

Health

Reference Pricing For Drugs

By Chuck Farkas and Preston Henske

If an existing drug reduces cholesterol by 26% and a new one by 29%, would that make any difference to you? Not if you are a German public health official, a Massachusetts state legislator or, increasingly, a U.S. insurance or HMO payer.

That certain drugs are interchangeable in terms of their health benefits is the idea behind "reference pricing," in which officials judge the therapeutic effectiveness of drugs within a disease group and reimburse based on the least expensive option. The concept started taking hold in Europe and has driven down pharmaceutical prices significantly in Germany.

Reference pricing is also likely to shape life for U.S. consumers and profits for pharmaceutical companies as Massachusetts' new deal in health care emerges. A bill signed by the state's governor this week mandates universal health care coverage by requiring all of its residents to have medical insurance. Although the Massachusetts plan has yet to define what an "affordable" health care plan is, the principles of reference pricing all point to what the future may look like.

Reference pricing is supposed to save money for governments and patients. Those who want the more expensive brands *can* pay the difference between the cost of those drugs and the lower reimbursement, but that might amount to tens or even hundreds of dollars per week.

The cost could be huge for the pharma-

ceutical industry as well, reaching \$30 billion to \$35 billion in lost profits over the next three to four years, according to analysis by Bain & Company. In effect, reference pricing allows payers to impose generic prices on drugs still under patent protection. That power will change the pharmaceutical landscape.

Pfizer ([nyse: PFE - news - people](#)) learned exactly that in Germany with Lipitor, a statin that can help reduce cholesterol levels. Lipitor quickly gained a market share there when it was introduced, but between 2003 and 2005, as statin drug sales rose dramatically, Lipitor's share of the German market actually collapsed by 75%, and revenues for the entire category declined by 25%.

The reason? German officials had created a reimbursement ceiling based on simvastatin, the generic equivalent of **Merck's** ([nyse: MRK - news - people](#)) Zocor, another cholesterol-lowering medication. Pfizer chose not to lower the price of Lipitor to match the new reimbursement rates. As a result, its customers were faced with substantial out-of-pocket costs for Lipitor if they didn't switch to its less costly substitute.

For pharmaceutical companies, the effect of reference pricing is immediate and dramatic. The past decade's slide in earnings could turn into an avalanche, forcing many firms with drugs that have no clear clinical advantage to make tough

investment trade-offs.

One likely consequence will be a shift in research toward diseases not currently treated by multiple drug therapies. The reason is simple: These drugs would be literally incomparable.

And in the testing phase, reference pricing forces companies to make their own therapeutic comparisons during clinical trials—to cite significant improvements in outcomes compared with competing drugs, not placebos. Since worldwide standards don't exist, that is a gray area.

It is clear, though, that pharmaceutical companies will need new strategies to cope with the shift toward reference pricing. So far, pharma companies are looking at three ways to preserve profits in a world with diminished patent price protections.

First, pharma firms have started to screen their research pipelines differently. A once tried-and-true path for drug industry research was to focus on incremental improvements. A drug that was third or fourth to market was given the green light if it had a different active compound to fight a disease and companies could reasonably expect to earn some kind of return on their investment.

Today, though, companies must re-examine the value of such "me too" innovation. Drugs that are not first or second to market will have to demonstrate clear superior efficacy for a targeted set of patients—or get cut.

Hence, they are shifting even more attention to the markets where medical needs remain unmet. Some of the big underserved markets are obvious, such as Alzheimer's disease, multiple sclerosis, diabetes and oncology. But others aren't as well known, which has prompted a scramble to understand these unmet needs.

Second, companies with drugs far along in the development process are considering additional investments to show clear differentiation. With today's murky standards, "new and improved" doesn't get too far. The pressure is on to demonstrate rigorous and dramatic differences in efficacy.

For instance, **Eli Lilly and Co.** ([nyse: LLY - news - people](#)), which is developing

a drug called Prasugrel to reduce the risk of blood clots, recently decided to spend as much as \$400 million to run trials against **Bristol-Meyers Squibb's** similar drug, Plavix.

Lilly's drug, if approved, won't reach market before 2008, about three years before Plavix comes off patent and generic drugs kick in. But Lilly is placing a large bet that its drug will distance itself far enough from Plavix in clinical trials to survive the onslaught of generics. That kind of calculated risk will become increasingly common.

Finally, drug companies have begun to pull the plug sooner on compounds that offer little likelihood of therapeutic differ-

entiation. This will drive up overall development costs, but it will also prevent money-losing marginal "successes."

Although Massachusetts still has a lot of ground to cover to make its mandate a practical reality and a national model, bringing insurance coverage to every citizen is a worthy societal goal. So is creating better medicines. What remains to be seen is whether the pharmaceutical industry can keep innovating while generating enough profits to stay healthy itself.

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