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Intended consequences

By [Pamela Taulbee](#) Updated 03:45 PM, Oct-11-2013 ET

Biotechnology companies are basking in a valuation bubble, with many initial public offerings being expanded and oversubscribed and share prices soaring in first-day trading. But other changes in the business environment are gaining momentum that could put pressure on these companies' valuations, notably market forces resulting from health reform.

Several trends, most of them nudged forward by President Barack Obama's Affordable Care Act, are coalescing and point to pressures on drug companies to lower the prices they charge consumers for pharmaceuticals. One of the goals of the ACA is to decrease the cost of healthcare. Putting on pressure to lower drug prices is one way the law aims to do that. The result could be declines in profits from new drugs.

The reasons are easy to see. Healthcare costs are shifting to consumers at a faster rate than ever before, and with the Oct. 1 opening of the healthcare exchanges, higher deductibles and copays are becoming more the norm rather than the exception. The most affordable of those plans have high deductibles and copays.

Additionally, expenditures in consumer-directed health plans, or CDHPs, have grown at a slower rate than other types of plans, according to a recent survey of employers by benefits consultant Aon Hewitt. Such plans have higher deductibles and copays, paid by the employee through a personal fund, which grows every payday through pretax contributions. Indeed, consumer-directed health plans could be the most common type of coverage offered by companies with 500 or more workers in the next three to five years. In its annual survey of over 800 large and midsize employers in the U.S., Aon Hewitt found that 56% offer CDHPs. Another 30% said they're considering offering one in the next three to five years. At present, 10% offer a CDHP as the only option and 44% are thinking about making it the only choice.

Just at a time when consumers are having to bear more of the freight for healthcare costs, scientific advances, especially in gene-based drug discovery, have allowed biotech and pharmaceutical companies to develop personalized biologics, therapeutic vaccines and targeted small molecule drugs that work better than ever, but carry ultra-high price tags.

Prescription drugs make up about 10% of the U.S. healthcare budget, according to the federal [Centers for Medicare & Medicaid Services](#). Orphan drugs — those that treat disorders that affect small patient populations — make up about 0.5% of healthcare spending in the country. But some of those drugs carry oversized price tags.

In the Oct. 2 issue of the Journal of the American Medical Association, Brian O'Sullivan, who oversees drug trials at the University of Massachusetts, contends that the U.S. market will not bear increasingly big price tags for drugs that treat niche diseases. O'Sullivan offered the example of **Vertex Pharmaceuticals Inc.**'s Kalydeco, a drug for cystic fibrosis patients with a specific genetic mutation, G551D. Approved in January 2012 by the FDA, Kalydeco is the first marketed drug that treats the underlying molecular defect. **Vertex** set the drug's price to consumers at \$294,000 per year, and it has since grown to \$311,000. Kalydeco "will likely need to be taken for decades by individual patients, with the potential cost of many millions of dollars," O'Sullivan noted.

"An unsustainable price structure for novel drugs developed by pharmaceutical companies for this rare condition and others is developing," the physician declared. "As personalized genomics-based medicine advances, there will be even more examples of medications designed to treat a single mutation or molecular defect found in a small subset of patients."

But even for other, more widespread conditions, the price of drugs can also run into tens of thousands of dollars. Some cancer treatments and those for chronic conditions such as multiple sclerosis and rheumatoid arthritis can run to several thousand dollars a month.

Drug companies and not-for-profit groups offer assistance programs to help needy patients cover out-of-pocket costs. But to sign up for the programs takes time, so even when consumers qualify for the programs, they may have to pay for the first few purchases. And not everybody qualifies.

As biotech and pharma companies develop more and more targeted drugs, neither the U.S. healthcare system, nor any other, can bear such high prices for every new therapeutic agent, O'Sullivan noted.

The pharmaceutical industry defends the high prices some manufacturers ask for drugs because often, half the patent life of a drug is gone before it ever hits the market. Estimates vary, but many in the industry believe it costs from \$1 billion to \$2 billion to bring a drug to market.

Ron Cohen, president and CEO of **Acorda Therapeutics Inc.**, said the fact that drugs can lead to overall significant cost savings is often lost in the debate over high price tags.

He noted that one provision of the Affordable Care Act, the **Independent** Payment Advisory Board, could be used to limit Medicare payments for some high-cost pharmaceuticals. If Medicare costs exceed a certain threshold, the IPAB can make cuts in the prices paid for good and services.

The pharmaceutical trade group PhRMA has said it believes the IPAB, which is a 15-member appointed board, has been given "overly broad powers" to make sweeping changes to Medicare payments. Congress can overturn an IPAB decision through a supermajority vote. In the past, a Medicare Payment Advisory Committee voted on such changes, but they had to be enacted by Congress.

"The IPAB could be given authority to cut indiscriminately reimbursement on medicines, drive certain medicines out of the market or make them unavailable to people who need them," Cohen said in an interview.

Drugs that control heart failure reduce hospitalizations; drugs that could delay or prevent Alzheimer's could reduce long-term care stays, so "it is incredibly short-sighted to get a quick fix by cutting the prices of innovator medicines" when they can pay for themselves in the long term, he said.

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