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Competition Alone Won't Cut It On Drug Prices

Luke Timmerman / 2 /

All, Drugs, Payers, Strategy, The Edge

Industry leaders like to say we should put our faith in market competition to keep drug prices in check. Merck CEO Ken Frazier, the chairman of the PhRMA board, repeated this old bromide last month at the **Forbes Healthcare Summit.**

He may as well have said, “everything’s fine here. Let’s do nothing.”

Wouldn’t it be nice if we could believe that?

While this line of thinking surely has some knee-jerk appeal, drug pricing has never been governed by competition in the same way other markets are, where there is much more consumer choice.

For starters, let’s not forget that even the most competitive pharmaceutical categories resist downward pricing pressure. Novartis’ Gleevec is one example. It blazed the trail in chronic myeloid leukemia, and provided a clear molecular template for fast followers. The next-in-class drugs were marketed as differentiated products, for slightly different patient populations, even when the differences were minor when considered in the totality of clinical trial data. The minor differences on the population level, however, can be important medically to individuals. And that’s precisely the point. The second, third, and fourth-in-class drugs aren’t exactly interchangeable. Only when drugs are truly, easily, interchangeable (i.e. biosimilars) can the system treat them as commodities that can be ruthlessly bargained down on price.

The outcome in the case of Gleevec was entirely predictable. No one lowered the price. Novartis responded, rationally, by raising its price.

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That's not unusual. Multiple myeloma, and ALK-positive lung cancer, are a couple of other cancer drug categories that are becoming more competitive, without downward pricing pressure. In another supposedly competitive market — interferon-beta drugs for multiple sclerosis — Biogen was able to raise its price for Avonex by **an average of 16 percent a year** for a decade. Rheumatoid arthritis is a similar story. Only in rare instances (**Regeneron vs. Genentech** in macular degeneration) have innovative drug developers sought to undercut incumbents on price.

Further down the road, with no changes on the policy front, pricing leverage will tilt even more heavily toward manufacturers. The science of what you can call **precision medicine** is leading toward ever more narrow molecular definitions and subtypes of disease. When the underlying biology of disease is better defined, we often get more effective therapeutics out the other end, and more effective therapeutics command high prices. This slicing up markets into ever smaller segments promises to be quite profitable.

Think about it for a second. If we end up with 10, 12, or 20 different molecular subtypes of diabetes or Alzheimer's, then a simple numbers game tells you the industry in its

current configuration isn't likely to produce a half-dozen entrants hustling for market share in each niche. We're more likely to get one or two drugs in each slot, as manufacturers constantly look out for open spaces they can dominate. It will take many years for next-in-class drugs or biosimilars to come along and offer lower-cost alternatives.

Bluntly put, we're heading toward a pharmaceutical world with a lot more monopolies and duopolies. The industry had a banner year in 2014 with **41 FDA approvals** of new molecular entities, and topped that last year with 45. Each new drug represents added cost, at least until the manufacturer can demonstrate the drug subtracts cost from the system by reducing hospitalizations, which most can't. The way our dysfunctional system works, in which Medicare isn't legally allowed to negotiate prices, the manufacturer has all the leverage. Without any serious pushback from the other side, competing manufacturers have no reason to undercut each other on price.

"Competition is clearly not holding pricing in check," said **Steve Miller**, the chief medical officer of Express Scripts, the pharmacy benefits manager.

Cystic fibrosis provides an interesting case study. Well-defined molecular subpopulations are eligible for Vertex's

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Kalydeco and Orkambi. There are no direct alternatives. Vertex sets the price, like any manufacturer, at what the market will bear. Kalydeco is a genuine breakthrough for 4 percent of CF patients with the G551D mutation. There's no moral case for denying that drug to eligible patients. The payers are in a weak position. What are they supposed to do, deny a drug to desperate young patients with a horrible disease because it's expensive?

UnitedHealth is just one payer wrestling with what to do. If you look at the clinical trial data, Vertex's bargaining power with Orkambi isn't as strong as with Kalydeco. The big private health insurer has sought to make sure that cystic fibrosis patients who are eligible for Orkambi can show genuine improvement on a couple different clinical measurements after six months of real-world use before getting a reimbursement renewal, said Roger Longman, CEO of Westport, Conn.-based Real Endpoints. Responses to the drug vary quite a bit from one patient to the next.

If I were an insurer paying **$259,000 a year** for a drug that a young person might take the rest of their life, I'd want to know that it's working after six months, and stop paying if it's not.

Roger Longman, CEO, Real Endpoints

That might sound like logical, but this is the real world. This spring, UnitedHealth will have to decide if it's going to enforce such a tough position. "If they do, then we'll know payers have the balls to say no to a drug and to patients in CF with a horrible disease who have no alternative," Longman said. He added that if coverage denials start to accumulate, Vertex may push back, arguing that patients actually are experiencing some benefit on other parameters. It also wouldn't be a surprise if a newspaper expose cast "the big nasty payers" as **villains**, forcing desperate patients off a drug just because it's expensive.

If this does come down to a boxing match, it would be easy to handicap. "Advantage: Vertex."

With a bumper crop of effective niche drugs coming down the pike, and nothing close to equilibrium between buyer and seller, you have to worry about the percentage of healthcare spending to come from drugs. It's true that we spend about $300 billion a year in the U.S. on drugs – about 10 percent of total healthcare spending – and that amount has remained relatively steady over time. (Express Scripts' Steve Miller points out that the true pharmaceutical spending number is much higher, about $372 billion, when you count spending on hospital-based drugs like chemotherapies).

The only reason that drugs have remained fairly constant at 10 percent of healthcare spending is because we enjoy the dividends from past innovation, in the form of cheap generics, as Alnylam Pharmaceuticals CEO **John Maraganore pointed out** in a November interview with TR.

The problem is that generics don't work for every condition under the sun, and doctors can only write so many generic prescriptions before you get maxed out. The trend line is favoring more expensive drugs. The pipeline of today is full of promise, and the understanding of biology has never been better. Developing a cure for hepatitis C was a great triumph of the past five years. There are surely more drugs like that to come.

All the wondrous new products, naturally, come at a price. The cancer immunotherapy revolution is real, but as the science leads us to **rational combination treatments**, then we could easily be looking at $250,000 a year per patient. NASH, aka fatty liver, is a big market emerging from the obesity crisis. Antibodies for migraine prevention appear to have multi-billion dollar potential. Anything remotely promising for Alzheimer's will make hepatitis C look like small fry.

If prices aren't going to come down through free market competition, then payers will get more draconian, restricting the number of

people who get the pricey new drugs. It's happening with the **PCSK9 inhibitors**, Longman said. "Most payers are fine paying $10,000 for a PCSK9 inhibitor as long as there are only 17 guys in their population who will get the drug. They have figured out restrictions," he said. That can work, but only in certain situations where patients have good alternatives (cheap, effective statins), and the novel competitors are basically interchangeable.

Competition can be a powerful force that compels producers to make great products for consumers. But because of the quirks of the healthcare market, it's not going to bring us to a position of bargaining equilibrium between producer and consumer in pharmaceuticals. The industry needs to help come up with framework it can live with that connects price paid to value delivered. Companies ought to be able to make a profit, but what is fair, and what's sustainable? This would be a good time for industry leaders – whoever they are – to step up and craft a viable new social contract.

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