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New Medicines Seldom Contain Anything New, Study Finds

By MELODY PETERSEN

Two-thirds of the drugs approved from 1989 to 2000 were modified versions of existing drugs or even identical to those already on the market, rather than truly new medicines, according to a new study.

The report also said that most of the increased spending on new prescription drugs was on products that the Food and Drug Administration had determined did not provide significant benefits over those already on the market.

Some of the reformulated prescription drugs are now among the most heavily advertised. For example, Nexium, a recently approved ulcer medication, is a modification of Prilosec, which is soon expected to lose its patent protection. Clarinex, an allergy drug, is a reformulation of Claritin. Sarafem, for premenstrual irritability, is the same drug as Prozac but has been renamed and repackaged in capsules of pink and lavender.

"The plain fact is that many new drugs are altered or slightly changed versions of existing drugs, and they may or may not be all that much better than what's already available," said Nancy Chockley, president of the National Institute for Health Care Management Foundation, which wrote the report. "Consumers should be more aware of that."

The institute receives 40 percent of its financing from the Blue Cross Blue Shield health insurers and has often clashed with the pharmaceutical industry because of its reports on the rising cost of prescription drugs. The drug industry's trade group, the Pharmaceutical Research and Manufacturers of America, criticized the study yesterday, saying that it was "flawed and misguided."

Richard I. Smith, vice president for policy and research at the group, said that even if a medicine was similar to one already on the market, it could still offer many benefits to patients. For example, he said, even though there are several similar drugs that fight depression — including Prozac, Paxil and Zoloft — many patients may not respond to one medicine but will to another.

"If a new drug does not have sufficient advantages, it will not be used," Mr. Smith said.

He said the report by the National Institute for Health Care Management "appears to be little more than a political and financially motivated cheap shot masquerading as science in the public interest."

While it has been known for some time that many of the drugs approved were similar



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to existing medicines, the institute's study appears to be the first to use data from the F.D.A. to try to determine just how prevalent these medicines are. Often such modified versions of medicines are called me-too drugs.

Of the 1,035 drugs approved by the F.D.A. from 1989 to 2000, only 361, or 35 percent, contained new active ingredients, the study said. The rest contained active ingredients that were already available in other medicines on the market.

Of those 361 drugs, fewer than half were given priority reviews by the F.D.A. because of their significance. The agency grants priority reviews to medicines that are believed to be more effective, have fewer side effects or otherwise perform better than existing drugs.

Considering those statistics, the institute found that highly innovative new medicines — those with new chemical ingredients that offer significant improvements over existing drugs — made up only 15 percent of those approved in the period. These medicines included Fosamax, for osteoporosis; Avandia and Actos, for diabetes; and Viagra, for erectile dysfunction.

The study said that drug companies were increasingly relying on the me-too products as patents on top-selling drugs expired, and they could not discover enough truly new medicines to increase revenue as fast as investors expected.

The modified drugs also provide a high return on investment, the study stated, since developing them is much less expensive and also less time-consuming than trying to find a new medicine.

"This is more evidence that the pharmaceutical companies are turning more into marketing companies," Ms. Chockley said. By using advertising to sell drugs that are essentially line extensions of existing medicines, she said, the companies have learned to be like [Procter & Gamble](#), the maker of Tide.

The institute's study said that the modified medicines were often more expensive than were older medicines, even if the F.D.A. had found that they did not offer significant advantages. In 2000, the average price of a modified drug not given a priority review by the F.D.A. was about \$65 — almost double the price of a drug approved before 1995, the study said.