The New York Times https://nyti.ms/1GQ7GYI

BUSINESS DAY

Drug Makers Sidestep Barriers on Pricing

By ANDREW POLLACK OCT. 19, 2015

The pain reliever Duexis is a combination of two old drugs, the generic equivalents of Motrin and Pepcid.

If prescribed separately, the two drugs together would cost no more than $20 or $40 a month. By contrast, Duexis, which contains both in a single pill, costs about $1,500 a month.

Needless to say, many insurers do not want to pay for Duexis. Yet sales of the drug are growing rapidly, in large part because its manufacturer, Horizon Pharma, has figured out a way to circumvent efforts of insurers and pharmacists to switch patients to the generic components, or even to the over-the-counter versions.

It is called "Prescriptions Made Easy." Instead of sending their patients to the drugstore with a prescription, doctors are urged by Horizon to submit prescriptions directly to a mail-order specialty pharmacy affiliated with the drug company. The pharmacy mails the drug to the patient and deals with the insurance companies, relieving the doctor of the reimbursement hassle that might otherwise discourage them from prescribing such an expensive drug.

Horizon is not alone. Use of specialty pharmacies seems to have become a new way of trying to keep the health system paying for high-priced drugs. Valeant Pharmaceuticals International, which has attracted government and media scrutiny for its huge price increases, does much the same thing for its dermatology products with a specialty pharmacy called Philidor Rx Services.

"They are all trying to get rid of the sticker shock of using their drugs," said Dr. Kenneth Beer, a dermatologist in West Palm Beach, Fla. "They become the drugstore now," he said.

He said Valeant's program, which he had used, buffered physicians from insurers and complaints from their patients about high prices.

"It lowers one barrier to using their products," he said.

Valeant revealed last week that it had received subpoenas from federal prosecutors in Manhattan and Massachusetts seeking information about its financial assistance programs for patients, pricing decisions and the distribution of its products. It is not clear if the probes are related in any way to Valeant's relationship with Philidor.

Philidor, based in Hatboro, Pa., reveals little about itself on its website. It was denied a license in California in 2014 because, the state said, its application had not truthfully identified its owners and financial officers. Calls on Monday asking to speak to Philidor executives were not returned.

Valeant had said little about Philidor until Monday, when J. Michael Pearson, Valeant's chief executive, revealed on his company's quarterly earnings call that Valeant had purchased an option to acquire Philidor late last year. He said that Valeant consolidated Philidor's results in its own financial reports.

Mr. Pearson also said on the call that the pricing environment had changed, and that the industry was "being aggressively sort of attacked for past pricing actions." He said that Valeant was considering divesting the division selling neurological drugs where, he said, the biggest price increases had occurred.

He also said that in the future, price increases would be "more modest," probably not more than 10 percent a year. Last year, he said, increases in list prices averaged 36 percent for the branded drugs sold by Valeant in the United States.

Specialty pharmacies are most known for providing patients with assistance with complex drugs, many of them requiring refrigeration and injections, for diseases like cancer, multiple sclerosis and rare genetic disorders. But the drugs dispensed through the specialty pharmacies used by Horizon and Valeant are for common ailments like arthritis pain, acne and toenail fungus.

"What was started as administering complex, costly drugs has been co-opted as a sales/marketing tool to drive the growth of minor differentiation standard retail drugs," Ronny Gal, a pharmaceutical analyst at Bernstein, said in a note on Friday. The programs do offer advantages to patients. The drugs are delivered quickly and co-pays are subsidized. Horizon said 98 percent of patients getting Duexis have co-payments of no more than $10, less than the co-pays would be for generics in many cases.

Moreover, if the insurer refuses to pay, the patient already has the drug and the manufacturer absorbs the cost. A spokesman for Horizon said that happened for a large number of Duexis prescriptions. Still, Horizon and Valeant apparently come out ahead because enough insurers do pay.

The practice is legal, said Mr. Gal, the analyst, providing that co-pay assistance is not used for patients covered by Medicare or other federal programs. For federal programs, co-pay assistance is considered an illegal inducement to get someone to use a drug. Both Horizon and Valeant say they confine their programs to commercially insured patients.

On Horizon's second-quarter earnings conference call in August, one analyst asked the company to discuss the positive points of the Prescriptions Made Easy program.

"I think simply, the positive is we drove over $100 million in net revenue in the second quarter, rapidly increased prescriptions," Timothy P. Walbert, the chief executive, replied. He then said the program was "doing the right thing for patients."

Duexis is a combination of ibuprofen, an anti-inflammatory drug, and famotidine, the ingredient in Pepcid, which is supposed to prevent the serious and even lethal gastrointestinal problems that can result from chronic use of ibuprofen or similar drugs. Both drugs are available as generics, and over the counter. Horizon says that by combining the two drugs into one pill that is taken three times a day, that makes it more likely that patients will get the benefit of the stomach protection.

Horizon has increased the price of Duexis about tenfold since the drug was introduced in late 2011. In 2013, it acquired the main competitor to Duexis, a drug called Vimovo, which is a combination of the pain reliever naproxen and the stomach protector Nexium. Horizon immediately raised the price of Vimovo about 600 percent, and has roughly doubled it again since then, so both drugs now cost about the same amount per month.

Geoff Curtis, a spokesman for Horizon, said the company needed to recoup the $100 million it invested to develop and manufacture Duexis and the $35 million it paid to acquire Vimovo. He noted the low out-of-pocket payments for patients.

Deepak Jindal, a pharmacist in Netcong, N.J., said his wife was prescribed Vimovo and he could not fill the prescription in his own store because his insurance would not cover it. But when the doctor submitted the prescription to Horizon's program, a specialty pharmacy called Linden Care sent the drug to her for a $10 co-payment. He said he later learned that his insurance was not billed for the drug.

It has become common in the last several years for pharmaceutical companies to offer co-payment assistance to make sure patients are not deterred from using a drug by out-of-pocket costs. Once the patient uses the drug, the pharmaceutical company is paid by the insurance company. Insurers say co-pay assistance circumvents their efforts to encourage the use of cheaper drugs by setting lower co-pays for them, thereby driving up overall medical spending.

Starting this year, the nation's two largest pharmacy benefit managers, Express Scripts and CVS Health, said they would not pay for Duexis and Vimovo.

Despite that, Horizon said in its regulatory filing for the second quarter, "with the successful adoption of our PME program by physicians," sales volumes for Duexis increased by 72 percent in the first half of this year compared to the first half of 2014. In dollars, sales of Duexis rose 131 percent in the first half to $73.1 million. In the second quarter, 71 percent of Duexis prescriptions and 61 percent of those for

Vimovo went through the Prescriptions Made Easy program.

"Horizon has perfected an innovative program to distribute its high-priced pain medications that have been actively excluded from reimbursement by a number of large payers," Irina R. Koffler, an analyst at Mizuho Securities, wrote in a report earlier this month recommending the company's stock. The report was titled "Outrunning Payers & Not Standing Still."

Ms. Koffler said Horizon targeted physicians whose patients had strong commercial coverage. "Patients whose insurance covers Horizon's medications serve to support co-pay buy-downs for patients with less generous coverage," she wrote.

Horizon said in its regulatory filing that prescriptions filled through the program "are less likely to be subject to the efforts of traditional pharmacies to switch a physician's intended prescription of our products to a generic or over-the-counter brand." It said that if it were unable to get physicians to direct prescriptions to Prescriptions Made Easy, "We may experience a significant decline in Duexis and Vimovo prescriptions as a result of formulary exclusions."

A version of this article appears in print on October 20, 2015, on Page B1 of the New York edition with the headline: Drug Makers Sidestep Barriers on Pricing.