

Drug value in the new health ecosystem

July 2013

Highlights

Public and private purchasers are emerging as the new arbiters of drug value.

Real-world data about cost and performance is crucial to a new product's success.

New payment models are tied to how a drug performs in the broader healthcare market.

To remain competitive, drug companies should forge partnerships across the health sector and harness the power of Big Data.

For pharmaceutical companies, a product's success used to hinge on measures such as FDA approval, clinician preference, and patent protection. However, as the health sector undergoes significant transformation, how a drug is valued—and its makers compensated—is changing rapidly. The new criteria? Real-world performance.

Feeling the burden of high medical bills, purchasers are demanding proof that their pharmaceutical costs are smart investments. Today insurers and healthcare providers expect new, and often more expensive, drugs to demonstrate benefit over existing treatments. They prefer therapies that help reduce the total cost of care, meet unmet medical needs, reduce unnecessary procedures, or improve the quality of life.

Meeting these new expectations requires significant changes in how medicines are researched, marketed, manufactured, and priced. Pharmaceutical makers must look to new partnerships and payment approaches, among other strategies, to cement their place in the new health ecosystem.

Changing expectations

PwC's Health Research Institute (HRI) surveyed executives at health plans and pharmaceutical benefits managers to hear what they want from drug makers.¹

- **More quality data.** Just 5% of health plan executives are very confident in the economic data provided by the drug industry when making coverage and formulary placement decisions. Only 7% are very confident in the information to evaluate a drug's comparative effectiveness.²
- **Evidence of improved performance.** Among insurers, 82% want to see proof of a drug's significant clinical benefit compared to current treatments to be considered for favorable formulary placement. Some 78% agreed that a clear cost savings argument was necessary.³
- **Payment tied to outcomes.** Today only 16% of health plans use novel payment and contracting models such as bundled payments or risk-sharing agreements. However, 37% expect to support one or more alternative payment models in the next few years.⁴

1 PwC Health Research Institute, *Unleashing Value: The Changing Payment Landscape in the Pharmaceutical Industry*, May 2012.

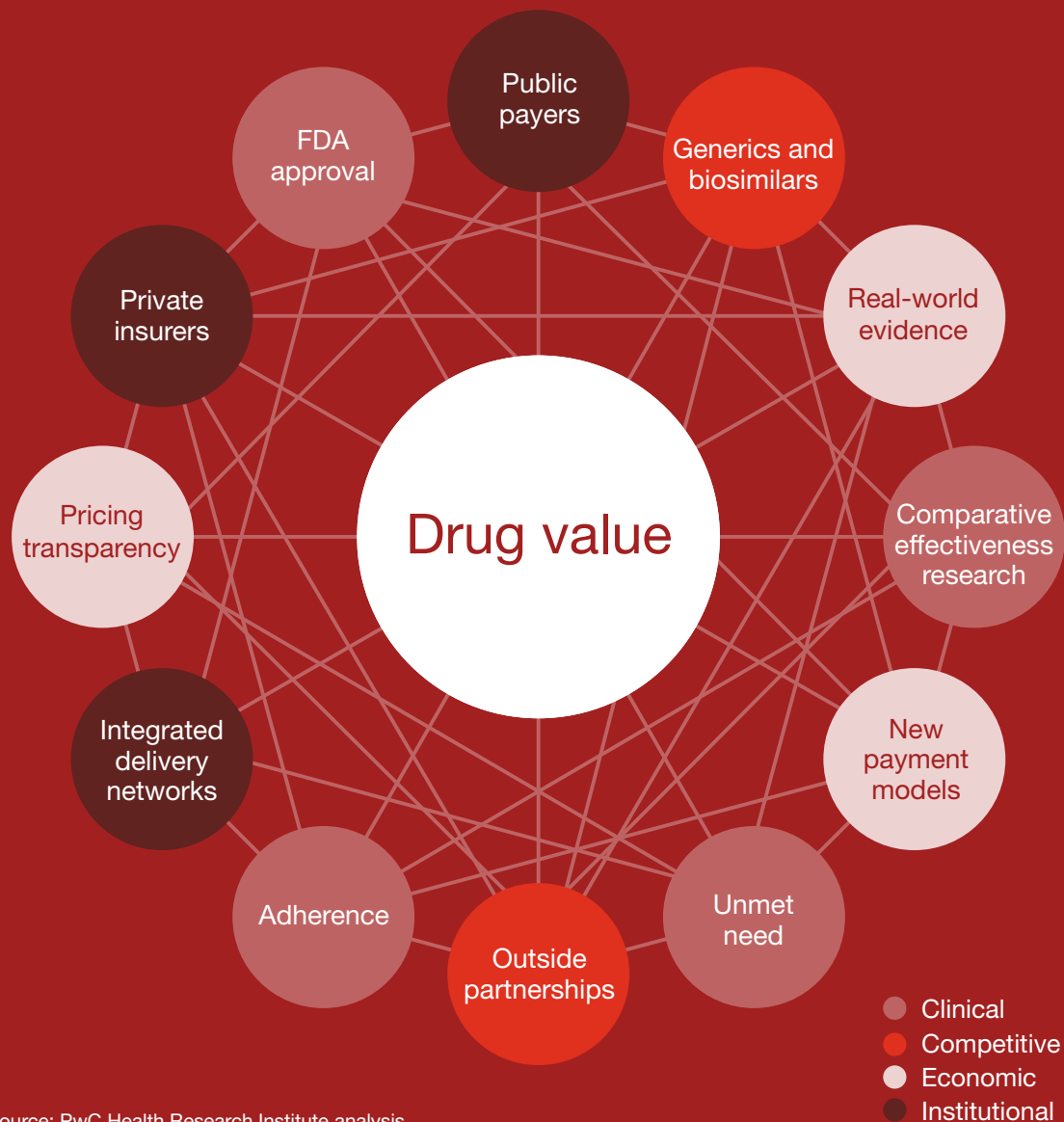
2 PwC, *HRI payer value survey 2012*.

3 Ibid.

4 Ibid.

At a glance

Drug value is the sum of many dynamic forces determining the success of any one product.



Health executives should be finding solutions to address these questions...

What are the implications of new care delivery models on drug development?

How do my products and services reduce total care costs, address unmet medical need, or improve the patient experience?

Do I have the right talent and resources to generate comparative effectiveness research, early and often?

Does my organization have an effective strategy in place for tapping Big Data to improve drug performance and health outcomes?

What outside partnerships should I have in place around real-world evidence and is my organization attuned to collaboration?

How can insurers and drug makers partner to deliver greater value to patients and purchasers?

Understand how players in the new health economy are introducing changes

New players in the healthcare system

Healthcare players	What they are doing
CMS bundled payments	Four payment models implemented by 460 hospitals cover up to 48 conditions.
Patient Centered Outcomes Research Institute	\$159 million in comparative effectiveness research-related funding in 2012. \$355 million expected in 2013.
Accountable care organizations	252 accountable care organizations cover 3.2 million lives and are paid partly on 33 quality metrics.
Health insurance exchanges	Fifty states, plus the District of Columbia, will have online insurance marketplaces covering up to 7 million people in 2014.

Public and private purchasers are bending the “waste curve” across the health sector and shaping the value of a drug based on cost, quality, and effectiveness. Drug makers, already trying to cope with dwindling product pipelines, are feeling the pressure to respond—and rethink how they operate.

Government purchasers

Federal and state governments are helping drive the migration from fee-for-service medicine to quality-based payment. The Centers for Medicare and Medicaid Services (CMS) is testing new reimbursement models such as “bundled payments,” in which the agency pays groups of doctors for the total cost of care, rather than for each individual service. This gives providers more incentive to offer cost-effective treatment options, including high-value, affordable medications. The approach requires much greater accountability as providers operate within stricter financial constraints and they in turn become more selective about drug choice.

Insurers

Even earlier than government purchasers, insurers have been seeking proof that drug purchases deliver value. In addition to making **bundled payments**, many now track a medication’s therapeutic performance, basing coverage and reimbursement decisions on the data. Underperforming or inappropriately expensive drugs can be knocked off preferred drug coverage lists.

New care delivery organizations

New payment and care delivery structures—such as accountable care organizations (ACOs)—aim to reduce costs through team-based, coordinated care. Providers and insurers share in the financial risk and reward, which means greater emphasis on evidence-based outcomes. As ACOs gain a deeper foothold, brace for closer scrutiny of drug costs. “For the first time, bundled payments and ACO-like models are giving pharmaceutical companies the chance to position their drugs as having a quality component related to the performance metrics,” says Robert W. Dubois, chief science officer for the National Pharmaceutical Council.

Comparative effectiveness researchers

Government and private insurers continue the quest for evidence on comparative performance of competing interventions. The goal is to equip individuals with information to make wise healthcare decisions. For example, the Patient Centered Outcomes Research Institute awarded Children’s Hospital of Philadelphia \$1.9 million for a three-year contract to evaluate intravenous versus oral antibiotic therapy for severe bacterial infections.

Consumers

As more of the cost burden—and decision making—shifts to consumers, price and results are taking on even greater importance. Patients consult websites such as WebMD or MedHelp for information on treatment options. Another site, Patient Power, offers webcasts of top medical experts and inspiring patients.

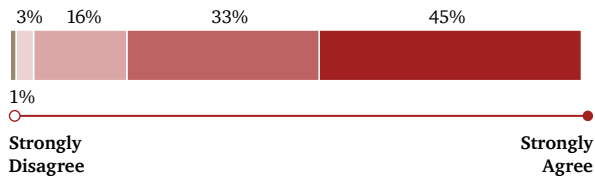
Capture and mine the right data

Insurers are asking for more

Insurers' expectations of cost and clinical benefit for reimbursement

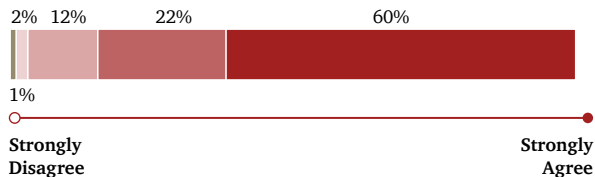
A clear cost savings

Pharmaceutical companies must demonstrate a clear cost savings compared to current treatments to be considered for formulary placement.



A clear relative clinical benefit

Pharmaceutical companies must demonstrate a clear relative clinical benefit compared to current treatments to be considered for formulary placement.



Source: PwC HRI payer value survey 2012

To keep pace with changing market demands, pharma and life science companies are looking to new kinds of data to help make the case for their products. This means going beyond traditional clinical trial information, which comes in prior to a product's launch, and instead looking to real-world evidence.

The performance data is becoming critical: If insurers and large providers don't see proof that a new drug fills an unmet need or outperforms similar products at a competitive price, the drug may not be covered by insurance or prescribed by doctors.

For products already on the market, the data is instrumental in retaining share. For example, the UK's National Institute for Health and Clinical Excellence had planned to recommend against the use of Novartis' Xolair for certain asthma indications. Yet once Novartis submitted additional evidence and agreed to lower prices for certain patients, the Institute **reversed its decision** in a matter of months.

From the patient's mouth

Pharmaceutical companies are mining insurance claims and electronic health records to help them identify unmet medical needs, current waste, and evidence of performance. Yet claims and records data only scratch the surface. In particular, they are collecting data directly from patients and providing it as evidence to insurers, health systems, and government purchasers. One study reports that 23% of FDA drug approvals since 2000 included patient-reported outcomes.⁵

Pairing up

Many drug makers intend to combine high-end medications with diagnostic tests to ensure the therapy works on specific populations. A drug that is paired with a diagnostic also promises to reduce the total cost of care by avoiding potentially harmful or ineffective treatments. The FDA **has approved** 17 such drug-diagnostic combinations so far. One, for example, detects non-small cell lung cancer-related gene mutations so that the proper drug is administered.⁶

Other data such as clinical notes on nutrition, exercise, and medication adherence habits also hold promise and may eventually fill the gaps about what makes an effective treatment. Yet this type of information remains difficult to collect and utilize. The first step is marrying clinical data with insights from patients about their daily activities and any reactions to medications.

5 Gnanasakthy, Ari, Sandra Lewis, Marci Clark, Margaret Mordin, and Carla Demuro. "Potential of Patient-reported Outcomes as Nonprimary Endpoints in Clinical Trials." *Health and Quality of Life Outcomes* 11, no. 1 (January 2013): 83.

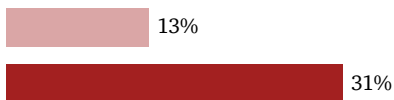
6 FDA okays companion diagnostic test for Tarceva (May 15, 2013). Reuters Health.

Tie payment to outcomes

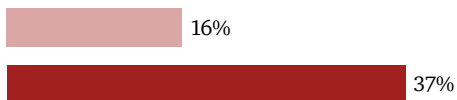
Emerging payment models

Insurers are increasingly tying reimbursement to patient outcomes

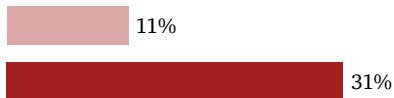
Bundled payments



Outcomes-based payments



Risk-sharing agreements



■ Now (%Yes)
■ Within three years (%Yes)

Source: PwC HRI payer value survey 2012

The focus on performance evidence—at a time of increased concern over medical spending—is redefining the way medications are sold. Tying reimbursement to outcomes is becoming a compelling prospect for both drug makers and insurers. Insurers get lower costs and better performance.

Meanwhile, drug makers may be able to improve the drug’s position on a health plan’s preferred drug list, accelerate availability of new treatments, secure reimbursement when long-term benefits are less known, and gain faster access to the market.

“The days of selling drugs by volume are numbered,” says Andy Gaughan, director of payer and real world evidence informatics at AstraZeneca.

Testing the waters

New payment models being tested include: variable pricing for different therapeutic indications, outcomes based contracts, and discounted pricing for combination therapies that use two or more drugs.

For example, Prime Therapeutics, a pharmacy benefit manager for 13 Blue Cross Blue Shield plans, and EMD Serono, Inc., a specialty pharmaceutical company, sealed the first outcomes-based rebate contract for a multiple sclerosis drug.⁷

Starting in 2012, Prime began keeping close tabs on how patients fare with the new therapy and rebates will be paid to EMD Serono based on the outcomes.

Where should companies focus?

Beyond providing evidence for reimbursement, data fosters the creation of patient registries, which can provide deeper insights into the trajectory of a particular disease and the performance of various therapies.

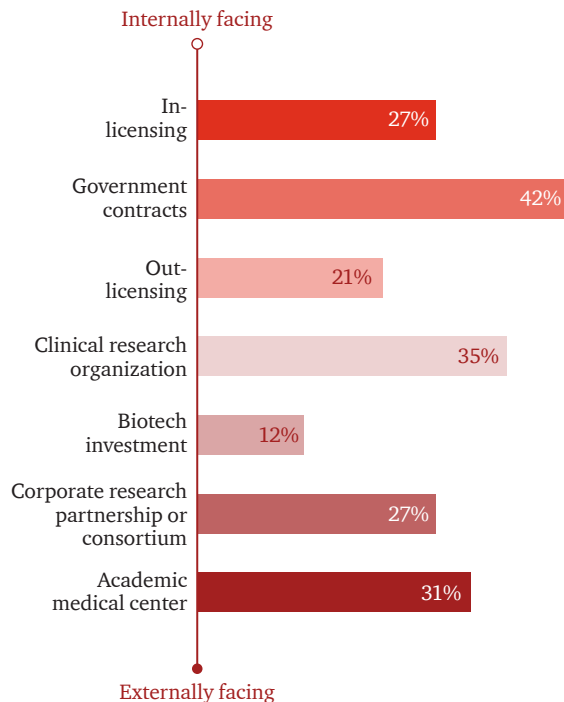
Yet today few drug makers have the capabilities or infrastructure to measure and report outcomes at a population level. Companies must also agree on the right outcomes to measure with one or more purchasers, and have mechanisms to verify them. Time frame of payment is also an issue, since treatments can sometimes last many years.

⁷ Prime Therapeutics company website, *Prime Therapeutics announces CareCentered contract with EMD Serono, Inc. for MS drug Rebif*, March 2012.

Look for the right partners

Pharmaceutical collaborations

Medical device and pharmaceutical companies are exploring a range of new partnerships. (percent responding they have one of the following partnerships in place)



Most drug companies are in a state of organizational upheaval. The industry as a whole has suffered a loss of more than 311,000 jobs over the past decade and research and business models continue to shift.

Identifying and forming the right partnerships must be part of the new focus on value. Success for drug manufacturers in the future will be linked to how well they establish and maintain robust networks that cross traditional boundaries.

Partnerships will revolve around accessing, collecting, and harnessing the growing body of information—gleaned from electronic medical records, claims data, electronic prescribing data, and wireless and remote monitoring.

Pharmaceutical companies have inked at least 10 data-sharing agreements since 2011 and the practice is expected to accelerate. For example, Humana, a health insurer, has signed multi-year collaboration agreements with several leading pharmaceutical organizations to identify methods to improve health care delivery and health outcomes for patients.

Broad benefit

Partnerships can benefit the industry as a whole. In 2012, 10 large drug makers formed *TransCelerate* to identify methods to make the clinical trials process more efficient and reduce overall R&D costs.

The new consortium has an ambitious agenda to develop clinical data standards and a new risk-based monitoring approach for clinical trials. Membership has grown to 16 companies. And in 2013, 70 medical research organizations across 41 countries *established a framework* to share genetic and biomarker data.

Vertex and the Cystic Fibrosis Foundation's 12-year R&D partnership has resulted in an FDA-approved treatment in less than average time, with two more drugs in further development. The partnership gave Vertex access to experts, trial participants, and rich patient information; the foundation fulfilled its mission of accelerating treatments and extending life for those diagnosed with this genetic disorder.

The new health ecosystem is a historic opportunity for pharmaceutical and life science companies to secure their role as symbiotic partners to health plans, healthcare providers and ultimately consumers.

Source: HRI Survey on human capital in the health industries, 2012

How PwC can help

For more information on how these changes may impact your business, please contact:

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