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Proving The Value Of Value-Based Deals

As controversy continues over pharmaceutical pricing, more drugmakers are eyeing deals that peg health plan cost to outcomes to boost volume and win formulary placement. But these deals are challenging to construct and to date there is little evidence that they reduce costs for patients.

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BY ED SILVERMAN

Despite all the talk about outcomes-based contracts between pharmas and payers, not very many have been signed to date because they are so tricky to execute.

One key hurdle is investing in the infrastructure needed to capture data showing whether a patient is actually benefiting from a medicine. Federal regulations may keep some on the sidelines over concerns about requirements for reporting Medicaid pricing and anti-kickback stipulations.

So what? As they forge these contracts, drugmakers and payers will also have to grapple with impatient consumers who want lower drug prices now, not behind-the-scenes deals that may lower premiums, broadly speaking, sometime in the future.

Several times a month, Michael Sherman, MD, gets a call from someone curious about his deal-making. Sherman is not a venture capitalist or head of technology transfer at a university, though. He is chief medical officer at **Harvard Pilgrim Health Care Inc.**, which is the second largest health insurer in New England. But his willingness to embrace a controversial approach in the US toward negotiating with drugmakers has placed him at the center of a growing debate over the value of prescription medicines.

Over the past two years, he has inked half a dozen outcomes-based contracts with drug companies, making Harvard Pilgrim something of a trailblazer among payers. The arrangements vary, but basically revolve around the notion that the insurer will get a medicine at a lower cost if the patient doesn't benefit as planned. Deals have been reached with **Novartis AG**, **Amgen Inc.** and **Eli Lilly & Co.**, among others.

"There's tremendous interest in discussing value for medicines," says Sherman, who has inadvertently become a spokesman, of sorts, for the concept. "The current pricing environment is making everyone – payers and manufacturers – more aware of the need to do so, and this approach is attracting attention, although my position is evolving. I think it may be better suited for some drugs more than others."

To be sure, value has become the hot new buzzword in the pharmaceutical industry as Americans spend more for their prescriptions – and grow angrier as a result.

On one hand, total spending on medicines in the US rose by 5.8%, to $450 billion, in 2016, which was less than half the rate seen in the previous two years. In 2015, for instance, drug spending climbed 8.9% after reaching 12% the year before. But after subtracting rebates and discounts that drugmakers pay insurers, net spending was $323 billion, a 4.8% increase over 2015.

Moreover, this is like inside baseball chatter to most Americans, who aren't seeing any price drops. That's because their co-pays remain wedded to rising list prices, even though payers claim they are negotiating harder, notably for medicines where competitive choices are clear. And although manufacturer coupons are available for a growing number of drugs, cash-paying customers have it even tougher.

This explains why Americans believe they are not getting good value for so many medicines.

Too Many Americans Are Angry Over Rising Drug Costs

As a result, 40% of Americans say that taking action to lower drug prices should be a top priority, according to a recent poll by **Harvard University**'s T.H. Chan School of Public Health and Politico. And a Kaiser Family Foundation poll conducted last spring found a majority of Americans favor various actions to lower the burden of high drug costs, from allowing Medicare to negotiate pricing and importing medicines from Canada to limiting what companies can charge and getting generics to market faster.

A few drugmakers have responded by publicly committing to keeping increases below double digits. And though headlines would suggest otherwise, there actually has been a gradual de-escalation recently. Increases for brand-name drugs in this year's second quarter were 7.1%, below the 9.7% hike that occurred in the same period a year earlier, according to Sector & Sovereign Research. (*See Exhibit 1.*)

Yet price hikes continue to outpace inflation. This is significant. Any company that thinks it can dodge a bullet by raising prices, say, 9.8% a year – in hopes of avoiding nasty headlines – is unlikely to escape notice in such a heated environment. Consider the critical reaction to recent price hikes taken by **Celgene Corp.** – three increases in less than a year that amounted to an 18% cumulative rise.

These developments raise several crucial questions: To what extent might outcomes-based contracts make a difference? Can drugmakers and payers, who are perennially wrestling over costs, use these to provide value or are the hurdles too daunting? Will policy-makers view them as a solution to high prices? And might these deals make it possible for consumers to actually pay less for their prescriptions?

Talking About Value Is One Thing, But Getting There Is Another

The answers are unlikely to be known for some time. But some say skepticism is warranted. The sorts of deals that Harvard Pilgrim has reached may make noise – and appeal to policy-makers to encourage value-based contracting – but not everyone is convinced these contracts can deliver, yet.

"Despite the examples you may read about, it's actually been very slow going," says Lou Garrison, PhD, a **University of Washington** health professor who specializes in pharmaceutical economics and a past president of the International Society for Pharmacoeconomics and Outcomes Research. "There are still lots of barriers to doing these deals ... It does make you wonder if there's an iceberg phenomenon."

Not including contracts that drugmakers may have reached with Medicare, Garrison counted less than 50 examples of outcomes-based contracts in the US in his database. And he points out that, on average, only a handful have been reached each year. "I don't see a tipping point unless there's some other way we can encourage them," Garrison says.

To be sure, some encouragement is needed, because not everyone is rushing to do a deal. Only 25% of drugmakers use value-based drug contracts of any kind and just 38% of pharmaceutical executives believe the potential rewards of a value-based contract are worth the risks, according to a recent survey conducted by the PricewaterhouseCoopers Health Research Institute.

Yet, 60% believe their existing deals are somewhat or very successful, 50% reported they are very likely to renew current contracts or sign new ones, and 71% agreed that value-based contracts could improve patient outcomes and provide rewards.

Pharma Has No Choice But To Explore Value-Based Deals

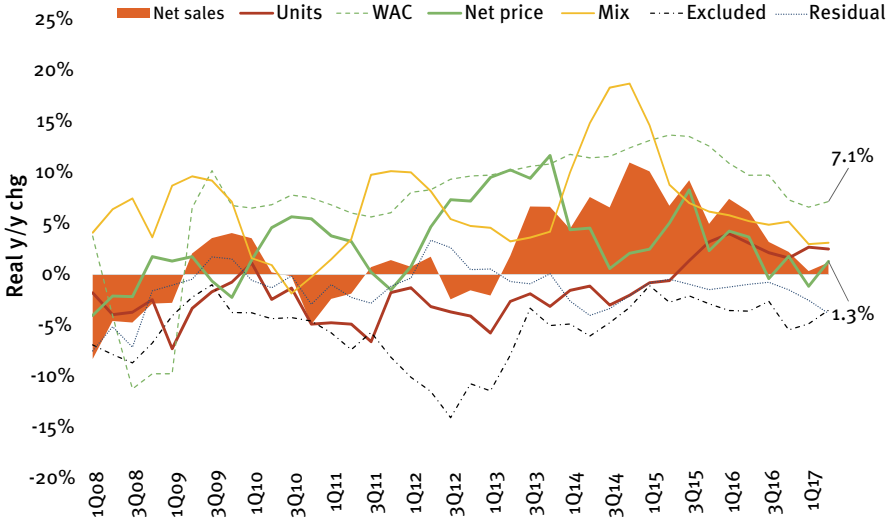
The findings may appear somewhat contradictory, but the varying responses also reflect the different commercial landscapes that executives encounter in the US and elsewhere. In Europe, most notably, pay-for-performance agreements, as they are often called, have been in effect for some time as drugmakers negotiate with cash-strapped government gatekeepers.

In the US, however, interest in outcomes-based deals – and value-based arrangements, in general – is still evolving and, of course, growing out of necessity.

Drugmakers face a keen predicament. They're simultaneously grappling with harsh criticism over pricing strategies and increasing market access hurdles, even for highly innovative treatments, as payers impose restrictions that make it more

Exhibit 1

US Brand-Name Drug Price Inflation



SOURCE: Sector & Sovereign Research LLC

difficult for patients to obtain prescribed medicines. To some, the dilemma calls for creative thinking, especially if drugmakers have less room to maneuver.

"We're in the very early days, so for anyone to say the approach won't work, when the entire medical community is moving in the value-based direction, is premature," says Roger Longman, who heads Real Endpoints, a consulting firm that focuses on pharmaceutical reimbursement. "The issue is how do drugmakers get around the problem of formulary restrictions? And what's the alternative if they don't?"

This explains why some drugmakers are trying different arrangements, or at least exploring the possibilities. Some contracts give insurers unique terms if a drug provides a certain outcome or if a medicine improves a key barometer that suggests good health is being maintained.

Have A Heart Attack And Your Insurer Gets Money Back

For instance, Harvard Pilgrim gets a full refund if a patient on Amgen's *Repatha* (evolocumab) injectable cholesterol-lowering drug has a heart attack or stroke. In another deal, the insurer can get bigger rebates from Eli Lilly if fewer patients using the *Trulicity* (dulaglutide) diabetes drug reach their A1C targets compared with those on similar medicines. But if more Trulicity patients hit their goals, then Lilly is paid a higher net price.

Here's another example: **Aetna Inc.** and **Cigna Corp.**get a discount if Novartis' congestive heart failure drug *Entresto* (sacubitril/valsartan) does not reduce hospitalizations by a set amount. In exchange, Novartis gains volume and its medicine will win preferred status on the formularies, subject to prior authorization.

Such deals reflect a growing move toward cost-effectiveness. At launch, Entresto cost about $4,560 per year, but this was more than what Wall Street and health industry analysts expected. Moreover, the Institute for Clinical and Economic Review (ICER), an independent non-profit group that assesses pricing, determined the price should have been 9% lower.

"All we're asking for is a level playing field. Maybe our drug doesn't stack up, but we're willing to take that bet and ask to get incentivized," says Stephen Moran, PhD, who is global head of strategy at Novartis. "Price, per se, is not really the question, though. It's more about the absolute spending on medicines and I think that's the motivation so far for payers."

As he sees it, these arrangements should, ultimately, help improve access, demonstrate true benefits to insurers, and address costs over the long term. But value, he suggests, is a more nuanced argument that encompasses clinical metrics, improving a patient's quality of life, convincing insurers that costs can be reduced while care is improved and putting people back to work, which is a win for society.

"The problem is that value has never been really captured properly in the pricing discussion. Where we really want to go is to value-based pricing," Moran explains. "We'd like a proper risk-bearing agreement. If our product delivers more value, then we'd get more upside ... Even if prices might be high, at least it is reflected in true value of the product."

Numerous Hurdles Make These Deals Challenging To Achieve

But getting from here to there will be challenging. And there are plenty of reasons. On one level, there are the nuts and bolts of assembling these deals, and a crucial hurdle involves data collection. To truly understand if a deal is working, of course, companies need to know if a patient is actually benefiting from a medicine. The trick is having the infrastructure in place to capture that information, which is typically a notable investment, and many payers are not up to speed.

"There is a lot of work involved to get there," because drugmakers and payers must first agree on which data to collect, says Karla Anderson, a principal in the pharmaceutical and life sciences practice at PricewaterhouseCoopers. And then, it "takes time for payers to build the right systems to track what might be a small amount of the drug spending relative to total spending."

A related challenge is getting enough of the correct data. Take laboratory results. If an insurer does a deal that measures outcomes such as heart attacks, the hospital claim will provide that information. But if an insurer wants to track changes in cholesterol, it would need agreements with multiple laboratories to know whether LDL levels changed, because that sort of data are not usually passed along. "You have to figure out smart data points to tell whether a drug is working or not," says Longman. "Otherwise, it can be expensive and difficult."

Why Some Drugmakers Are Skittish About Value-Based Deals

Another concern that nags at drugmakers is government regulations and requirements. Drugmakers must report pricing to the federal government to determine Medicaid rebates, Medicare Part B payment rates and the maximum price that some government agencies can be charged. But the nature of an outcomes-based deal is not compatible with these requirements and, therefore, may cause a drugmaker to shy away to avoid being cited for a violation.

For instance, current Medicaid regulations require that rebates paid to a commercial insurer as part of an outcomes-based contract would also have to be made available to state Medicaid programs. Yet those Medicaid programs would not, otherwise, participate in the terms of any arrangement. This is not a particularly desirable arrangement for drugmakers.

Another issue that can vex some drugmakers is the federal anti-kickback statute, which prohibits drugmakers from offering inducements. Would an outcomes-based contract with a specified money-back guarantee run afoul of the law? Unfortunately, it remains unclear how enforcement agencies would view these arrangements.

In a similar vein, drugmakers have been chafing over regulatory constraints that restrict what they can discuss with insurers prior to winning approval from the US Food and Drug Administration. Two years ago, Lilly and **Anthem Inc.**teamed up to push a white paper that suggested the agency issue new guidelines that would make it easier to review such things as trial data so that value-based deals could be struck.

"For these deals to take off, we need regulatory reform," says Joshua Ofman, MD, SVP of global value, access and policy at Amgen. "Once those occur, I think we'll see a lot more activity."

One-Size-Fits All Is Not A Good Approach

One payer, however, sees some promise, at least theoretically. "We want to manage both pharmacy and medical together,

so I'm in favor of a deal that puts us in a good position to manage total cost of care," says Susan Scheid, vice president of pharmaceutical trade relations at **Prime Therapeutics LLC**, the pharmacy benefits manager, which likes deals that can gauge patient adherence. "We'll spend more on pharmacy benefit if it means we can reduce our medical costs."

For the moment, though, these contracts are one-off deals and, essentially, are customized to fit the medicine and the health plan. So the more frequently a company enters into non-standard contracts, the more work a company must do on the back end to make sure everything is in order – and to avoid anything that may impact government regulations and inadvertently raise a red flag.

Their one-off nature raises another point, which is the extent to which outcomes-based contracts are even suitable for a broad range of medicines.

There are various reasons to consider this. Sometimes, a particular drug simply might not have enough impact on a health plan to make it worth investing in gathering and tracking patient data. This could hold true for a medicine that isn't likely to be widely prescribed or when a health plan already receives a reasonably good discount from the drugmaker.

Equally challenging is the time needed to determine some outcomes. Different diseases play out differently, of course, so the ability to competently measure patient benefit will vary. "Not every product is going to be a good candidate," says UW's Garrison.

What Happens If Beneficiaries Change Plans?

Another test is sorting out movement among health plan beneficiaries. Many people change employers and insurance coverage, so drugmakers and insurers must consider such variables, assuming it's even possible, according to Steve Pearson, MD, who heads ICER. "How do you track people if they change insurers? This is the sort of thing that will create a lot of interesting problems."

Indeed, imagine a deal in which there is a cardiovascular outcome that may not be seen for, say, five years. By then, some patients are covered by different payers. "We prefer [arrangements that run] less than a year so we can be assured the member is still part of our plan," says Scheid.

These are among the unknowns that have Harvard Pilgrim's Sherman thinking hard about which deals to pursue next. Of special concern, he says, are some of the newest therapies that carry high price tags, but are not necessarily going to be widely prescribed. As more of these medicines win FDA approval – and more are expected to do so thanks to advances in science and political pressure on the agency – he believes drugmakers should automatically explore outcomes contracts.

"I think if you're going to move the needle, you need agreements for high-cost rare disease drugs that are priced in the mid-to-high six figures," says Sherman. "If you're a company that is charging a price of that magnitude, there should be pressure to enter into these agreements. But the payment for a failure should be miniscule or nothing." *(Also see "Orphan Drug Pricing And Reimbursement: Challenges To Patient Access" this issue.)*

Why A New Novartis Deal Is Being Closely Watched

One such drug that is being closely watched is *Kymriah* (tisagenlecleucel), which was recently approved to treat children with an aggressive form of leukemia. Novartis is charging an eye-popping $475,000 for the gene-therapy cancer treatment, but is also touting a money-back guarantee: if a patient fails to respond in the first month, there will be no charge to Medicare or private insurers.

But it remains unclear how patient response to the drug will be measured, because full details have not been released. Moreover, there is a 30-day cutoff, which can easily work in the company's favor, since a short-term benefit is more typical among cancer patients. Moran, however, says this is in keeping with the product labeling.

In general, "there is a very important question around timing," he acknowledges. "But this represents the first full no-response contract based on a significant amount of value. I believe it's quite unique. But yes, you have to assess each drug on its own merits. Sometimes, the endpoints aren't as clear and so the value will be different. You have to take them on a case-by-case basis."

Meanwhile, both drugmakers and payers alike will have to grapple with consumer unrest, especially because there is skepticism that outcomes-based deals – or any sort of value-based arrangement – will lessen the burden on the American wallet.

Beneficiaries Want Lower Prices And They Want Them Now

"We want lower prices for patients and we want that at the outset. These contracts don't do that," says David Mitchell of Patients for Affordable Drugs, a consumer advocacy group. "That's why I don't think there's a lot of value for the patient at the moment. Take the deal between Amgen and Harvard Pilgrim for the cholesterol drug. If you land in the hospital with a cardiac event, then there's a money-back guarantee. But at that point, it doesn't do me a lot of good, does it?"

Mitchell has a point. Insurers talk about contracts that can lower costs, but for the most part, insurers may use a price break to lower premiums. And a medicine that is the subject of an outcomes-based deal may yield a lower member cost share, since it's been placed on a preferred tier. Even so, that's not the same thing as a lower price. It's simply too indirect for most people to appreciate.

"It will take a long time to scale this and have a meaningful impact at the system level," says PwC's Anderson. "Value-based deals are a component and not the silver bullet. On its own, it's not really enough to address the pricing issue. But I don't see it fading away, either, because the pressure to demonstrate value for a medicine is too great."

Indeed, earlier this year, the Trump administration drafted an executive order on health care that included a section on value-based arrangements and pharmaceuticals. The leaked version was vague and, so far, nothing has come of it. But it does suggest that policy-makers are eyeing the concept, even if it does little to nothing to convince Americans that drug prices will soon decline.

"Right now, the playing field is not there," says Moran, "and outcomes-based contracting is just a first crude step on the pricing journey."

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Comments:
Email the editor: *Nancy.Dvorin@Informa.com*