Drug Prices Soar, Prompting Calls for Justification

By **ANDREW POLLACK** JULY 23, 2015

As complaints grow about exorbitant drug prices, pharmaceutical companies are coming under pressure to disclose the development costs and profits of those medicines and the rationale for charging what they do.

So-called pharmaceutical cost transparency bills have been introduced in at least six state legislatures in the last year, aiming to make drug companies justify their prices, which are often attributed to high research and development costs.

"If a prescription drug demands an outrageous price tag, the public, insurers and federal, state and local governments should have access to the information that supposedly justifies the cost," says the preamble of a bill introduced in the New York State Senate in May.

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"There is no relief in sight because drug companies keep challenging the market with even higher prices," the doctors wrote in the journal Mayo Clinic Proceedings. "This raises the question of whether current pricing ofcancer drugs is based on reasonable expectation of return on investment or whether it is based on what prices the market can bear."

Pressure is mounting from elsewhere as well. The top Republican and

Democrat on the United States Senate Finance Committee last year demanded detailed cost data from Gilead Sciences, whose hepatitis Cdrugs, which cost $1,000 a pill or more, have strained the budgets of state and federal health programs. The U.A.W. Retiree Medical Benefits Trust tried to make Gilead, Vertex Pharmaceuticals, Celgene and other companies report to their shareholders more about how they set prices and the risks to their businesses from resistance to high drug prices.

A demonstration last year against Gilead Sciences, whose hepatitis C drugs, which cost $1,000 a pill or more. AIDS Healthcare Foundation

The trust cited the more than $300,000 per year price of Vertex's cystic fibrosis drug Kalydeco and roughly $150,000 for Celgene's cancer drug Revlimid.

Even former President Bill Clinton, in a speech to pharmaceutical executives in Philadelphia last month, said it would be in the industry's best interest to say more about its costs and pricing.

"Explain, explain, explain and disclose, disclose, disclose," Mr. Clinton said, according to The Philadelphia Inquirer. "Don't expect everybody to love you, but at least they will hear your side of the story."

The pharmaceutical industry has already had the veil lifted on various practices. Drug companies now have to report the payments, including meals and entertainment, that they make to doctors for research, consulting and giving promotional speeches. The companies have also had to disclose more results of their clinical trials and in some cases have started to provide raw data to outsiders.

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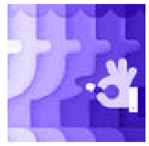

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It is unclear if cost and pricing will become the next such area. The state bills, which are supported by some health insurers and consumer groups, have not progressed. The two senators, Republican Charles E. Grassley of Iowa and Democrat Ron Wyden of Oregon, have not reported the results of their inquiry. And shareholders of Gilead, Vertex and Celgene voted down the resolutions proposed by the U.A.W. trust, though the trust says it reached settlements with Eli Lilly and with two other drug companies it would not identify.

The pharmaceutical and biotechnology industry trade groups say the transparency bills would be costly to comply with and would provide misleading information.

Even some people concerned about drug prices say that the cost to develop a particular drug has little to do with that drug's price and that knowing such information will not keep prices down.

"The past R&D cost is really kind of a red herring," said Len Nichols, a health care economist at George Mason University, referring to research and development. "The current revenue doesn't pay for past R&D; it pays for current R&D."

Prices for cancer drugs, some of which extend lives by only a couple of months, routinely exceed $100,000 a year, and some new ones exceed

$150,000. And it is not unusual for the list prices of existing drugs to rise 10 percent or more year after year, far beyond the rate of inflation. The prices of older drugs for multiple sclerosis have risen from about $10,000 per year in the late 1990s to more than $60,000 now, according to a study, even as competition in the market has intensified with the introduction of new products.

Cost transparency bills have also been introduced in California, Massachusetts, North Carolina, Oregon and Pennsylvania.

Three of the bills require disclosures for drugs costing $10,000 or more per year. The others have different criteria. Besides development costs, some of the bills would require disclosure of the costs of manufacturing, marketing and advertising. At least some of the bills also ask for a history of price increases, the profit attributable to the drug and how much a company spends in providing financial assistance to patients using the drug.

Two of the bills would allow the states to act on the information, not just require disclosure. Pennsylvania's would allow insurers to refuse to pay for a drug if the manufacturer did not file the required report. In Massachusetts, a state commission would be able to set a maximum price for a drug if it determined that the price set by the manufacturer was significantly high compared with the benefits, costs or prices in other countries.

Most of the bills have not been acted upon, though hearings were held in California and Oregon.

The sponsor of the California bill, Assemblyman David Chiu, pulled it back shortly before a committee was to vote on it, apparently because it did not have sufficient support. The bill could be picked up again next year.

"This is a new topic for many of my colleagues to grapple with," said Mr. Chiu, a Democrat from San Francisco. He said the bill was necessary because "greater transparency leads to better policy results."

Mitch Greenlick, a Democrat from Portland who is chairman of the Health Care Committee in Oregon's House of Representatives, said the bill was prepared with input from the health insurance industry, but was "not ready for prime time." He added that the issue would be further studied.

"What are we going to do with that information?" he said. "It's interesting to have, I suppose, but the drug companies are shameless, and they charge what they can get away with."

Insurers and consumer groups told the Oregon Legislature that more disclosure was needed because the state had to decide whether to pay for certain drugs. Representatives of the pharmaceutical industry said the bill was unfair and would discourage industry investment in Oregon.

Lori Reilly, executive vice president for policy and research at the Pharmaceutical Research and Manufacturers of America, the industry's main trade group, said it was misleading to look only at the cost of developing a particular drug because that ignored the money spent on the drugs that fail during development. Only about 12 percent of drugs tested in people reach the market, she said.

Ms. Reilly said that publicly traded drug companies already disclosed their overall research and development costs, as well as other financial information. She also said that focusing on costs ignored the value of the drugs. Some drugs, for instance, can save money for the health system over all by keeping people out of the hospital, she said.

Pharmaceutical executives do not typically tie the price of any particular drug to its development cost. But they do say that their sales have to recoup their investment in research and development if the companies are to stay in business.

They often cite the Tufts Center for the Study of Drug Development at Tufts

University, which last year said companies spent an average of $2.6 billion to bring a drug to market, up from an estimate of $800 million in 2003. That includes the cost of failures. And almost half the figure is opportunity cost, the amount a company might have earned if it had invested money elsewhere rather than spending it on drug development.

Critics are skeptical of that figure, saying that the Tufts center gets funding from the pharmaceutical industry and uses data supplied by the drug companies, but does not disclose which drugs are used as the basis of the estimates.

Pharmaceutical executives often say they price the drugs based on the value they provide, though often a detailed explanation of that is not provided. In many cases, it appears, the price of new drugs is set in comparison to rival drugs already on the market, and usually a bit higher. Companies then can raise their prices for the older drugs.

"We all look at each other and keep pace with each other," said a director of one multiple sclerosis drug developer, who spoke on the condition of anonymity. "Honestly, there is no science to it."

John Rother, chief executive of the National Coalition on Health Care, a group of insurers, consumer organizations, labor unions and employers concerned about drug prices, said his group hoped to introduce transparency legislation in Congress, but aimed at determining how drug companies estimate the value of their drugs, not the research and development costs.

"The industry has used R&D costs for the justification, but anyone who is reasonably sophisticated understands those are sunk costs and have little to do with pricing," Mr. Rother said. "The more important information is any calculation of value. If the drug actually cures people, then what costs in health care are you saving?"

Dr. Jerry Avorn, a professor at Harvard Medical School and critic of some drug company practices, said the industry "has brought this on itself by charging prices that are so astonishing, it makes citizens wonder, 'Where did this figure come from?' "