accelerate access

Pharmaceutical and life sciences companies should partner with the FDA to facilitate early access to experimental drugs for eligible patients with articulated risks. Additional protections once a product goes to market may help allay fears that patients could be placed at risk by drugs or devices that are moving rapidly through the review process. Continued investment in new tools and technology, such as biomarkers, may help manufacturers and regulators assess risk more accurately and quickly.

Expanding the FDA's expedited programs to include a broader array of therapies, or creating new accelerated approval pathways, may require additional resources. Congress, the FDA, and industry ought to evaluate whether a targeted investment for these programs is warranted as they consider new reforms to the review process.

Additionally, the recent outbreak of Ebola demonstrates that new incentives may be needed to encourage early and sustained investment in discovering cures and vaccines for rare diseases.

Demonstrate value to regulators and purchasers

Although the FDA doesn't currently consider drug cost as a condition of approval, regulatory bodies in other mature markets such as Germany and the UK have made price a critical criterion of the approval process.[67]

Advancing innovation through new partnerships

Speeding the delivery of medical devices from lab to market serves the interests of manufacturers, caregivers and consumers. A team of health professionals, including industry, non-profits and regulators, came together to create the Medical Device Innovation Consortium (MDIC) for this purpose. The need for faster patient access to medical devices exists across the health ecosystem, and these stakeholders believe they can find an easier way to do it. The trick: standardization and collaboration that spans competitors and organizational lines.

"There are no easy questions left in medicine," Bill Murray, the CEO of MDIC, said in testimony delivered to Congress.[68] "We need big collaborations to conduct big science, and to rapidly and efficiently improve human health."[69]

As the New Health Economy places pressure on companies to efficiently develop innovative and cost-effective therapies, the industry recognizes the need for a dedicated forum in which it can work in tandem to meet these demands.

Although consortia are common in other industries, the concept is new in the realm of medical devices. MDIC was founded because regulators and industry saw the need for greater consistency in the product development cycle at medical device companies. Various companies have similar core processes to take a product to market, but implementation often differs. Aligning the methodologies across companies may make new medical products easier and faster for the FDA to review.

To reach a level of common ground among the disparate players in the medical device industry, MDIC encompasses members from patient advocacy organizations such as FasterCures, government agencies such as the FDA, CMS and NIH, as well as major medical device manufacturers including Medtronic and Johnson & Johnson.

All of these players stand to gain from the collaborative environment. "Industry likes it because it improves predictability and efficiency in understanding expectations when they bring products in for review and approval," said Murray. This inclusive structure also stands to benefit regulators, who must give their stamp of approval before medical products can be sold. "It's very hard and time consuming for regulators to work with individual companies. Here regulators can work with 19 companies at once. It's much easier for them," said Dalvir Gill, CEO of TransCelerate BioPharma Inc.—a pharmaceutical industry consortium.

Consortia break down the barriers in industry among stakeholders and competitors, and may often produce better outcomes for consumers. For example, MDIC is currently streamlining clinical trial design to reduce complexity and time to conduct the trials; ultimately, delivering quicker access to new products. The anticipated outcome of the project is published case studies of alternative clinical trial designs that medical device companies can use to achieve these consumer-centric goals.

In the US, the FDA and the Centers for Medicare and Medicaid Services are exploring how to work together more closely. For instance, the two agencies are examining whether to modify their parallel review program, which is intended to streamline decisions on safety, effectiveness and reimbursement for medical devices. Pharmaceutical and life sciences companies should find ways to demonstrate product benefits to the FDA by incorporating value metrics into the application process.

As spending on drugs and devices continues to rise, purchasers will increase their scrutiny of the value of new medical products. In the New Health Economy, manufacturers will need to demonstrate value over existing therapies as both purchasers and consumers—who are shouldering more of their costs—seek to clamp down on healthcare expenditures.

Seek new alliances

Organizations developing therapies on the cutting edge of biological science should collaborate with regulators to identify preferred testing methods in order to facilitate a more predictable review cycle. A greater reliance on public-private partnerships or consortia could provide forums for the exchange of ideas on scientific advancements and streamlining the product development process.

However, industry and the FDA should carefully manage and coordinate these efforts so as not to strain the available resources. "Industry collaborations help, but they can also lead to consortium fatigue that results in competition for scientists' time. It comes down to an issue of properly managing resources," said Dr. Ray Woosley, former head of the Critical Path Institute.

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Acknowledgements

About this research

Periodically, PwC surveys industry executives on their views about its relationship with the FDA and how it is changing to reflect recent trends. In the summer of 2014, PwC's Health Research Institute surveyed 100 senior executives on issues such as regulations, the development of new therapies, and patient engagement. Previous surveys were conducted in 1995, 1997, 1999, 2006, and 2010 as part of PwC's *Improving America's Health* series. In the most recent survey, respondents included chief executive officers, chief operating officers, presidents, vice presidents and department directors responsible for managing the company's relationship with the FDA. The industry trade association, Biocom, located in Southern California, helped recruit survey respondents. Survey respondents represented a broad cross section of the pharmaceutical and life sciences industry in terms of head count, revenue, and product lines. For the first time since launching this periodic survey, 1000 adult consumers were also polled about their views of the FDA, the pharmaceutical/life sciences industry and consumer access to therapies. Consumers were US registered residents randomly selected to participate in an online survey.

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