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The issue: value-based contracts will only become mainstream if manufacturers and payers come together in a safe, transparent forum to develop solutions to common issues related to defining and measuring outcomes and data sharing.

One solution: the creation of "Value Labs," joint ventures between industry, payers and other stakeholders to research, evaluate and deliver value to the health care system.

So what? Value Labs provide a road map for replicating the findings from successful value-based pilot programs across multiple payers to drive more rational resource utilization, improve patient outcomes and accelerate their collective impact.

The Value Lab:
Moving Value-Based Health Care From Theory To Practice

Although stakeholders are interested in value-based models that link a drug's performance to emerging evidence of improved patient outcomes, such agreements are difficult to implement and too limited in scope to drive a shift to value-based reimbursement. The authors suggest a new, structured approach to bring these contracts into the mainstream, thus transforming product reimbursement and fueling the shift from volume to value.

BY SUSAN GARFIELD, MICHAEL SHERMAN, ROGER LONGMAN, SUSAN SHIFF AND ELLEN LICKING

Medical product costs remain a central concern to payers, employers and individuals in the US. Although the Trump administration has yet to issue formal policies altering drug and device reimbursement, it continues to highlight the issue via public statements and social media supporting "competition in the drug industry" and promising "pricing for the American people to come way down."

The private sector, however, is not waiting for government-led change. US payers continue to struggle to manage costs on two fronts: first, high-volume, high-cost chronic diseases; second, high-cost specialty products. As a result, they are interested in new value-based models that link a drug's performance to emerging real-world evidence of improved patient outcomes. Announcements by **Harvard Pilgrim Health Care Inc.**, **Cigna Corp.**, **Aetna Inc.** and several other payers of newly signed value-based contracts (VBCs) are examples of this trend. Moreover, a recent study by Avalere suggests that as of May 2017 nearly 25% of all US payers have already constructed at least one value-based contract. *(Also see "Brilinta/Bydureon's Measurable Outcomes Are Smooth Fit For Contracts" - Pink Sheet, May 31, 2017 and "Lilly's Performance Contract For Trulicity Hinges On Head-To-Head Superiority" - Pink Sheet, June 26, 2016.)*

Drug manufacturers are also increasingly willing to consider the access advantages that arise via such novel contracts, partially due to evidentiary gaps between a medicine's performance in highly controlled clinical trials and its real-world utility. *(Also see "A Road Map To Strategic Drug Pricing" - In Vivo, March 2016 and "Smart Segmentation: Success In The Payer-Dominated Pharma Marketplace" - In Vivo, July 2016.)*

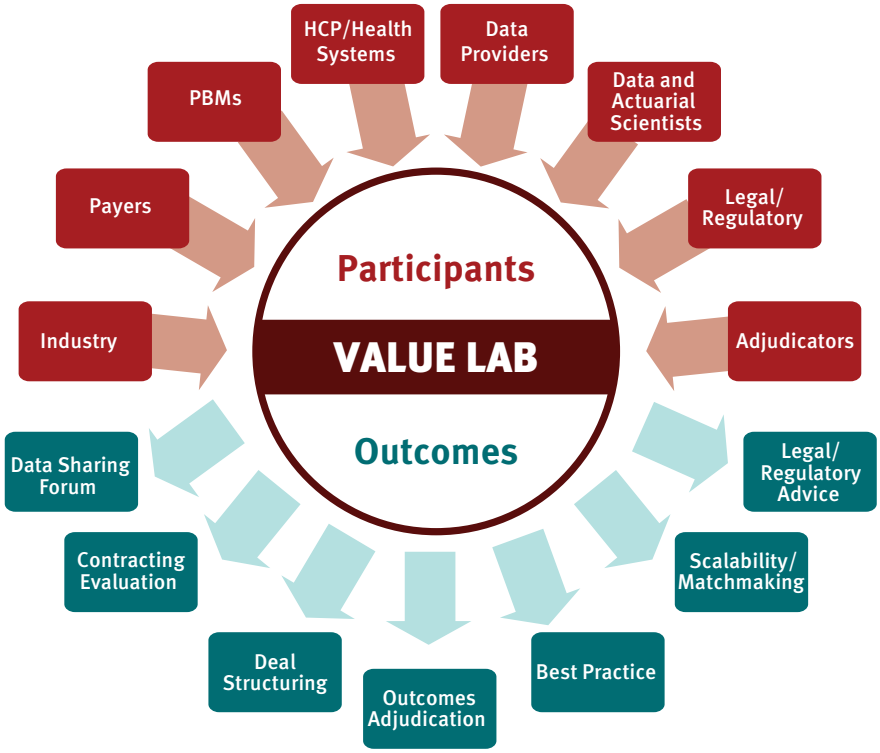
Indeed, an analysis by EY shows that 44% of drugs launched between 2005 and 2013 underperformed compared with forecasted sales expectations two years after launch; roughly 20% of these underperforming products were medicines to treat cancer, an area that historically has been free of reimbursement pressure.

In addition, VBCs represent a method for measuring important patient-centric mechanisms such as quality of life, improved medication adherence and reduced worker absenteeism. Such outcomes are not usually prioritized by health technology assessment groups or traditional payers, unless there are accompanying real-world data demonstrating improved outcomes.

Unfortunately, while growing in prevalence, the current crop of value-based contracts is still too limited in scope to drive a meaningful shift to value-based reimbursement. Most of the current contracts involve diabetes and cardiovascular medicines, whose outcomes, or surrogate markers, are easy to measure or

Exhibit 1

A Variety Of Stakeholders Would Benefit From Value Labs



Notes: PBMs = pharmacy benefit managers; HCPs = health care providers
SOURCE: EY

binary in nature, and for which the time to demonstrating such outcomes is weeks or months. Measurement is even more difficult in other therapeutic areas where pharmaceutical costs are growing quickly, such as pain, oncology and inflammatory disease. *(Also see "US Outcomes-Based Contracts: Big Uptick In Interest, But Not Execution" - In Vivo, November 2016.)*

There is also a need to construct agreements that tie a greater percentage of a drug's cost to the desired outcome. Currently, few of the existing VBCs risk much – either for the payer or the pharma. And, even in therapy areas where there is significant competition, only a minority of VBCs have scaled beyond the pilot phase. Moreover, because VBCs are typically structured between a specific payer and manufacturer, it is difficult to expand their use to additional payers and at-risk providers quickly. Ultimately, that makes it challenging to share best practices and lessons learned that would more broadly accelerate the shift to value-based reimbursement in the current regulatory environment.

Because of the numerous present hurdles, it's not surprising that payers and pharmas continue to resort to easier to implement, blunt mechanisms such as rebate-driven formularies to limit product costs. *(Also see "Price Rebates Will Continue As 'Fact Of Life' In Drug Contracting" - Pink Sheet, January 16, 2017.)*

Innovation Needed

A new approach to VBCs is required so that these contracts move from being exceptions to mainstream practice. Only then can we transform product reimbursement and fuel the shift from volume to value.

"Value Labs," or structured collaborations between manufacturers, payers, health care systems, data providers and adjudicators are one way to explore value-based contracts in a safe forum. (*See Exhibit 1.*) Inherently multi-stakeholder, these Value Labs are a "sandbox" to promote experimentation while mitigating known pain points, such as defining and measuring outcomes and building systems to share data. And, because they provide an opportunity for participants to work together to address and operationalize core challenges, Value Labs will increase transparency, which further promotes trust and drives collaboration between stakeholders.

It is important to note there won't be one Value Lab, but many. Depending on the therapeutic area, different stakeholders will need to be involved. An oncology Value Lab, for instance, might bring together representatives from patient advocacy organizations, diagnostics makers, biopharma developers, community oncology practices, commercial payers and professional societies such as the American Society of Clinical Oncology or the National Comprehensive Care Network. These different groups would work together to solve industry-wide challenges, such as defining the most relevant patient outcomes for a particular cancer or developing methodologies to measure those outcomes.

We are already seeing ad hoc experiments promote the Value Lab concept in spirit, if not in name. In May 2017, the **Duke University** Margolis Center for Health Policy announced the creation of a consortium to overcome legal and regulatory hurdles associated with value-based payments for drugs and devices. The consortium, which includes patient advocacy groups, insurers, biopharma companies and policy experts, will also tackle operational challenges related to fragmented and difficult-to-track patient outcome data. Meanwhile, the National Health Council, a US-based advocacy organization for patients with chronic diseases, has created a framework for health care cost reductions that includes value-based pricing strategies. Another experiment worth noting: **Merck & Co. Inc.** and Optum, the health services group of **UnitedHealth Group Co.**, have formed a partnership to explore various value constructs. (*See sidebar, "A Learning Lab For Outcomes-Based Risk-Sharing Agreements."*)

The Value Of Efficiency

The development of new VBCs will be more efficient because participating stakeholders can apply learnings from prior experiments. There is no need to reinvent processes for common challenges, including creating systems to

safely share data or define and measure outcomes. Indeed, one need only look at the precedents set when payers began collaborating with providers around alternative payment models to see how Value Labs might contribute to a more rapid diffusion of current best practices.

To reduce the administrative burdens associated with these provider contracts, payers have tried to utilize similar outcomes measures across different provider groups. And in 2016, America's Health Insurance Plans (AHIP), a trade association representing US health plans, helped further streamline efforts by convening a work group of payers, patient advocacy groups and professional medical societies to define a core set of outcomes measures that could be used by all parties.

A Structured Forum For Experimentation

Value Labs offer a structured forum to experiment in four key areas where current hurdles have limited the uptake of VBCs:

- Value-centric clinical and economic study design
- Innovative contracting structures
- Data tracking, technology infrastructure and interoperability models
- Strong evaluative and administrative protocols

Value-Centric Clinical And Economic Study Design

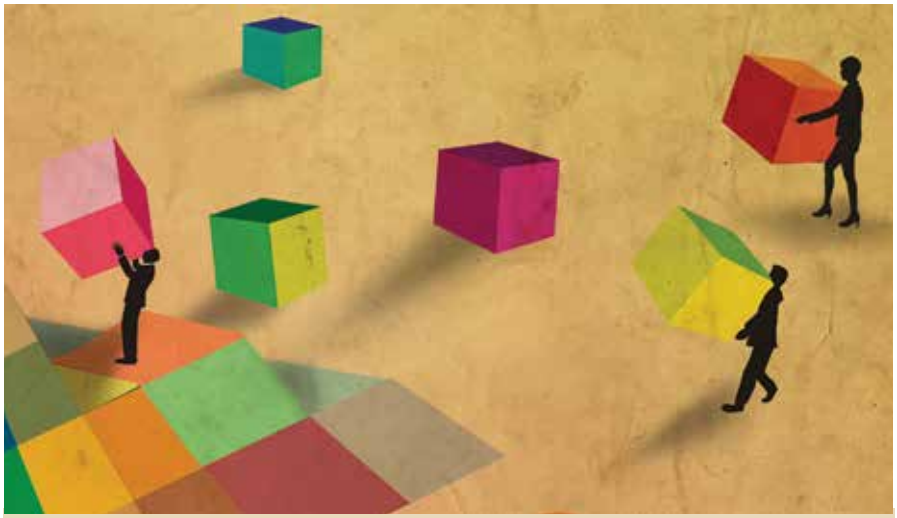
By creating an environment where payer-manufacturer discussions occur earlier in the drug development life cycle, the Value Lab will facilitate the collection of jointly relevant health economic and outcomes research and relevant scientific and clinical data when a product is still in investigational trials. Collaborating early allows different stakeholders to understand which data are most relevant while streamlining processes for their collection. In addition, these early efforts would bolster pharmaceutical companies' efforts to gather real-world, patient-centric evidence in the post-launch phase of a product's life cycle.

Early modeling also allows stakeholders to more realistically forecast the potential future impact of products in development and plan accordingly. Many manufacturers today generate these learnings episodically via payer market research and payer advisory boards rather than through collaborations. As a result, learnings are siloed within drug companies, rarely validated, or applied to other products. Regulatory hurdles also exist that prevent the optimal and early collaboration between stakeholders, though industry groups continue to advocate for changes.

Innovative Contracting Structures

Contractual terms in outcomes-based deals dictate the amount of risk either side assumes, directly influencing the willingness of stakeholders to engage. Both parties must agree on risk exposure as well as mechanisms and time lines to track and adjudicate product performance. Specific items that must be agreed upon early in the process include the outcomes measures of interest, eligible patient populations, duration of analysis and data used to track performance.

A real-world challenge to scaling VBCs has been the host of unknowns and confounding factors that affect the risk distribution between contracting parties. For instance, both manufacturers and payers are concerned about being held responsible for risks that can't adequately be controlled (e.g., medication adherence). By promoting a regular reconciliation process and housing risk assessment experts for all parties, Value Labs can help address larger uncertainties tied to data availability, reliability and ease of adjudication. Leveraging experts within the Value Lab to adjudicate outcomes and help manage risk transparency also provides a way for both parties to jointly



A LEARNING LAB FOR OUTCOMES-BASED RISK-SHARING AGREEMENTS

The Learning Laboratory developed by **Merck & Co Inc.** and **UnitedHealth Group**'s Optum division is a multi-year collaboration. The primary goal is to learn how to design and conduct feasible, high-quality outcome-based agreements that will be acceptable to all stakeholders.

To achieve this goal, the Learning Laboratory is tackling questions such as: "How do different predictive modeling approaches compare?" and "How can contract design minimize financial and clinical risk for all stakeholders?" An additional goal of the project is to develop case studies that highlight policy or regulatory barriers to payment innovation.

The project will utilize Optum's integrated claims and clinical records to provide data reflective of real-world patient care and outcomes. Acknowledging the lack of publicly available information and the need to learn from others, both companies are dedicated to sharing the results of their research where possible.

respond to variations in risk exposure and fine-tune the deal parameters in real time.

Value Labs enable partners to discuss and overcome deal roadblocks while aligning different stakeholder interests and providing the structural support to overcome such barriers. In addition, as proposed, the Value Lab creates a bi-directional forum to discuss evidentiary gaps ahead of, and after, a product launch. As a result, the Value Lab provides a medium for determining what information is needed to close that gap and a methodology for its collection.

To be widely used in the market, VBC contracts must be able to account for non-binary outcomes, and apportion risk appropriately across multi-factorial interventions. For example, to understand the impact of a depression medication, stakeholders need to measure multiple elements such as mood, participation in activities of daily living, worker productivity, and sleep duration. Moreover, the effects of a medication need to be assessed in conjunction with the other services the patient receives, whether those are additional medications, psychotherapy, digital health support services, nutritional counseling, or all of the above. Creating a VBC that assesses the discrete impact of any one element, versus the combined impact of the continuum of care, becomes a Value Lab challenge that stakeholders can determine together.

This ability to assess multiple endpoints that are subjective rather than dictated by objective lab values is one of the major benefits of the Value Lab. Current VBCs have been limited to simple endpoints (e.g., fracture rates or reductions in hospitalizations) that can be monitored via claims or electronic medical record data. However, in many therapeutic areas, it is not so easy to agree on the clinical outcome to measure or the mechanisms that will enable consistent longitudinal collection of data in an electronic setting.

Payers and manufactures acknowledge the difficulties associated with capturing more subjective outcomes measures. Because of the up-front investment required to build systems that validate and capture some of these outcomes, the reality is no individual company, whether a payer or a drug company, has the resources needed to create them. But since Value Labs generate economies of scale, they can enable greater use of "hard to capture" outcomes measures, and therefore expand the number of therapeutic areas amenable to performance-based agreements.

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Data Tracking, Technology Infrastructure And Interoperability Models

To make VBCs a reality, all parties need to surmount the technical, cost and cultural challenges associated with gathering and monitoring the outcomes data. Existing information technology systems, data collection protocols and data analytics capabilities vary across organizations, while interoperability and data sharing are rare. Systems that allow safe and regular data sharing between payers and manufacturers don't routinely exist. Indeed, most payers still feel very uncomfortable sharing even anonymized patient data with companies given unknown, but increasing, cybersecurity threats.

Value Labs can promote the development, standardization and interoperability of data management infrastructure. They can also provide participants access to vanguard thinking in the area of data tracking and integration, while experimenting with emerging enabling technologies, such as blockchain, which allows data management via a secure, decentralized network of participants.

Indeed, data and analytic infrastructure platforms can be constructed not just for current needs but for future ones as well. Interoperability and data sharing enable value-based contracts to expand beyond traditional, single variable measures to contracts based on a more complex set of interrelated endpoints, including patient-sourced data and real-world evidence. Early Value Lab participants should include those who already have broad data sharing and evaluation platforms or deep knowledge of how these programs should be set up at the company, industry, and payer levels.

Strong Evaluative And Administrative Protocols

Implementing and maintaining the operational requirements of a value-based deal requires time, expertise, and significant clinical and back-office resources – each of which may be constrained among smaller pharmaceutical and biotech companies or smaller payers. And, for truly rare diseases, where therapies are likely to be extraordinarily expensive, the fact that even large payers may only have a handful of patients may make developing VBCs impractical in the absence of a structure that enables "pooling" across organizations.

Even relatively straightforward agreements can involve multiple steps, starting with the development of a shared understanding of the relevant outcomes measures based on cost, quality and ease of measurement. In addition, both payers and manufacturers must create models based on real-world performance assumptions and then agree to multiple, detailed elements of the contract, including number of patients enrolled, patient adherence levels and the length of the

measurement period. For payers, these discussions can be further complicated by existing agreements that designate certain medicines as preferred drugs, thus limiting their formulary flexibility. Payers also need to create a "true-up" process that routinely reconciles agreements.

The Value Lab can help reduce some of the hassle factors associated with VBCs that limit their wider deployment. These factors include data collection across multiple platforms, and harmonizing processes for governance and risk mitigation.

As collaboration and stakeholder engagement shift earlier in the product life cycle, participants can jointly define and develop the terms, administrative processes and payment mechanisms underpinning the deal. In the Value Lab, driving adherence to administrative processes will become less an exercise in control and more an opportunity to engage stakeholders to identify points of friction. As such, increases in transparency and trust result directly from the ongoing collaboration.

Concept To Scale Framework

Given the complexities associated with VBCs and the known downside risks, it is no wonder VBCs have had limited traction in the US market. In essence, until these issues are collectively addressed, a successful, large-scale shift to value-based pricing will be unlikely.

Thus, the most important aspect of the Value Lab is that it provides a road map for rapidly moving VBCs from "concept to pilot" (i.e., the first VBC) and "pilot to scale" (i.e., taking a successful pilot VBC and replicating it across payers, or using findings to drive pricing/coverage decisions).

In the "concept to pilot" phase, the drug developer and the coverage decision-maker can engage early in the product development life cycle to hypothesize and test various endpoints or data capture processes as part of the contract. This phase of the VBC is designed to determine how the product delivers value and in what patient population. Additionally, it describes a scenario where parties pilot ideas to test hypotheses.

On the road from "pilot to scale," there is the interim step underpinned by data capture, outcome measures and analytics. In this phase, the Value Lab provides the structure and environment to incorporate key learnings iteratively into future arrangements.

Inherent to the Value Lab are numerous opportunities to build capabilities, share insights, and, thus create trust between parties that historically don't have high confidence in one another. The ultimate goal of the Value Lab is to encourage transparency so that efforts to advance new value-based pricing models are not sequestered among a handful of manufacturers or payer organizations, and stakeholders can optimally leverage key learnings.

Moving From Vision To Reality

From the payer perspective, new value-based pricing models are still needed to help create more predictability in expenditures and higher rates of clinical and economic return on investments in drug therapies. Recent experiments with bundled payments and forays into risk-sharing contracts between payers and drug companies represent steps forward in the shift to value-based reimbursement. The future state, however, is more than a collection of VBCs across payers' books of business; rather, it's an industry-wide collaboration that creates incentives for biomedical innovations along a consistent and predictable set of value metrics. This becomes critical to help stakeholders understand the independent and comparable value of innovations, and to allocate resources accordingly.

A number of new tools allow stakeholders to better understand the relative and absolute value of products. Some of these enablers include analytic platforms that can leverage multi-source real-world evidence and cloud-based data sharing. Others are evaluation frameworks to consider specific medicines. These value frameworks allow private organizations to apply a distinct methodology to understand the potential value of specific treatments. While the notion of "good" or "fair" value is arrived at differently by each organization, the underlying concept remains the same: a product's overall value is independently defined via a framework that can be understood by various stakeholders. In this way, the value frameworks become enablers of the Value Lab concept, creating systematic approaches to value assessment that can be utilized in the design and execution of value-based contracts. *(Also see "Scoring Value: New Tools Challenge Pharma's US Pricing Bonanza" - In Vivo, October 2015.)*

Conclusion

The Value Lab construct begins to address the complex relationship between manufacturers and payers/purchasers, creating an opportunity to build trust and transparency through aligned incentives. As such, it becomes a "joint-venture" between industry, payers and other stakeholders to research, evaluate and deliver value to the health care system – creating efficiency, improving outcomes and increasing quality.

At the heart of the Value Lab is a focus on improving patient outcomes and more rational resource utilization, which enables collaboration between two groups of stakeholders that, historically at least, were driven by different incentives. Creating a forum to reduce the hassle factors associated with VBCs is necessary but not sufficient to creating an environment that will promote value-based reimbursement. The future-state will undoubtedly be more hospitable to outcomes-based deals if and when stakeholders embrace a collective migration toward a more collaborative model.

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