

Through Charities, Drug Makers Help People—and Themselves

By Donating Money, Firms Keep Patients Insured And Medicine Prices High

Mrs. Gushwa's \$2,000 Pills

By **GEETA ANAND**

Nancy Oliva hadn't paid much attention to her insurance plan's requirement that she pay half the cost of prescription drugs. Then the cashier at ShopRite told her she owed \$636 for seven pills.

Ms. Oliva, 60 years old, was diagnosed with a rare type of brain tumor earlier this year. She was prescribed a new drug to be taken in combination with radiation. The retail price of a one-week supply of the pill, called Temodar, is \$1,272.

Ms. Oliva, who earns about \$40,000 a year managing a clothing store in Long Beach Island, N.J., pulled out her American Express card that day in September and paid, unsure where she was going to find the money for the next week's supply. Fortunately, the nurse at her doctor's office found help for her from a charity, Patient Services Inc., which picked up her drug co-payments—\$3,800 for a six-week course of treatment.

The twist: The money for her co-payments came from Schering-Plough Corp., the drug's maker. To cope with rising medical costs, insurers are requiring patients to pay higher premiums and co-payments for drugs. While poor uninsured patients can often get expensive medicine free from drug companies, people with insurance are increasingly finding it difficult to afford these drugs. In response, drug companies are giving money to charities that are specifically set up to help patients pay such costs. Under this support system, drug-company money keeps patients insured—and keeps insurers paying for the high-priced medicine.

"It's a win-win situation," says Dana Kuhn, co-founder and president of Patient Services, a Midlothian, Va., charity, which solicits money from drug companies. "Patients are helped and companies are helped. They make a small contribution to help the patient and get much more money back when the insurer pays for the drug."

Drug companies also often take a tax deduction for their donation.

But critics contend the arrangements unfairly let drug companies protect the prices of their most-expensive medicines. "I don't want to discount the legitimate help they provide to people in need," says Scott Howell, an internist who serves as vice president of phar-

macy affairs at Highmark Inc., a Blue Cross and Blue Shield company in Pittsburgh. "But it's really a clumsy way for manufacturers to game the system so they can continue their high pricing."

The efforts, critics say, are a short-term fix that doesn't address the underlying problem: the soaring cost of ultra-expensive drugs. They argue that by paying patients' premiums or co-payments, drug companies are shifting most of the price of these medicines to the patients' insurers, who in turn spread the cost onto the other people they cover.

"This is not a sustainable level of spending," says Alan Garber, chairman of the Medicare Coverage Advisory Committee and director of the Center for Health Policy at Stanford University. "The idea of making drugs available to people who can't afford it is very appealing, but the net effect is for the drug company to appropriate most of the gain."

Drug companies say the high prices of new drugs allow them to recoup development costs and invest in research, as well as provide return for their shareholders. Donating to groups that make insurance payments helps people get their medicine.

A Schering-Plough spokeswoman says the company contributes to Mr. Kuhn's charity "as a resource for patients." She declined to say how much Schering-Plough donates to such programs.

Patients are grateful for the help. "Whoever thought a week's worth of pills could cost \$1,200?" says Ms. Oliva, who is now taking another round of Temodar. "But I'm so pleasantly surprised that someone is trying to help me stay alive and it's the drug company of all people."

The need for financial-assistance programs is growing. The biotechnology revolution has created hundreds of drugs for chronic, life-threatening illnesses. But many are coming to market at high prices. In May, the U.S. Food and Drug Administration approved a drug for a rare genetic disease, called MPS-VI,

Coverage Cycle

Some drug companies support charities so patients on expensive medicines can keep their insurance.



Note: Patients need to meet certain income guidelines to qualify.



THE MOST EXPENSIVE DRUGS

Third in a Series

Drug Makers Help Patients—and Themselves

Continued From First Page

made by California-based BioMarin Pharmaceutical Inc., which costs an average of \$300,000 a year. Other new drugs cost less, but are still pricey, such as cancer drugs Avastin, at \$50,000 a year, and Erbitux at nearly \$120,000 a year.

Unlike traditional medicines that are made by mixing chemicals, many newer drugs are proteins grown in cells, which is a complex, expensive process. Companies say costly manufacturing also leads to higher prices. On the other hand, the gross profit margins on some of these drugs can exceed 90%.

While Patient Services developed the concept of soliciting drug-company money to pay insurance premiums, the National Organization for Rare Disorders, a Connecticut nonprofit, recently began performing the same kind of middle-man role. “Everybody knows what has to happen—that these prices have to come down,” says Abbey Meyers, the group’s president. For now, she says, “we’re trying to work with drug companies in a way that’s acceptable to them and that also helps patients. We’re doing the best we can.” A few smaller charities have sprung up recently with similar plans.

Companies including Amgen Inc., Genentech Inc., Genzyme Corp., Teva Pharmaceutical Industries Ltd., Baxter International Inc., Novartis AG and ZLB Behring also donate to these programs.

Approaching Companies

Mr. Kuhn, 52, who suffers from hemophilia, co-founded Patient Services, also known as PSI, in 1989 while working as a counselor at a Richmond, Va., hospital. He saw hemophiliacs struggling to pay rising premiums to maintain insurance coverage for Factor VIII, the blood-clotting protein they need to stay alive. The drug today costs about \$100,000 a year.

Mr. Kuhn approached companies making the drug for a donation to help patients pay premiums. “Our argument was, ‘If you donate \$50,000, we can keep these people insured and provide revenue for you,’” he says.

Baxter and Armour Pharmaceutical Co., two of several companies that made the drug, each contributed \$50,000 the first year. The program has grown steadily, now assisting people with 19 different chronic illnesses.

Last year, Patient Services raised \$22 million, helping nearly 20,000 patients pay premiums and co-payments. About \$17 million of that came from 13 drug companies.

When he makes his pitch to companies, Mr. Kuhn says he emphasizes that they can make money by donating. During a 2003 visit to Genzyme, for instance, he brought along a chart showing how a donation would affect a patient who needs the company’s drug, Fabrazyme. Genzyme says the drug typically costs between \$175,000 and \$200,000 a year. The chart showed that if Genzyme donated \$5,400 to cover the patient’s premium for a year, it would bring in about \$185,000 by getting its

drug paid for by the patient’s insurance.

Genzyme signed up. “We wanted to do whatever we could to make sure all patients who needed our treatment could get it,” says a spokesman for the company, based in Cambridge, Mass. He declined to say how much Genzyme donates to Patient Services.

‘Who Can Afford It?’

One of the first to get help was Jeremy Taylor, a 25-year-old auto mechanic in Phoenix, who suffers from Fabry disease, a rare genetic disorder that can cause kidney failure, heart attacks and death. It costs about \$224,000 a year for him to receive Genzyme’s drug. His insurance pays for most of that, but under the plan, he is required to pay about \$27,000 annually, PSI says. Mr. Taylor declined to be interviewed.



Dana Kuhn

“It’s a real miracle drug for us,” says his father, Larry Taylor. “But who can afford it?”

Patient Services says it provides \$27,000, all donated by Genzyme, to keep Mr. Taylor insured. Mr. Taylor’s insurer pays the remaining \$197,000 cost of his treatment, according to PSI.

Until Mr. Taylor’s drug was covered by insurance, Genzyme provided it to him for free, his father says.

Genzyme helps keep 167 patients with Fabry disease insured through its charitable program, PSI says. Genzyme is the only donor for PSI’s Fabry program and it makes the only drug for the disease. The company donates less than \$2 million to the program, Mr. Kuhn says.

It isn’t clear how much revenue Genzyme receives from the sale of the drug to these patients. Assuming each patient receives the low-end estimate for a year’s dose, that could generate revenue of about \$29 million.

“Of course we get revenue from patients who are insured,” says a Genzyme spokesman. But he declined to be specific on how much revenue the company receives for patients it helps stay insured, saying that would incorrectly imply the company makes donations “simply for financial gain.” He says the company makes donations “simply to insure access to care for patients.”

Genzyme struck a similar arrangement with the National Gaucher Care Foundation in 1993, soon after the company brought a drug to market to treat Gaucher disease. Genzyme makes the most widely prescribed treatment for this disease, which causes organs to swell and bones to deteriorate.

The foundation’s patient-assistance budget this year is \$1.6 million. The biggest donor is Genzyme, according to Bar-

bara Lichtenstein, program director of the foundation. It helps about 200 patients with insurance premiums and other medical expenses. Genzyme says its drug for this disease costs an average of \$200,000 per year.

Genzyme has a staff of 34 insurance specialists who try to keep patients who take its drugs insured. If no insurance can be found, the company gives the drug to patients free.

Gaucher patients “are like gerbils on a wheel,” continuously finding and losing insurance, Ms. Lichtenstein says. Some who call her have hit their maximum lifetime caps of several million dollars on insurance coverage and have to find new jobs to get additional health-care coverage, she says.

Teva Neuroscience Inc. markets a multiple sclerosis drug that retails for about \$18,000 annually. “Market research told us early on we needed to do a patient-support program” because some people wouldn’t be able to afford their co-payments, says Denise Lynch, director of customer management.

Teva donates to the National Organization for Rare Disorders to provide co-payment assistance. Ms. Lynch says Teva didn’t calculate the profit it could receive when making its donation, “but from a common-sense perspective, you can get there.” She says Teva takes a tax deduction for its donation.

Teva considered setting up a foundation on its own, she says, but concluded it was “cleaner from a regulatory point of view to work through a third party.”

Some companies have been nervous about donating to his charity, Mr. Kuhn says, fearing they might violate federal anti-kickback laws. These laws, passed in the 1970s, forbid drug companies from giving financial assistance to Medicare and other federally insured patients which could be an inducement to choose one drug over another. The laws don’t apply to people who are privately insured.

To reassure drug companies it was legal to donate to his program, Mr. Kuhn sought an opinion in 2000 from the Office of the Inspector General of the U.S. Department of Health and Human Services.

In 2002, the Inspector General’s office issued its opinion, saying it wouldn’t seek civil or criminal penalties from participants in Mr. Kuhn’s program. It said the program “interposes an independent charitable organization between donors and patients in a manner that effectively insulates” patients and doctors from making prescribing decisions based on the donations.

This is because PSI sets up programs not by individual drug, but rather by disease—so that all the companies making, say, multiple sclerosis drugs, donate into a pool for patients with the disorder. Applicants receive help based on financial need, regardless of what drug they are prescribed, and even if the maker of a prescribed drug doesn’t contribute to the program.

For certain rare diseases, however, only one company makes a drug to treat the condition.

After the favorable opinion, Mr. Kuhn says he found drug-company executives eager to donate. “You could see the dollar signs shining in their eyes and they would jump over the table and say, ‘When can I start?’ ” he says.

He has raised \$30 million so far this year and is assisting 25,000 patients.

Patient-assistance programs must walk a thin line. In 2002, the Inspector General also issued a separate, unfavorable opinion on the subject. This was to an unidentified drug company seeking to establish a nonprofit foundation to cover co-payments only for patients on its drug.

“The proposed arrangement poses all the usual risks of fraud and abuse associated with kickbacks,” the opinion said. It said physicians would have an incentive to prescribe the drug in question, which is infused in doctors’ offices, over another because they would be certain of being paid rather than risk collecting the co-payment from the patient.

The opinion noted patient-assistance programs can be “very profitable to manufacturers...Given that the marginal variable cost of a drug can be quite low, the profit can be considerable, especially for an expensive drug for a chronic condition.”

A Working Balance

Third-party charities struggle to maintain a working balance with corporate donors. Maria Hardin, vice president of patient services, at the National Organization of Rare Disorders, says companies routinely press the group to give out more patient information than it can legally provide. “There’s a lot of whining going on with them asking, ‘What percentage of the fund is taking care of our patients?’ We can’t provide that information,” she says.

Mr. Kuhn’s charity is growing so much that it plans to build a \$1.7 million, 15,000-square-foot building. One reason he expects demand for assistance to rise is that next year, Medicare will start a program to help the elderly afford drugs. Currently, Medicare doesn’t pay for most prescription drugs.

But the new Medicare program is structured so that some patients on expensive drugs will still have to come up with thousands of dollars to pay out-of-pocket costs.

Vivian Gushwa, 70, was prescribed the cancer drug Gleevec after her rare gastrointestinal tumor recurred last year. Her husband, Ronald, went to Rite Aid in Marion, Ohio, to pick up the medicine and came home crying. The retail

price of her prescription was \$2,000 for two weeks’ supply, which would consume the couple’s \$2,000 a month in pension and Social Security income, they say.

“There’s no way on God’s green earth we can afford that,” says Mr. Gushwa, 74, who worked most of his life at a local electric-power company.

He bought a two weeks’ supply of the drug, using about half of their \$4,000 in savings. Novartis, the Swiss company that makes Gleevec, provided free medicine for several months and then directed the couple to apply to the federal government for coverage under a pilot Medicare program.

The Gushwas again suffered sticker shock. Their income of \$2,000 a month put them in a group required to pay \$3,600 a year before being eligible for the drug benefit. They also have to pay 5% of each prescription.

“Medication has to be paid for. We understand that,” says Mrs. Gushwa. “But how do people afford it? Do you just die?”

She says she overheard her husband weeping on the phone as he called around seeking help. An official from Medicare referred him to PSI, which had just started a program funded by Novartis. Mrs. Gushwa got help from the charity and received the Novartis drug. “I’m just thankful to my doctors and God and PSI,” she says.

Paul Pochtar, executive director of oncology-managed marketing at Novartis, says his company began donating to PSI last year. “It’s a fairly new phenomenon,” he says.

Novartis donated several million dollars to PSI this year to help patients make

Last year, Patient Services raised \$22 million, helping nearly 20,000 patients.

drug co-payments, a spokeswoman says. She says the donation was less than \$10 million, but wouldn’t be more specific.

This generates revenue for the company. PSI says it helped 1,255 patients in two cancer programs for which Novartis is the only donor—with almost all of them receiving Gleevec. The average wholesale price of the drug at the recommended dose is about \$37,000 a year. If the patients in the program receive the recommended dose, that could generate tens of millions of dollars in revenue.

A Novartis spokeswoman wouldn’t comment about the revenue generated. In a statement, she said that the company’s donation to PSI “helps insured patients with co-pay obligations.”

If these patients weren’t insured, some might qualify for free drugs. Novartis says it gave away \$100 million of Gleevec in 2004. The company says its patient-assistance programs have helped 12,000 people world-wide gain access to Gleevec. Sales

of the drug last year were \$1.6 billion.

Long-term support from the charities is uncertain. Mr. Kuhn says patients are guaranteed assistance for two years. After that, it is hoped that they can be weaned off the program, by finding a different insurance plan or a new job with better benefits. “We don’t want to become a social-service agency,” he says.

This is difficult for many. Carolyn Samit, 63, of Caldwell, N.J., suffers from primary immune deficiency, an inability to produce enough antibodies to fight off diseases. Because her care is expensive, her insurance premiums are high. Last year, PSI paid her health-insurance premium of \$53,000.

A Letter to Ms. Samit

But Mr. Kuhn called her late last year, saying she needed to find some other way of paying for insurance this year. He followed up with a letter, saying, “This letter is being written to you, not to create panic, but to share the truth with you about your assistance being in jeopardy.” The letter, written to all patients with immune disorders, said PSI couldn’t guarantee help for them because corporate donations for their particular drug program had fallen.

Ms. Samit called Mr. Kuhn, crying and begging him not to drop her, saying she had failed for years to find another insurer that would cover her care for less. She takes Gamunex, an immune globulin or mix of antibodies purified out of donor blood, sold by Talecris Biotherapeutics, for which she says her insurer pays \$47,000 annually. She also needs an antibiotic, vancomycin, which costs about \$46,000 because of her frequent use. Her insurer, Celtic Insurance, of Chicago, didn’t return calls.

The widow of an American Airlines executive, Ms. Samit lost coverage under his plan after he died. She lives on his \$22,000-a-year pension and says she wiped out her savings and her daughter’s trying to pay her rising premium until PSI stepped in.

Mr. Kuhn says he told Ms. Samit he could continue to pay her premium only if the charity received more money from companies that make her drug. So she began calling around, asking drug makers to boost their donations.

Officials at Baxter and Talecris acknowledge receiving Ms. Samit’s calls. Both companies say they donated to PSI this year, but note that they don’t control decisions on which patients get helped by their donations. Mr. Kuhn says the new money allowed him to pay Ms. Samit’s premium and help other patients for another year.

“I feel grateful every day for PSI and the companies that support them,” Ms. Samit says. “I was a middle-class person living a comfortable middle-class life. It never occurred to me in a million years that I could lose insurance and die.”

Mr. Kuhn says it’s important to focus on the fact that people are being helped by drug companies’ contributions to his charity. “Although they are making money hand over fist, they are doing wonderful things for patients,” he says.