

Guest Column | March 27, 2017

6 Issues Facing Pharmaceuticals To Improve Accessibility, Affordability, And Prices



By Richard Brand, M.B.A., CFO, BeyondSpring Pharmaceuticals

How society responds to a problem is amply demonstrated by the current issue of pharmaceutical prices. Following a period when drugs were coming off of patents and overall prices were relatively benign, we've experienced breakthroughs, such as Hepatitis C cures. The initial two companies with approved breakthroughs set high prices, and although beneficial to patients, these breakthroughs ratcheted up the overall cost of pharmaceuticals to society. Thus, the topic became a major issue – first, with simple calls to rein in prices, and later with more specific policy prescriptions.

As a result, here are six issues facing pharmaceutical companies to not only improve accessibility, affordability and prices but also to continue incentivizing innovation in an effort to bring highly effective, yet less expensive, drugs to market in a quick, efficient manner:

1. Drug Prices

The global pharmaceutical industry generated sales of over \$1.07 trillion in 2016. Such a large dollar amount can be an attractive target for politicians. One of the smart things that President Trump has said is that other countries should not be able to benefit from U.S. drug innovation at far lower prices, as is the case now. His objective is to level the prices that are paid in the U.S. and elsewhere. According to a new study by the Berkeley Research Group, [only 47 percent of total U.S. prescription drug spending was retained by brand biopharma companies in 2015.](#)

The prospect of President Trump addressing drug prices has gotten the attention of the Pharmaceutical Care Management Association (PCMA), the lobbying group for America's pharmacy benefit managers (PBMs) who administer drug plans for the over 266 million Americans with health insurance. Per an [internal memo](#) from Mark Merritt, president and CEO of the PCMA, "The sense that this President could make any decision, at any time, for any reason, on any issue is rattling industries in the healthcare sector and beyond."

Lasik and cosmetic surgery are two areas of healthcare that are exhibiting actual price declines, and these are two areas with competition. An interesting recent development is the formation of a patient advocacy group, Patients for Affordable Drugs, whose focus is on drug prices. Other advocacy groups in their calls to the U.S. FDA to approve drug candidates may have the unintended consequence of emboldening drug companies to set high prices.

2. The New Administration and Innovation

Jawboning and the stock market uncertainty that results have compressed multiples in biopharma stock prices compared to 2015. The consequence may be more M&A, with large pharma adding to its pipeline more through acquisitions and further de-emphasizing internally generated R&D. If these acquisition prices are lower than in the past due to the sector's stock market multiple being compressed, the VCs may reallocate some of their funds for new investments – more to industries other than to healthcare (an M&A banker recently told me that he expects acquisition premiums to continue to be 40 to 60 percent over where the target's stock was trading before word of a potential deal got out. If stocks are

trading at levels lower than in prior years, then acquisition prices could be lower, as well). This could result in an overall reduction in innovation.

Although not nirvana for biotech, this is likely better than if Bernie Sanders had won the Democrats' nomination and presidency, and the current governmental environment may also be better than if Hillary Clinton had been elected. However, Clinton may have followed a more standard path for politicians: paying lip service to the populist message while actually following the wishes of the big donors by doing very little.

3. The New FDA Commissioner

The new commissioner is very likely to continue with the overarching mission of maintaining patient safety. This is firmly rooted in the Hippocratic Oath to “first, do no harm.” One might guess that accessibility may become more important to the new commissioner, both in terms of affordability and availability of promising drugs.

Sweeping changes that have been proposed by elected officials, such as reciprocity and the right to try (see below), may give way to targeted solutions from the new FDA commissioner. Scott Gottlieb, Trump's pick for commissioner, [told a Senate committee on Oct. 16](#), “Congress should consider legislation to modernize the generic drug framework to allow FDA greater discretion in the kinds of data it relies on for its generic approvals in this narrow category of complex drugs. This would require, for example, granting FDA the ability to ask for more than just bioequivalence and bioavailability data in making judgements around sameness.” Before that, in 2015, he was more general [in a column that he wrote for *Forbes*](#): “Congress should be tapped to give FDA the latitude to look at the science necessary to make comfortable and reliable determinations.”

4. Reciprocity

The calls for reciprocity over the last few months could not have gained a bigger boost than in the case of Marathon Pharmaceuticals. The company's Emflaza was approved by the U.S. FDA on Feb. 9, 2017. This is a steroid to manage the symptoms of, but not cure, Duchenne muscular dystrophy. The generic deflazacort has been routinely used since 2005, priced at \$1,600 in the U.K.

Taking advantage of orphan drug regulations, Marathon announced \$89,000 as its annual price. As expected, Bernie Sanders and others have criticized this. When Marathon's drug is available in the U.S, American patients will be restricted by the U.S. FDA from importing deflazacort from international sources. An unintended consequence of U.S. government regulation with the primary objective of avoiding the repeat of Thalidomide babies may be to impede / inhibit competition.

5. Patients' Right to Try

In addition to reciprocity, another theme suggested recently by elected officials is the right to try. This would allow terminally ill patients to try therapies that are not yet approved by the U.S. FDA but have completed a clinical Phase 1 trial.

6. Integrating IT into Healthcare

Trump advisor Peter Thiel and others propose bringing elements of information technology to healthcare. Although this is no small undertaking, the goal is admirable, and steps should be taken toward exploring what may be achievable along these lines.

Societal issues like pharmaceutical prices and accessibility are seized on by elected officials who are effective at shining a spotlight on these types of topics. Relatively simple solutions are proposed initially and, eventually, experts propose more sophisticated policies that are more likely to be implemented down the line. Today's solutions are only beginning to take shape, and now more than ever is the time to pay attention to what comes next.

BIO:

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Read Richard's other guest column, ["Drug Pricing: 2017's Challenge Confronting Biopharma."](#)

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