

The Outlook On Drug Pricing: At What Cost?

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Law360, New York (December 14, 2016, 11:59 AM EST) --

Investors and operators in the pharmaceutical industry are paying careful attention to the political and regulatory environment, which may impact drug pricing going forward.

Over the past several years, drug companies have faced criticism for price increases from the media, prosecutors, members of Congress and both presidential candidates. During the recent elections, Hillary Clinton and Congressional Democrats even advocated for legislation that would have controlled drug prices. Additionally, California voters faced Proposition 61, a ballot initiative that would have prohibited California state agencies from buying prescription drugs at prices higher than those paid by the U.S. Department of Veterans Affairs. In the aftermath of the victories of Donald Trump and Congressional Republicans and the defeat of Proposition 61, conventional wisdom in many quarters has been that drug manufacturers dodged a bullet. However, this may not entirely be the case.

Factors That May Influence Drug Pricing

Popular Anger With High Drug Prices

Drug companies have recently come under fire for price increases, resulting in Congressional hearings in which pharmaceutical executives have been castigated by representatives of both political parties. Indeed, Senator Marco Rubio — not known as a populist or a foe of the pharmaceutical industry — stated that some industry pricing practices were “pure profiteering” that threaten to “bankrupt our system.”

The outcome of the recent elections should not be viewed as a sign that popular anger at drug price increases has fully abated. While the Affordable Care Act (ACA) has been the focal point of voter dissatisfaction, two other major concerns lurk beneath the surface: rising health insurance premiums and out-of-pocket costs. One of the main contributors to this latter category is prescription drug costs — an issue that would not vanish even if the ACA were repealed. This discontent may well translate into politicians and regulators scrutinizing drug prices and, in some



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cases, demanding that drug companies justify any proposed price increases for certain prescription drugs.

Trump's Campaign Proposals

While President-elect Trump is widely regarded as business-friendly and did not support drug price controls during the campaign, he has expressed support for introducing more competition into the healthcare marketplace. Several of his campaign proposals, if implemented, could have the effect of depressing prescription drug prices.

First, Trump has taken the position (one shared by many Congressional Democrats) that the prohibition against the Centers for Medicare & Medicaid Services (CMS) negotiating the price of prescription drugs for Medicare beneficiaries should be lifted. The objective of this proposal is to allow CMS to use its enormous purchasing power to negotiate significant discounts to the prices of drugs covered by Medicare Part D. If this prohibition was lifted and CMS successfully negotiated significant discounts, private payors might demand corresponding discounts as well.

Second, Trump and some members of Congress (many Democrats and some Republicans) have supported lifting the ban on American consumers purchasing prescription drugs in foreign countries — particularly in Canada where drugs are subject to price controls. If a significant number of consumers begin purchasing high-priced drugs from foreign markets, drug companies may be pressured to lower the cost of those drugs in the U.S. to order to reduce the incentive to purchase those drugs elsewhere.

Whether either of these proposals will be implemented is highly uncertain. Since the election, Trump has not mentioned either proposal, and the Congressional Republican leadership has expressed opposition to both proposals. That being said, Trump won the election on a populist platform, and in a recent interview, he reiterated his concern about drug pricing, so it would not be surprising if Trump decided to push one or both of these proposals or pursue another path to lowering drug prices.

Law Enforcement Investigations

Several of the recent high-profile increases in prescription drug prices have triggered law enforcement investigations. For example, over the past year, the New York attorney general has announced antitrust investigations of Turing Pharmaceutical after it raised the cost of a 62-year old infection drug from \$13.50 a tablet to \$750 overnight and Mylan after reports that it increased the cost of EpiPen auto-injector, which is used to treat life-threatening allergies — by 400% since 2009. Law enforcement and other regulators are likely to continue examining large drug price increases in the future.

Bayh-Dole "March In" Rights

Some Congressional Democrats and health organizations have also proposed leveraging the National Institutes' of Health's (NIH) funding for drug development as a means of controlling prices. Under the Bayh-Dole Act of 1980, the federal government permitted universities and other nonprofit institutions that received NIH funding to patent and license inventions arising out of that research. Such a license is subject to "march-in" rights, which can be invoked if NIH believes that the invention was not being adequately commercialized or was not being used in a way that met the needs of the American public. Under those circumstances, NIH could require the patent holder to issue a license to a third party or NIH itself could issue such a license. These Democrats and organizations have argued that the high cost of certain prescription drugs have effectively made them unavailable, and that NIH should therefore

compel the issuance of licenses to manufacturers that would sell the drugs at lower prices. NIH, however, has repeatedly rejected similar proposals over the past decade and it is unlikely that Trump — who has consistently opposed price controls — will change course.

Considerations When Deciding Whether to Raise Drug Prices

In the current environment, prudent drug companies should develop a holistic strategic around drug pricing that anticipates and disarms potential criticism about any price increases. Drug companies should consider whether they can tie price increases to legitimate economic concerns such as:

- Recouping research and development spending on a drug that treats a rare condition and thus has a limited market;
- Recouping R&D spending on costly drug development projects that ultimately failed;
- Funding R&D on the next generation of a drug that is either more effective or has fewer side effects;
- Compensating for increases in the cost of manufacturing inputs.

By contrast, drug companies are at risk of scrutiny if they appear to be taking advantage of accidental monopolies, resulting, for example, from being the only company that currently has the capacity to manufacture a generic drug. While every situation is different, drug companies that proactively calibrate pricing not only to market forces but also to current political and regulatory trends will be best positioned to respond to whatever challenges may be thrown their way.

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