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VALUE SOLUTIONS ARRIVE AS A STRATEGIC COMMERCIAL DRIVER

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PHARMA COMPANIES HAVE LONG UNDERSTOOD HOW TO WRAP SERVICES AROUND A DRUG. BUT THAT IDEA GAINS A WHOLE NEW POWER WHEN THE FOCUS IS NOT ON THE PRODUCT BUT ON THEIR CUSTOMERS.

It's no secret that the key to commercial success in pharma is differentiation—and no secret that because of declines in R&D productivity, today's disease markets are competitively intense, making differentiation harder and harder to achieve. Product innovation is no longer enough. To win today, companies need stop running from the changes taking place in the healthcare market and, instead, embrace and capitalize on them, using commercial creativity to change how they deliver value to the marketplace. In this paper, we will show how a new approach called value solutions, based on services that "go beyond the drug," can help enhance pharma products' value proposition market and improve the return on companies' huge investments in development and commercialization.

MARSH & McLENNAN COMPANIES

In the pages that follow, we will examine why value solutions are different, when they should be applied, and how to identify, develop, and implement compelling concepts to serve a comprehensive set of customers in the healthcare value chain.

Value Solutions

An offering from a pharmaceutical manufacturer that is provided to external stakeholders—patients or their caregivers, healthcare providers and payers—in which innovative programs and services that can include drug address the needs of stakeholders in a manner that advances the standard of care.

BEYOND THE DRUG (AND WRAPAROUND SERVICE)

Companies have understood the basic concept of enhancing a drug's market position by surrounding it with services for well over 20 years. Even in the 1990s—at the height of the blockbuster era—we worked on programs in the neuroscience and immunosuppression markets to reduce disease costs and improve outcomes. There have been many attempts in recent years to extend the model, but most fell short for a variety of reasons: lack of staying power, fear of triggering regulatory scrutiny, and pricing compliance challenges, to name just a few. Pharma companies have occasionally ventured to become more than suppliers of drugs, but the idea of pursuing that as a full-blown commercial strategy hasn't received much consideration. Instead, we've seen the ubiquitous emergence of wraparound services focused on compliance and patient access. These services are offered today in about 85 percent of new molecule launches and tend to be constrained to a small set of easily replicable tactics. They often fail to advance the standard of care or deliver lower costs.

Today all of that is changing. Spurred by shifting healthcare market dynamics in the US and EU, plus a secular decline in R&D productivity, pharma companies have recognized they can deliver more. They are more motivated than ever to attune themselves to their customers' needs and use their wide range of competencies to do more: from matching the right patients to the right therapies to enabling compliance via technology, from guaranteeing outcomes to addressing ancillary needs of customers even for conditions outside the disease addressed by the therapy in question. They realize that, faced with the competitive intensity of many disease markets, they need to go further in the effort to stand out from the competition by strengthening their value proposition to patients, providers, payers, and other key customer groups.

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Oliver Wyman believes pharma players with this "beyond the drug" mentality are headed in the right direction. But they have a long way to go. And while today's wraparound services are familiar, the revolutionary solutions that will replace them are uncharted territory with few success stories to emulate. Moreover, it is not always clear how free pharma is to take on a larger role in patient care—and the rules are constantly changing. Some forward-thinking ideas on how to create value for customers may test the limits of today's regulatory and compliance frameworks. And pharma companies, with two decades of increasing regulation behind them, will be tempted to retreat to familiar, unequivocally compliant strategies.

To help our clients go beyond the drug to create enhanced customer outcomes and experience, Oliver Wyman has developed a service offering around what we call value solutions. We have used our value solution methodology and framework with a range of clients and for therapies targeting diseases with very different profiles. This work has led us to see the challenges of going beyond the drug in terms of four questions:

1. All disease markets are different; so how do we tailor solutions to meet the specific needs of stakeholders within a given disease market?
2. Given the breadth of our portfolio, which disease markets would benefit most from a value solution approach, and which customer groups should be in sharpest focus?
3. How do we overcome regulatory and compliance barriers that vary across country markets?
4. How do we apply strategic frameworks and methodologies to inculcate this kind of thinking into our commercial organization?

If pharma companies can answer these questions correctly, we believe they can provide the healthcare market with value that extends far beyond the drug. We also contend that delivering this sort of value is more than just a noble cause—it is good business. In many competitive disease markets, the winners will be those with a compelling offering that goes beyond the label. Every launch in every market with moderate to high competitive intensity can benefit from this approach. Over the past two years launches into competitively intense markets represent 78 percent of all launches.

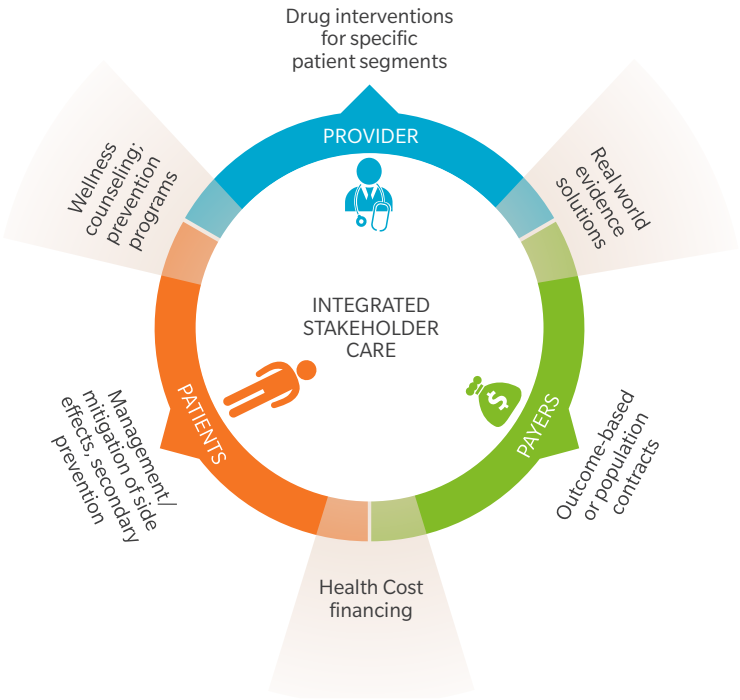
In the rest of this paper we will describe where and how to apply value solutions and share experiences of how the concept can be used to turn the competitive dynamic of complex disease markets on its head.

PUTTING CUSTOMER EXPERIENCE AT THE CENTER

Over the last 20 years, the industry has developed many new terms for services and solutions offered to patients in conjunction with a branded, prescription medicine: patient services, customer support, compliance programs, and disease education among others. Common examples include adherence programs, 24-hour drug information hotlines, and injection training services. The drug is at the center of what is offered. These services, and others like them, all focus on getting patients quicker access to drug therapy and helping them stay on the drug—honorable if not critical objectives. Patients are the stakeholders most commonly targeted, typically on an opt-in basis, with participation rates in the low single digits. Though these offerings are pervasive, few patients and physicians are aware of them, and those who are have a low opinion of their utility. Worse, they tend to be indistinguishable, even for the most discerning patient or physician. They are essentially table stakes, the cost of doing business within the disease market. Value solutions, by contrast, have at their center an acknowledgement of the way customers—some combination of patients, providers, and payers—experience the disease. They offer more comprehensive solutions designed to improve that experience and add value in the form of better outcomes, potentially at a lower cost.

Exhibit 1 offers one illustrative of how a range of services can be combined to meet the needs of patients, providers, and payers simultaneously in a holistic, integrated fashion. Segment-specific interventions help ensure that all patients get the right therapy at the right dosage. Additional services address patients' ancillary needs relative to side effects and wellness counseling. In addition to aiding the patient, this helps the provider, who is usually not well equipped to address these needs. The integration of a real world evidence offering as a learning tool to inform more effective clinical practice and provide justification for reimbursement is another prominent, complementary offering. And outcome-based or population-based contracts serve both payers and providers concerned with controlling total cost of care.

EXHIBIT 1: VALUE SOLUTIONS OF THE FUTURE (ILLUSTRATIVE EXAMPLE)



We believe basic wraparound services will continue to be market entry requirements for any new drug. Value solutions are different: They offer pharma a pathway to a new role in the healthcare value chain, providing new opportunities for differentiation, especially for early movers, and leading to superior customer experience, patient outcomes, and value capture by pharma.

THREE PATHS TO VALUE

In a recent conversation, the chief commercial officer of a major pharma said to us: "I get ideas for what we can do throughout the entire portfolio. But we can't invest in everything. How do I know where to start? How do I know if one solution makes more sense than another?" We hear these questions often, because it takes a significant investment to create novel, differentiated value solutions. To answer them, we need to understand the various models of value solutions and how they apply to our assets and the disease markets we participate in.

Experience suggests that value solutions come in three basic models.

Enabler

Improves outcomes and/or cost of care through a use of high-touch service or enabling technology

An enabler seeks to improve standard of care or its cost through a service, often employing technology and leveraging the differentiated aspects of a clinical profile and the clinical and economic evidence generated for the drug. For example, a pharma might develop a companion diagnostic to assess which patients benefit most from a drug. Or it might create a program to address depression comorbid with pain in patients with osteoarthritis or rheumatoid arthritis. A company with an asthma drug might introduce a remote monitoring technology that allows patient or provider to track respiratory function and adjust therapy as required. These examples, like many examples of enabler models, touch multiple customer groups; in these cases both the provider and the patient gain an easier experience with seamless, efficient interactions. Enabling programs are usually linked together. For example, we recently worked on a value solution that promised a faster response to therapy than competitors could deliver. The solution linked enabling programs aimed at patients, providers, and payers; for example, for payers there were interventions to track and monitor response, assuring payers that they had paid for the right therapy for the right patient.

Guarantor

Assumes risk for a drug's efficacy, safety or duration of therapy

The guarantor steps in to assume financial risk associated with drug treatment. For example, in a market with great competitive intensity and numerous therapeutic options leading to lower levels of unmet need (for example, chronic obstructive pulmonary disease), a company might guarantee outcomes based on real-world measures and bear the risk of treatment failure. This would benefit both payers and health authorities and contribute to competitive advantage.

The guarantor and enabler models are not mutually exclusive. When applied simultaneously, one approach will often bolster the effectiveness of the other and lead to a more compelling, integrated value solution.

Care owner

Coordinates care delivery and assumes risk for a population of patients

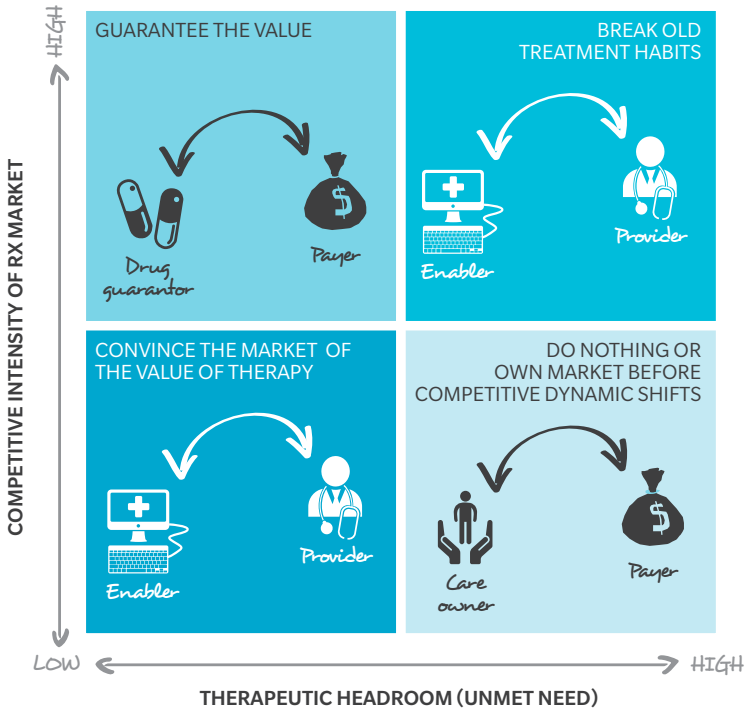
As a care owner, the pharma assumes the role of population health manager for a disease population. This model works best in a small disease market where drug usage accounts for a large portion of the cost of care, and the population is too small to lead payers and providers to develop their own care models to manage outcomes and cost. Usually markets like these haven't yet to become competitively intense, and the company can use its knowledge and position in the market to change the treatment paradigm. This model makes sense today and could work in the future in disease areas such as Fabry's disease, lupus, and cystic fibrosis. The care owner approach represents a significant shift from the traditional pharma business model.

ALIGNING PRODUCTS WITH MODELS

The question, of course, is which model to choose? To answer it, we constructed a framework that considers two important factors: How well a given product meets unmet medical need and the competitive intensity of its market. Exhibit 2 shows how the framework can be used to assess which models to use and which customer group to focus on in a given disease market.

Let's illustrate the process by returning to COPD, a disease that sits squarely in the upper-left-hand quadrant of Exhibit 2. A pharma with, say, a fourth-to-market combination COPD therapy faces high competitive intensity and will have a difficult time differentiating its drug on the basis of addressing unmet medical need; the clinical data for the drug will probably be seen as an incremental improvement at best. In this situation, *at a minimum*, the value solution should address payer needs through a guarantor model. But note the phrase at a minimum. There are more possibilities. For example, the manufacturer could play guarantor and enabler at the same time by both guaranteeing fewer exacerbations and providing lifestyle programs and health technologies to minimize their likelihood. In combination, the two offerings will improve outcomes and reduce the cost of hospitalization and treatment of exacerbations, providing value to payer (reduced healthcare expenditure), patient (maintenance of better health status), and provider (reduced complexity associated with managing unstable patients).

EXHIBIT 2: DIFFERENT SOLUTIONS FOR DIFFERENT RX MARKETS



The lower-right-hand quadrant raises two points. First, when competitive intensity is low and unmet need is high, it may be fine to do nothing. But, second, if you are concerned that your market position will be short-lived, you can help secure it against future competitors by becoming a care owner. Consider this option in any small disease market where payers have low interest in actively managing patient populations to reduce cost and your deep expertise will let you to work effectively with providers and payers to drive superior outcomes and lower total disease cost while improving the patient's experience.

CREATING A SOLUTION

To develop a specific value solution and to determine how to implement it, we use a four-phase methodology we call the Value Solutions Pyramid. This section describes the pyramid and the issues and key questions we address in each phase.

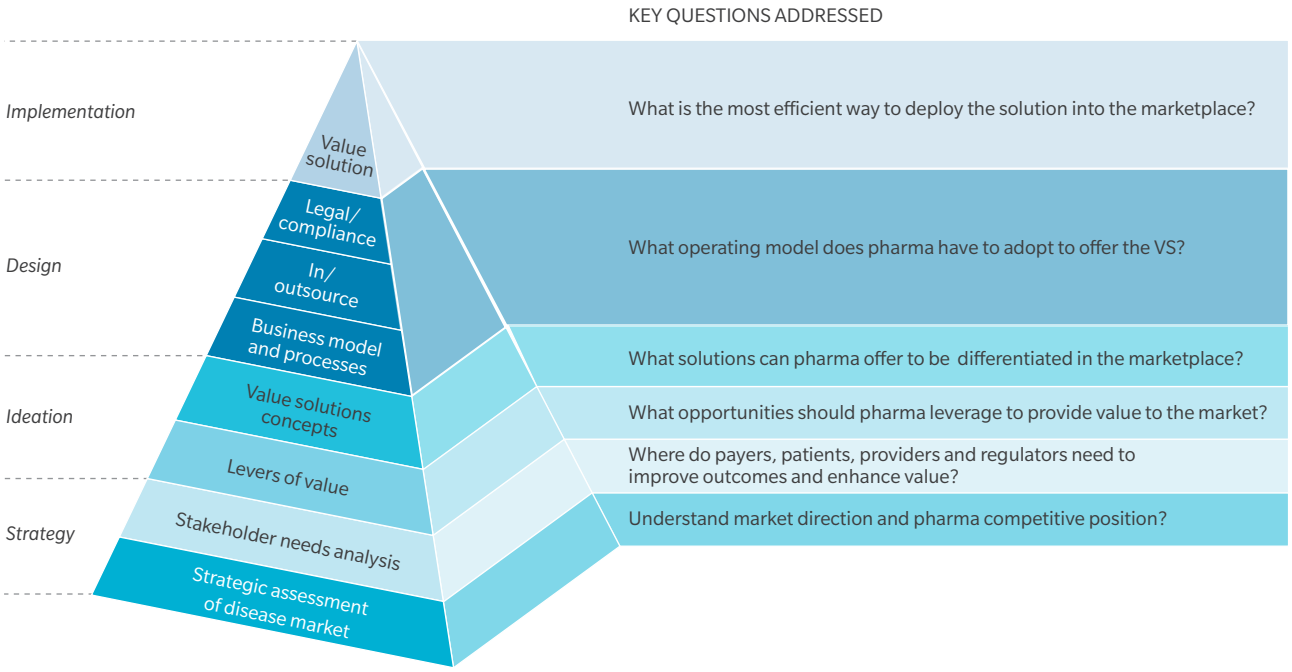
Four insights inform our methodology

1. **Needs analysis should extend beyond the patient.** We have frequently noticed that when pharma companies perform a needs analysis, they tend to delve deeply into patients and ignore everyone else: payers, physicians, caregivers, nurses. They also tend to treat all patients alike, even when it is clear they are not. Our own bias is to look at a wide variety of customer groups and to segment early. In considering the pharma company's needs, we go beyond simply considering revenue and factor in other needs, for example, the need to enter a category or establish a presence in a customer segment.
2. **There are many needs, but only a few levers of value:** Each disease market offers a different set of opportunities to create impact with a value solution—things like addressing a comorbidity, achieving faster onset of relief, identifying patients in a sub-population. Only a handful of these "levers of value," as we call them, will prove effective in any given disease market.
3. **Idea fragments—used in combination,not isolation—are the building blocks.** When we lead clients through ideation sessions, we get lots of ideas, and there are often concepts introduced that are variants of a single lever of value. These concepts can often be used in combination. It is that combination of ideas that contributes to the solution and differentiates the solution from an easily replicated wraparound service.
4. **Constraints shouldn't be addressed until the design phase:** We have seen many good ideas die on the vine in the name of compliance. In some cases, the constraints were real. In others, we're less certain. What we do know is that compliance concerns raised too early in the game stifle precious creativity. And even in the design phase, when we do hold a concept up to the compliance test, we have learned that it's better to ask, not yes or no?, but how? We've been pleasantly surprised how often there's a way.

We represent this methodology as a pyramid to keep front and center the idea that we are moving from many ideas to the few that capitalize on the levers of value and can be implemented by a pharma. The process moves systematically through four phases. The first phase, needs analysis, takes a process many pharmas already apply well to identify patient needs and extends it to a variety of customer groups. Segmentation hypotheses are developed early on, which allows us to explore and test more ideas on how to deliver value. We rely on qualitative as well as quantitative research, and we are great believers that a useful needs analysis should extend to payers, providers, and possibly other stakeholders in the value chain.

The ideation phase has three goals: prioritize needs, develop solution concepts, and, most important, build consensus that the status quo is not enough. Over two or three sessions (sometimes

EXHIBIT 3: THE VALUE SOLUTIONS PYRAMID



more accommodate country market requirements)multi-disciplinary teams from the clinical and commercial sides of the organization engage in exercises that produce ideas, and the ideas are converted into powerful value solution concepts.

Design is about making it real. This is the first time we approach legal and regulatory, and we take care to ensure that these conversations focus more on how than whether. We find that pharma companies can rarely design, develop, and operate all elements of a value solution on their own and so we consider the full breadth of external partnerships that will be required to execute the solution. We leverage our design and operations expertise and the client's internal capabilities to address needs in technology, operations design, creative support, finance, project management, and implementation planning.

We have seen companies complete needs analysis and ideation in about ten weeks. Design and implementation can take six to 15 months, depending on requirements for partnerships and infrastructure. We recommend starting a value solution initiative 18 to 24 months before launch.

THE ROAD NOT TAKEN

We hear many questions about value solutions: How much do they cost? How long does the process take? How do we define success? And, most of all, who has done this before? The answer is almost no one.

That answer surprises many people. "But we already do that today," they tell us. In response, we ask them four simple questions:

1. Does your solution revolve around experience with the disease versus the product?
2. Does your solution touch multiple customer types (patients, payers, providers, etc.)?
3. Does your solution improve the standard of care?
4. Is your solution difficult to replicate?

We would suggest that to have a true value solution, you need to answer yes to all four questions.

In our eyes, the clearest example of a value solution approach involves Biogen's multiple sclerosis drug Avonex. This was in the early days of self-injection, about 15 years ago, and Biogen realized that Avonex was not going to be prescribed unless the company did something to support its administration and ease the burden on doctors. Avonex invested millions in a system to support patients through the process of receiving their medication, injecting it, monitoring their progress, and caring for their disease. In addition to this technology, Biogen created a team to guide patients through each step and provided these services free to all Avonex patients.

This provided value to patients by giving them support for a product that helped them manage their MS; to physicians, by enabling them to more efficiently start patients on a more effective therapy; and to payers (at least in the long run), by ensuring that the product would be more effectively administered, reducing the need for additional drug—and disease-related spending. Avonex' s uptake took off with the program, and the drug has led the class ever since.

It is worth noting that Biogen built on its solution over time, enhancing its system to engage experienced patients while counseling new ones. At some point, however, the innovation slowed, and competitors replicated portions of the solution in a way that allowed them to close the gap. Nonetheless, Avonex's lead versus competing drugs (measured over years) contributed to an image and a level of customer loyalty that to this day has them positioned as market leader in a space with multiple entrants with peak sales approaching $3 billion in the United States.

CHF: A VALUE SOLUTION MODEL FOR THE FUTURE?

A top priority for payers and large integrated healthcare delivery systems is reducing the cost of care and improving outcomes in congestive heart failure. CHF affects more than 6 million Americans, with another half million expected to join them by 2020. It has an enormous rate of hospital readmissions, clearly indicating that a significant proportion of patients are not properly controlled, it accounts for a startling 43 percent of total Medicare Part A and B expenditures. CHF has attracted significant attention from pharma R&D organizations, and several potential new drug launches are on the horizon.

What would a pharma-led CHF value solution look like? Oliver Wyman convened thought leaders from the payer, healthcare provider, health technology, and pharma/biotech sectors to collaboratively develop one. The solution needed to create value for a broad set of stakeholders—from patients to population health managers—and had to address basic regulatory and compliance considerations (although we did not attempt to resolve all the complexities of today's murky, evolving regulatory environment).

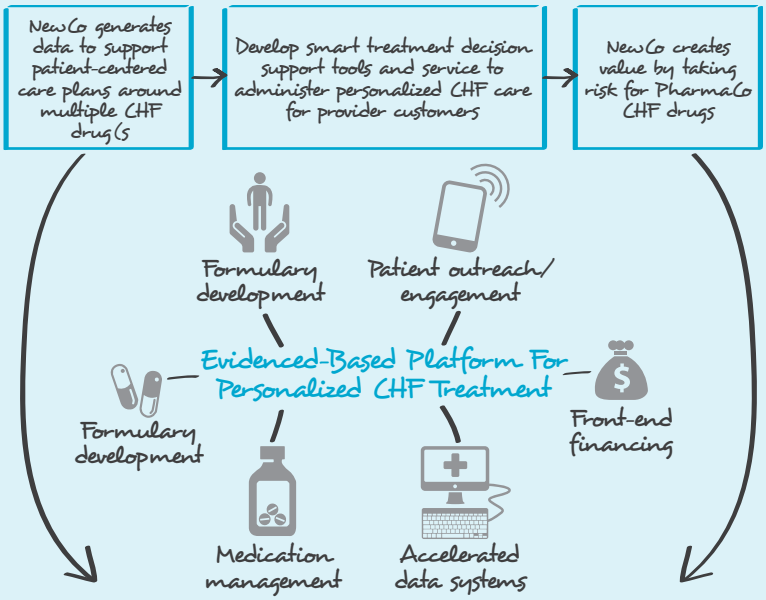
The group focused on a handful of levers of value: minimizing readmissions, improving nutrition and lifestyle, and remotely monitoring patients to identify those at high risk and ensure broad compliance with all interventions. And the concept they developed aimed to address several objectives critical to reducing CHF costs while improving outcomes:

- Delivering greater clarity around the cost and outcomes associated with competing CHF treatment options for different patient segments and treatment settings
- Providing user-friendly, real-time treatment decision-making and other enablement tools and services customized for different patient segments and treatment settings
- Offering outcomes, rather than single therapeutic products, based on insights from a robust clinical evidence base

The solution is described in the figure below. In this illustrative example, the pharma company would form a "NewCo" to offer significantly more than just a new drug option for acute CHF. In part, the NewCo would take on an enabler role by providing data to support patient-centered care plans and treatment decision-support tools and services. In addition, it would assume risk for a range of drugs—including medications developed by other pharma companies—taking on either the role of guarantor or care owner, depending on whether it assumed risk for the drug only or for overall patient outcomes.

Design objective: Enable the solution

- Ensure optimal integration of new drugs into existing treatment protocols
- Develop "Pill+" technology/care solutions that complement PHM goals
- Take risk on drug outcomes to insulate PHMs from near-term cost increases



- Clinical demonstration of superior efficacy on both near- and long-term outcome measures
- Data-driven real-world insights on best practice for integrating new drug with existing treatment regimens
- Financial risk on clinically relevant outcome measures related to CHF drug treatment
- Shared savings from improved patient outcomes, both drug and non-drug

This concept is bolder than anything we expect to see in the market in the next few years, but it shows the direction we think pharma can move in—and how individual ideas can be woven together to create a solution with the potential to redefine how pharma plays in a specific market.

SUMMARY

Value solutions won't just help pharma companies compete more effectively; they will also blaze a path for how commercial organizations transform in the face of a dynamic global healthcare market. It will be a lever that will enable commercial success and position pharma differently in the healthcare value chain. The ability to reap the return on a $1 billion-plus investment in development and commercialization is often at stake.

But to make the concept a reality, companies need to take the sort of systematic approach we laid out here for deciding which products to start with and how to proceed. It is essential to look holistically and objectively at stakeholder needs, levers of value, opportunities to enhance standard of care, and the mix of internal and external capabilities required to implement a solution that, instead of focusing on the drug, puts disease experience at the center.

Doing this requires business model change, which is never easy. But those who succeed stand to reap higher returns from the billions they invest in new product R&D and commercialization.

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Oliver Wyman's Health & Life Sciences practice serves clients in the pharmaceutical, biotechnology, medical devices, provider, and payer sectors with strategic, operational, and organizational advice. Deep healthcare knowledge and capabilities allow the practice to deliver fact-based solutions.

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