Portfolio Media. Inc. | 111 West 19th Street, 5th Floor | New York, NY 10011 | www.law360.com
Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

How Pharma Cos. Can Shape The Drug-Pricing Landscape

Law360, New York (October 25, 2016, 1:55 PM EDT) --
Unless you have been living under a rock, you no doubt have noticed that drug price increases have resulted in a wave of public criticism, playing right into the media's demonization of the pharmaceutical industry, and even becoming an election year issue. The United States is one of the only developed nations that largely does not restrict the drug prices charged to the public or government. This has led some in the industry to be complacent about the public perception of drug price increases.


Robin Adelstein

While pharmaceutical companies should be able to price their products at whatever level they determine is appropriate without government intervention, the industry would benefit by getting ahead of government regulation and public backlash. The old refrain that high drug prices are justified because drug development costs billions, while true, no longer moves the needle in the debate.


Cori Annapolen Goldberg

Each drug company should take action now to establish its own internal pricing committee that sets objective criteria for determining the pricing it will seek, including any price increases, as well as focuses on patient access. Pharmaceutical companies should think creatively in ways that show the public they keep patients at the heart of everything they do. Taking these actions will help change the public perception of the industry, proving (once again) that drug companies are a part of the solution to rising health care costs.


Krishna Kavi

Domestic and Foreign Government Response

On Sept. 15th, U.S. Senators John McCain, R-Ariz., and Tammy Baldwin, D-Wis., and Representative Jan Schakowsky, D-Ill., introduced the Fair Accountability and Innovative Research Drug Pricing Act.[1] Under the act, companies that increase the average manufacturer price of certain drugs by 10 percent or more over a 12-month period would be required to submit a transparency and justification report 30 days before the price increases become effective. While the provision would create transparency, there would be no mechanism for blocking price increases.

Prior to the introduction of this proposed legislation, states had taken the lead in trying to control drug pricing. Vermont enacted the nation's first pharmaceutical pricing justification law, S. 216, which focuses

on increasing transparency underlying drug price hikes.[2] Similar to the proposed federal legislation, the Vermont law requires drug makers to submit justifications, including detailed cost breakdowns, for price increases for certain drugs. The law permits the Green Mountain Care Board, in collaboration with the Department of Vermont Health Access, to establish a list of up to 15 drugs on which Vermont has spent "significant health care dollars and for which the wholesale acquisition cost has increased by 50 percent or more over the past five years or by 15 percent or more over the past 12 months."

The manufacturers of these 15 drugs must then justify the increases to the attorney general. This information is later made publicly available; however, the law prohibits the disclosure of any identifying information for the drug or manufacturer. While such justifications are required, the law does not prohibit price changes for these drugs "to the extent permitted under federal law." The penalties imposed on drug makers that do not submit justifications are injunctive relief and monetary penalties up to $10,000 per violation. The law does not address what happens if drug prices still remain high, which some commentators have noted may defeat the overall purpose behind the law to reduce high drug costs.

Similar proposals have been made in a handful of other states. California and Ohio have introduced legislation that would require state programs to pay the same or less for prescription medications as the U.S. Department of Veterans Affairs, which is allowed to negotiate the price that it pays for drugs, unlike Medicare and other government programs. As a result, the U.S. Department of Veterans Affairs pays up to 42 percent less than Medicare and significantly lower than state Medicaid programs. California's Proposition 61 will appear on the November 2016 ballot.[3] The Ohio Drug Price Relief Act faces a more uncertain future, as it has been met with much debate and even court action regarding the validity of signatures on the initial ballot action.[4]

As more states enact such laws, the risk and cost for the pharmaceutical industry may increase as manufacturers could be forced to comply with a nightmarish patchwork of varying pricing regulations on a state-by-state basis.

Drug pricing is also at the forefront of the 2016 presidential elections and has been called a priority issue for both the candidates and voters. A poll released by the Kaiser Family Foundation, found that 93 percent of Democrats, 83 percent of Independents and 74 percent of Republicans want the federal government to negotiate drug prices for Medicare.[5] Both Democratic presidential candidate Hillary Clinton and Republican presidential candidate Donald Trump have expressed the need for limiting and controlling the prices paid for drugs by government health care plans.[6]

Recently, Clinton unveiled a plan aimed at "unwarranted" price hikes for drugs that have been on the market for a long time.[7] Specifically, her plan would create a task force that would monitor drug price increases and determine if the increases were unreasonable given product improvements and the amount of competition in the market. Under the plan, the government could impose penalties on drug makers found to have made "unwarranted" price increases and then use the fines collected to speed up approvals for lower-cost, generic alternatives.

Moreover, Clinton's plan, which would not regulate drug prices directly but keep prices low through penalties and fines, if effectuated, may achieve the same result of low drug prices as some models currently in place in Europe. The EU uses a reference pricing system, where drugs with similar therapeutic benefits are placed into the same reference class and the insurer pays only one price for any drug in the class.[8] Drug makers can choose to sell their drugs at a higher price but the patient would have to pay the difference in out-of-pocket costs. This system leads to manufacturers lowering their

prices to remain competitive within the reference class.

Ultimately, this stringent regulation results in lower costs of drugs in most of Europe. The European drug payment system may see a radical shift, too, as countries embrace value-based drug pricing. For example, the U.K. partnered directly with a drug manufacturer and agreed to pay the cost for the manufacturer's myeloma drug only when a patient has a positive response within four treatment cycles. Italy has a similar system, in which payments for a cancer drug are made based on patient response.

Other countries are taking stricter measures to control prices. For example, Colombia's government announced recently that it seeks to lower and directly set the price for a leukemia treatment drug as a matter of public interest, instead of using more traditional methods to decrease prices such as pursuing generic alternatives. If carried out, this plan would set a new precedent for how drug prices are regulated in the country and may set an example for other countries to follow as well. The country, like many others, is actively searching for ways to lower drug costs for government health plans, with some resulting in significant control on drug prices.

Other Industry Responses and Risks

In addition to the governmental response, private entities such as pharmacy benefit managers (PBMs) are dropping certain high-priced drugs from their formularies. CVS Health recently announced that it will bar 35 more drugs in its 2017 formulary, bringing the total to 131, almost one-third of which are drugs that experienced a significant price increase in recent months.

Independent community pharmacies have also voiced concerns about increased drug prices. The National Community Pharmacists Association (NCPA) met with members of Congress in May to express concerns about what it perceives as the problems faced by independent community pharmacies as a result of generic price increases, namely that the rate of reimbursement from PBMs for these drugs does not reflect the higher prices of the drugs.[9]

NCPA explained that the difference in reimbursement rates between what is actually charged by the PBM to the health plans and what is paid by the PBM to the independent pharmacy leads to unsustainably low payments for these drugs. Ultimately, NCPA stated, the patients will face the greatest difficulties as fewer pharmacies will be able to afford to carry these drugs. NCPA thus asked members of Congress to assist in ensuring that pharmacy reimbursement from PBMs is updated to match actual market costs in order to preserve patient access.

In addition to public and government scrutiny and backlash related to these price hikes, there is also an increased risk of unwanted government investigation when drug prices are raised. For example, in response to one very recent price hike, the House Committee on Oversight and Government Reform held a hearing with a drug company's CEO and called on the Federal Trade Commission to also open an investigation.

The risks to pharmaceutical companies are not just government affairs risks. These companies face real, financial risks as well. Congressional, media and public criticism of drug pricing cause investor reaction and take a toll on pharmaceutical companies' market caps.

Recommendations

So what can the industry do proactively to address these complex concerns?

Internally, pharmaceutical manufacturers should establish a multidisciplinary pricing committee comprising representation from commercial (sales and pricing), legal, compliance, finance, government pricing, government affairs and communications so that all different perspectives are represented. The company also may consider soliciting input from physicians or scientists.

The pricing committee should take a disciplined approach in establishing objective criteria for all price increases and ensure that such criteria are met and that the increases are justified under the framework established. Pricing for a company's drugs must allow for a reasonable profit and recoupment of the investment in new drug development more broadly by each company. In addition, factors that could be considered by each company in setting its drug prices include the following, as applicable to the drug in question:

- Therapeutic impact on patients on disease progression and prognosis together with presence or lack of material side effects, ease of administration and other material medical characteristics;

- Availability of alternative treatments and their relative characteristics;

- Obligations imposed by ongoing regulatory requirements (e.g. phase IV and risk evaluation and mitigation strategies requirements) as well as ongoing supply, compliance and medical education risks and costs; and

- Support by such company made to patient access programs, both in the country in question and more broadly worldwide, including in least developed countries.

Externally, pharmaceutical manufacturers should work to shape the landscape of drug pricing regulations and laws. The industry must be a voice in the room, actively raising their concerns and thinking creatively about options that show the world that the industry keeps patients at the heart of their decision-making.

With blockbuster drugs being replaced by more targeted therapies that work on a higher proportion of patients, pharmaceutical manufacturers are looking at creative ways to deliver these gains to patients. For example, one leading pharmaceutical company has linked its drug prices to outcomes, where insurance companies do not have to pay for drugs that show no positive results for patients. Another drug maker has announced that it will use the value-based pricing method to charge more for those drugs that have led to better health outcomes. The manufacturer stated that the revenues generated from the higher-priced drug would be used for research into eliminating certain health conditions and thus lead to an overall benefit for patients.

A major issue with value-based pricing is determining what indicators or factors will be considered to determine value. Further, it may be easier to determine the success of certain short-term drug therapies compared to drugs used to treat long-term conditions.[10] Tying the pricing of drugs to positive health outcomes can show the public and government that there are objective standards set for drug reimbursement and it potentially positions the company in a more favorable light.

Of course, when drug companies are attempting to devise creative pricing programs, they must be mindful of certain existing laws, such as the federal False Claims Act and Anti-Kickback Statute, and similar state statutes, which may make it difficult to implement risk-based models. For example,

physicians could face scrutiny under these models for requiring patients to make additional visits if the first treatment fails.

Finally, many pharmaceutical executives have expressed frustration with payors that have raised the prices that consumers must pay for these expensive drugs. Payors need to be open to consider and adopt different payment models and focus on those models that will reduce overall health care costs for patients and thus for payors.[11] The issue of drug pricing requires a holistic solution — no one industry segment can solve this alone. By participating in discussions, drug manufacturers and payors should be able to work collectively to find the best solutions for patients.

One large pharmaceutical company has partnered with a leading insurer to identify flaws in the system and to determine how to create a better partnership between the two groups. The answer, again, may be value-based pricing and reimbursement methods, as both groups recognized that drugs with the best results and sold at high prices were justified by the overall savings to the patient, insurer and health care system.

The issue of pharmaceutical pricing is no doubt complex, requiring open and honest communication in order to achieve a long-term, sustainable solution. By taking proactive steps, drug companies have the opportunity to help shape the landscape, leading to better outcomes for patients.

—By Robin Adelstein, Cori Annapolen Goldberg and Krishna Kavi, Norton Rose Fulbright US LLP

Robin Adelstein is a partner in Norton Rose's New York office and former North America General Counsel of Sandoz, a division of Novartis.

Cori Annapolen Goldberg is a senior associate in Norton Rose's New York office who specializes in issues impacting the drug, device and food industries.

Krishna Kavi is an associate in Norton Rose's Washington, D.C., office who specializes in health care litigation and regulatory matters.

[1] See Fair Accountability and Innovative Research Drug Pricing Act.

[2] See Vermont's pharmaceutical pricing justification law, S. 216.

[3] See California's Proposition 61, originally titled The California Drug Price Relief Act.

[4] See Ohio Drug Price Relief Act.

[5] See Kaiser Health Tracking Poll: August 2015.

[6] See Hillary Clinton, Donald Trump spotlight prescription drug price hikes.

[7] See Factsheet on Prescription Pricing Plan.

[8] See EU Reference Pricing System.

[9] See NCPA Press Release.

[10] See Value-Based Pricing of Drugs in the United States.

[11] See Why the United States Pays More Than Other Countries for Drugs.
