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More Generics Slow Rise in Drug Prices

By STEPHANIE SAUL August 8, 2007 -- New York Times

A quiet coup is taking place in American medicine cabinets. Prescription bottles bearing catchy brand names like Zoloft and Flonase are being pushed aside by tongue-twisting generics like sertraline and fluticasone propionate. While the trend is already pinching the profits of big pharmaceutical companies, it is rare good medical news for American pocketbooks.

The nation currently spends \$275 billion a year on prescription medicines. But over the next five years, analysts forecast a golden era for generic drugs, as patents begin to expire on brand-name medications with more than \$60 billion in combined annual sales. That will open the door to copycats that may be 30 percent to 80 percent cheaper. “There’s a tidal wave of generic drugs, and we are just in the beginning of the tidal wave,” said Laizer Kornwasser, an executive for Medco Health Solutions, which manages prescription drug plans. The rise of generics has helped slow spending increases for prescription medications over all, even though an aging population is consuming more drugs and even as new medicines enter the market — including cancer drugs costing tens of thousands of dollars.

Ronny Gal, an analyst for Sanford C. Bernstein who follows generic companies like Teva Pharmaceutical Industries, Barr Pharmaceuticals and Mylan Laboratories, predicts 10 to 13 percent annual profit growth in the industry by 2010. He describes the generic trend as “good for everybody but the branded pharmaceutical companies.” Last week, the big drug maker Johnson & Johnson announced it would eliminate up to 4,800 jobs as it braced for generic competition to its drugs, Risperdal for schizophrenia and Topamax for seizures and migraine headaches. In the last year, combined United States sales of the drugs were \$4 billion.

Shortly after the Johnson & Johnson statement, Sanofi-Aventis announced that it had already been hard hit by low-cost alternatives to its sleeping pill, Ambien, which became available in generic form in April. As frequently happens when generics appear, sales of the name-brand Ambien plunged — to \$91 million in the second quarter, from \$420 million in the same period last year. Generics already account for 60 percent of prescriptions in this country. And that portion is expected to rise, as cheaper substitutes arrive to treat many chronic conditions. Already this year, consumers have flocked to new generic versions of five major drugs, including Ambien and discount alternatives to Norvasc for high blood pressure.

Next year, generic competition is expected to hit Fosamax, a \$2 billion drug in this country that slows bone loss and is often used by postmenopausal women. In 2009, the

heartburn and ulcer medication Prevacid, a \$3.5 billion product in this country, is expected to become available as a generic product. And by 2011, a generic substitute is expected for what has been the world's single best-selling medicine, the cholesterol drug Lipitor, a drug with annual United States sales exceeding \$5 billion.

Several experts predict that generic drugs will keep drug price inflation in the single digits for the next several years. "It's much better than it was in the '90s, before these drugs started going generic," said Dr. Steven B. Miller, chief medical officer for Express Scripts, another company that manages drug benefit plans. "The drug trend was always double digit."

Companies like Express Scripts are promoting the use of generics by setting lower co-payments for them, reducing the amount patients must pay out of pocket. Also helping to propel the copycat drug trend is the success of generic manufacturers in challenging patents held by brand-name companies. But another reason is that many patents are simply expiring on drugs that were introduced during the late 1980s and early 1990s, an unusually productive era of research and development for the pharmaceutical industry.

Patents provide 20-year protection from generic competition. But because companies often apply for patents in early stages of drug development, before drugs are approved, pharmaceuticals may have fewer years of what is called effective patent protection. And now, as nearly every big drug maker watches its best sellers fade away, there are fewer potential blockbuster drugs waiting to take their place.

"At the end of the day, it's basically a failure of innovation," said Richard T. Evans, a consultant with the firm Avos Life Sciences, a research and consulting firm for the drug industry. Mr. Evans said it was hard to know whether the drug industry was merely in a cyclical lull or whether it suffered from a systemic decline in productivity. But the Pharmaceutical Research and Manufacturers of America, the trade group for brand-name companies, said that company research and development budgets are increasing each year, even as generic competition cuts into profits. "I don't think we would support the contention that there's a lull," said Caroline Loew, the industry group's senior vice president for scientific and regulatory affairs. Citing diseases like Alzheimer's, Parkinson's and cancer, she said, "The companies are tackling diseases that are extremely complex. The biological mechanisms are very poorly understood. By definition, that sort of science, which is very much emerging science, is going to take longer." One way the pharmaceutical industry is working to counter the generic trend is through its own generic subsidiaries and contracts for the production of company authorized generics.

The Food and Drug Administration approves generic drugs that contain the same active ingredients as brand-name pharmaceuticals, and the agency says that generic drugs meet the same quality standards as brand-name drugs. Yet in a study conducted in 2002 by AARP, 22 percent of those surveyed indicated they thought that generic drugs might be less effective or of poorer quality than brand-name drugs.

Mr. Gal, the Sanford Bernstein analyst, said that the generic drug industry was still working to overcome such suspicions. Corporate drug plan managers like Medco Health Solutions and Express Scripts work aggressively on behalf of employers to encourage the use of generic drugs. One way is by setting lower co-payments for them. That may mean an out-of-pocket expense of \$20 less for generics than name-brand medication.

James and Rosemarie Cola, a retired couple in Queens, take 16 medications between them. Over the last few years, out-of-pocket costs for several of their drugs have fallen, as generics have become available. Mr. Cola, 82, a retired hairdresser and makeup artist who earned an Emmy for his work in daytime television, recently paid only \$9 for a 90-day supply of cilostazol, a substitute for the branded drug Pletal for leg pains. The drug became available as a generic in 2004. Mrs. Cola, 74, is expecting to see several of her medications become generic within the next few years, including Zyrtec for allergies, Lipitor for cholesterol, and Coreg for heart problems. “We’re living on pills,” said Mrs. Cola, a retired substance abuse counselor and social worker. Whatever the cost savings, Mrs. Cola says she must think twice before switching from one formulation to another whenever one of her drugs becomes generic. “I don’t like to change drugs,” Mrs. Cola said.