

Battle over generic drugs leaves doctors, drug companies at odds

The desktop computer in Dr. Louis Papa's Brighton office is equipped with software that has become part of a community effort to use generic drugs rather than pricey brand names.

When Papa types in the name of a patient, a chart showing the patient's history flashes on the screen — with a category in which he can write in a prescription and get instant feedback.

The appearance of a green smiley face on the computer screen tells Papa that his selection of a generic drug is putting him on the right track.

But if a red frownie face pops up, it might be because he has chosen a brand-name drug when a cheaper generic will likely work just as well.

A smiley face, however, isn't enough to make dramatic changes in the drug-use habits of the American public.

Although the nation has been moving toward greater use of generic drugs, progress has been slowed by the profit-minded pharmaceutical industry and a public that is slow to abandon old habits.

Pfizer, for example, has been pouring millions of dollars into marketing its cholesterol-lowering Lipitor since the drug's patent protection expired in November — the latest example of how pharmaceutical giants try to keep brand names in the public eye.

Consumers, experts say, often mistakenly believe that generics are dime-store knock-offs — not the real deal. In fact, brand names and their generic alternatives have the same active ingredients, but generics are often much cheaper — locally about one-tenth the cost of brand names — because they do not come with a hefty marketing campaign and the drugs' development costs have already been recovered.

"Generics conjure up the image of low quality. That's not the case," said Dr. Aaron Seth Kesselheim, a Harvard Medical School assistant professor who has examined the tactics used by pharmaceutical giants to delay the entry of generic alternatives.

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Using generic drugs is one thing that the public can do to help control skyrocketing health care costs, even though the financial returns are not easily discernible because insurance rates have not declined, here or elsewhere. Prescription drugs account for about 10 percent of the nation's almost \$3 trillion-a-year health care bill, with new brand names continually coming on the market and driving up the total spent on drugs.

In the Rochester area, generic drugs now account for about three-quarters of the drugs prescribed — about the national average. Each percentage point increase in generics chops off about \$30 million from local health care costs, according to Excellus BlueCross BlueShield, the largest insurer in the region.

Consumers have plenty of reasons to turn to generics.

Dr. Bob Panzer, chief quality officer of the University of Rochester Medical Center, said patients are far more likely to purchase generics because of their affordability and then to take the drugs longer.

They also are safer than new brands because their ingredients have stood the test of time, noted Dr. Sidney Wolfe, director of Public Citizen's Health Research Group.

Nothing binds Papa to prescribe what is recommended by the software on his computer and those of about 650 other

doctors under the umbrella of the URM. But sometimes exceptions must be made — although that can require the doctor getting prior approval from the insurer. However, experts say these exceptions should be rare.

Chris Wiest, vice president of public policy for the Rochester Business Alliance, said that it's important to communicate this message to doctors and patients.

"Consumers don't see ads on TV or in newspapers for generic drugs," Wiest said. "Instead, they're being told to go to their doctors and ask for drugs by (brand) name."

Generic checks

Under federal law, a brand-name drug has a 20-year patent that protects it from competition. Once the patent expires, a generic drug can be made using the same active ingredients as the original drug. A generic can be made by the pharmaceutical company that brought the

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original drug to market as well as by competing companies. The Food and Drug Administration must give approval to generic competitors, who need to show that their products are just as effective as the brand name.

One wrinkle in the federal law: Usually only one competitor can put out a generic version for the first six months after a patent expires — giving the pharmaceutical company a leg up in seizing market share.

State law is also helping prescriptions move toward generics.

Pharmacists, for example, must fill prescriptions with a generic drug unless the doctor writes DAW — dispense as written — on the prescription.

Insurers can demand prior authorization in any event — requiring the doctor to make a case for the more expensive drug and sometimes show that the drug preferred by the insurer failed to help the patient.

Medicaid recipients are governed by other rules. Brand-name drugs that have generic equivalents are not covered unless prior authorization from the state Health Department or the insurer is obtained. But the law provides for exceptions, and numerous brand names have been exempted from such authorization. In October, management of most Medicaid recipients' drug benefits was put in the hands of private insurers, which could result in even fewer brand names being prescribed.

"It's just hard to know how to jump through the hoops needed to get the drugs quickly," said Trilby deJung, a health law attorney with the Rochester-based Empire Justice Center.

Pharmacists find themselves caught in the crossfire between doctors and insurers.

"The patient comes to us expecting that if a doctor wants a prescription, we will be able to fill it. We find out that the patient can't get the medication without prior authorization," said Nadia Sefein, president of the Pharmacy Society of Rochester.

Sally Brooks, an owner of the Livonia-Lakeville Pharmacy in Livingston County, tells of the seemingly endless phone tag — with calls from patients inquiring about the status of the prescriptions and pharmacists trying to determine whether prior authorization has finally been granted.

"It's called the hassle factor," said Dr. Peter Deane, a local allergist and rheumatologist.

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Promoting smiles

The smiley and frownie faces are part of a communitywide effort to control rising health care costs.

The local initiative took shape in 2006 when the Rochester Business Alliance convened a group of local employers, physicians and insurance companies to find ways to improve the quality of care and rein in soaring costs.

"Each year we ask our member companies to identify the economic issue most hampering their ability to succeed," said RBA President Sandy Parker. "Each year they tell us it's escalating health care costs."

Generic drugs were identified as a key concern.

Excellus has seen the use of generics rise from 56 percent of all prescriptions filled in 2005 in the Finger Lakes region to 76 percent in 2011.

MVP Health Care reports similar results, from 59 percent in 2005 to 76 percent in 2011.

Such improvement, said Excellus, accounted for savings of \$31 million in the Finger Lakes region in 2010 and \$127 million in the 39-county upstate area.

Nationally, 78 percent of the prescriptions filled in 2010 were generic, according to the IMS Institute for Healthcare Informatics, a health care research company based in

Danbury, Conn., which bases its estimate on more than 36 billion health care transactions processed annually.

The other local hospital systems are also encouraging generics, and Excellus considers use of generics one of several criteria in awarding incentive money to hospitals for efficiencies and effectiveness.

Unity Health doesn't use smiley-frownie faces but red (stop) and green (go) bars. Unity includes Park Ridge Health Care Campus in Greece.

At Rochester General Health System, electronic records default to generics automatically unless there is no generic or the physician specifically requests a brand name, said spokesman Marty Aarons.

Cost of brands

Despite the progress, health insurance premiums continue to rise. Premiums on average nationwide are expected to go up by 8.5 percent this year. Locally, average

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annual increases have been near or above double digits for more than a decade.

Insurers point to such factors as the growing elderly population needing more medications and the high cost of new brand names as contributing factors.

Nationally, generics make up about three-quarters of prescriptions filled, while brand names account for about three-quarters of the money spent on prescription drugs — with the total spent growing to \$307 billion in 2010.

According to pharmaceutical companies, one reason brand names are expensive is the cost of all the research needed to bring the drug to market. They estimate that it costs about \$1 billion — a figure critics say is overblown — to get a drug on pharmacy shelves, a cost that they then must recoup.

Drugs for difficult-to-treat diseases, such as cancer, AIDS or autoimmune diseases, are among the new brands that are important for treatment but expensive.

Approximately 7,000 people in upstate New York take prescription drugs to treat multiple sclerosis, for example. Each of the six FDA-approved drugs for treating MS costs more than \$3,000 a month. The wholesale cost for a 52-week supply of Copaxone was \$47,190 in 2010.

"By 2020, 40 percent of the money spent on prescriptions will be due to these high-cost specialty drugs. Now it's 15 percent," said Jim Hopsicker, pharmacy vice

president for MVP.

Pharma resists

Dozens of brand drugs have recently lost or are about to lose their patent protections. In theory, this should make 2012 a banner year for generics.

Between 2010 and 2015, pharmaceutical companies are at risk of losing as much as \$102 billion because their brand-name drugs are coming off patent and face generic competition, according to data compiled by Healthcare Informatics.

"This is a very important time for health care plans to maximize the use of generics," said Wells Wilkinson, staff attorney for the Community Catalyst, a Boston-based nonprofit research and advocacy group focusing on health care.

The pharmaceutical giants are fighting back.

"We will continue to make our medicines

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available post loss of exclusivity, providing patients the ability to remain on the brand that they and their doctor have chosen," said Pfizer spokesman MacKay Jameson.

Pharmaceutical companies are also using such marketing tools as co-pay coupons to keep consumers on their drugs.

Such discounts create the illusion of big savings because the coupon holds down the consumer portion of the cost, but the employer portion of the bill is not lowered.

A new study commissioned by the Pharmaceutical Care Management Association says that the increased use of coupons by drug companies could raise the nation's health care costs by \$32 billion over 10 years.

Pharmaceutical companies also continue to dispatch sales representatives to doctors' offices.

Dr. David Newman, who has a practice in Brockport, described pharmaceutical sales as the profession with the best-looking bunch of people next to actors. And, he said, brand-name drugs — not even a drug company's own generic equivalent — are what they bring to his office.

Consumer advocates and legal experts also question whether deals are being cut to forestall generic competition.

Consider that CVS Caremark, which works with insurance companies to fill prescriptions, sent out a notice to

pharmacies saying that atorvastatin — the generic alternative to Lipitor — would not be covered by the Medicare prescription plans offered by about 30 insurers.

Instead, the notice says, Lipitor can be dispensed to consumers in these plans and they will pay the same out-of-pocket co-pay that they would for atorvastatin.

Excellus and MVP, which is the second-biggest health insurer in the region, say they are not going along with any offers to suppress generic competition.

Mixed signals

Confusion among patients is likely aiding the pharmaceutical companies.

When Lipitor, the nation's most prescribed drug, recently went off patent, pharmacies and insurers were left in a cloud of uncertainty over its cost and how it would compare to atorvastatin.

It was a guessing game for Al Fisher, 69, of

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Greece.

As the expiration date approached, Fisher called his insurer, MVP, four times to find out what to expect. He got four different answers.

Would he get atorvastatin or Lipitor when he picked up his month's supply for December at the Faris Pharmacy in Greece?

Fisher stuck with Lipitor because, under his MVP plan at the time, Lipitor cost him \$10 less than atorvastatin. His January refill, however, was with atorvastatin, which by then was \$37 cheaper than Lipitor.

"I'm going to live happily ever after," Fisher said.

Such variations in price, while puzzling, are typical when a drug goes off patent.

The Business Alliance's Wiest notes the importance of an informed citizenry.

"Consumers need to be actively engaged in managing their own health and to look at alternatives to more expensive options that are just as effective," he said. "With ever-spiraling and escalating health care costs, we have to look at where those costs are coming from, and name-brand drugs are a huge component of those costs."

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