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Report Says Drugmakers Innovate Less, Modify More

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Most drugs approved for use during the 1990s were not innovative new chemicals that treat diseases in novel ways but rather were modified versions of drugs already on the market, according to a new analysis.

The study, by the nonprofit National Institute for Health Care Management (NICHM), challenges a central argument of the nation's pharmaceutical drug industry: that it needs high profits to fund its risky and highly innovative research.

The emphasis on incremental change was especially pronounced in the last six years of the period studied, when the number of popular but less-innovative drugs increased dramatically -- as did the nation's spending on prescription drugs. The report says that while these new drugs may be beneficial to patients, they are not the kind of breakthroughs that consumers have come to expect.

The report concludes instead that drug industry advances are now far more likely to involve relatively minor improvements in how existing drugs are administered, dosed and combined with other existing active ingredients than the discovery of entirely new types of treatments.

"The pharmaceutical companies have migrated towards becoming more marketing than research and development organizations," said NICHM President Nancy Chockley. "Highly innovative drugs are rare."

The trade organization representing the drug industry, the Pharmaceutical Research and Manufacturers of America (PhRMA), criticized the study as "fundamentally flawed" and biased because it was done by a group sponsored by the health insurance industry. PhRMA Vice President Richard I. Smith said that he had not been provided the full report but that he had learned its key points.

"Today's NICHM report appears to be little more than a political and financially motivated cheap shot masquerading as science in the public interest," he said. "It comes as no surprise that its report conveniently ignores many of the basic facts about drug research, not the least of which is that innovation rests in the lives of its beholders."

In particular, he said, the study relied on Food and Drug Administration review categories that are irrelevant to assessing the usefulness of drugs and to how much patients might benefit from them. While some might dismiss the many anti-depression drugs on the market as "copycats," Smith said, studies have shown that half of depression patients try two or three varieties before finding one that works for them.

He also criticized the report for focusing only on the past and not saying anything about the many drugs in the pipeline, especially the products of biotechnology and gene therapy that some believe will transform drug treatments in the future.

The NICHM was founded nine years ago by 11 Blue Cross/Blue Shield companies, and the presidents of those companies constitute most of its board of directors. The group seeks to provide impartial information and has an independent advisory board of prominent health care experts.

The NICHM study looked at whether drugs were accepted by the FDA for "priority" or "standard" review, and whether they included new molecular entities or were improvements on existing ingredients on the market. The

group judged the "priority" drugs that contained new active ingredients as the most innovative and the "standard," "incrementally modified" drug applications as the least innovative.

The study found that of 1,035 drugs approved by the FDA from 1989 to 2000, 46 percent were in the least innovative category. During that period, only 15 percent, or 153 approved drugs, were medicines that both used new active ingredients and provided significant clinical improvements, the potential level of benefit needed to achieve a priority FDA review.

During the first six years studied (1989 to 1994), the FDA approved 168 drugs that neither provided significant clinical improvements nor had new active ingredients. In the second six years (from 1995 to 2000), the number in that category increased to 304.

The study also concluded that the doubling of prescription drug spending from 1995 to 2000 -- from \$64.7 billion to \$132 billion -- was largely attributable to new drugs in the least innovative category.

Yesterday's report, and the response to it, are another example of the bare-knuckles brawl that has broken out between the drug industry and the health insurance companies that pay much of the nation's fast-rising prescription drug bill.

Those costs have led to health insurance premium increases and caused the health insurance industry to step up legislative and legal efforts to reduce drug costs, especially through the expanded use of generic drugs. PhRMA and the drug industry have been fighting back fiercely.

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