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Debate Continues Over Drug Development Costs

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There's no question that drug development costs escalate when development time lengthens. But the question of just how much it really costs to bring a drug to market has been argued over the past several years, and it remains a subject of fierce debate.

Perhaps the numbers most widely accepted by economists and the government are those produced by economist Joseph A. DiMasi at the Tufts Center for the Study of Drug Development at Tufts University. On Nov. 30, 2001, Tufts announced an update of DiMasi's 1991 study, which pegged the average cost to develop a new prescription drug at $231 million in 1987 dollars. The new study estimates the average "fully capitalized resource cost" at $802 million in 2000 dollars--a 250% increase, adjusted for inflation, over 11 years.

Not everyone agrees with this figure. "The $802 million is extremely unreasonable," says Richard DiCicco, president and founder of consulting firm Technology Catalysts International. "It doesn't cost that much to develop drugs. But it costs that much to pay for the mistakes of people who have tried to develop drugs."

Two aspects of the Tufts number are particularly controversial: its inclusion of the cost of failures and its inclusion of opportunity cost--the amount of money that could be earned by a comparable alternative investment, which amounted to $399 million in the Tufts study.

"The opportunity cost is a theoretical cost, not a real cost," says Larry Sasich, spokesman for Public Citizen, Ralph Nader's watchdog group. Public Citizen claims that the Tufts figure exaggerates R&D costs not only by including the cost of capital and failed drugs but also by overstating the actual after-tax outlay for development costs and by excluding drugs that receive government support. "The pharmaceutical industry gets an awful lot of tax breaks, like credits for research," Sasich says.

Public Citizen believes that a more accurate figure would include only out-of-pocket expenses and would account for the fact that many drugs receive financial backing from the government sometime during their path to commercialization. The group says the drug industry's main trade group, Pharmaceutical Research & Manufacturers of America (PhRMA), is misleading policymakers and the public to scare them into accepting prices that result in excessive profits.

Public Citizen conducted its own study in which it came up with a cost of less than $240 million to develop a drug. Pharmaceutical companies "foster and nurture the belief that the industry spends a lot on R&D," Sasich says. Companies price drugs according to what the market will bear, not what they spent on R&D, he claims.

Another issue is the extent to which the Tufts report includes marketing costs. "We don't know if marketing goes into development costs," Sasich says. "I imagine there are some marketing costs in the Tufts numbers, but we may never know because it is confidential information."

In fact, Sasich continues, it is difficult to divide some late-stage development costs from marketing costs. For example, the writing and presentation of a scientific paper and the

publication of reprints is an important part of the research process but can also be used to help sell the drug.

"Our study gave some idea of the out-of-pocket cost to develop a real drug--what you would see on a tax return," Sasich adds. This number, he says, is what it costs to develop in-house a new drug in the U.S. and get it to the pharmacy shelf.

However, standard accounting practice includes opportunity cost, says accounting firm Ernst & Young. It was hired by PhRMA to rebut claims made by Public Citizen before the latest Tufts report was announced. Opportunity cost takes into account the fact that R&D investment may be very risky. Furthermore, Ernst & Young claims that rather than being lightly taxed, the pharmaceutical industry pays a greater percentage of its revenues in taxes than any other industry.

Equally notable as the size of the Tufts cost estimate is its increase since the 1991 study. DiMasi finds that much of the increase is due to rising clinical-trial costs. At a time when drug development programs are expanding, it is difficult to recruit patients, he says. Furthermore, drug companies are increasingly looking at chronic and degenerative diseases, which require longer trials.

Drug companies and PhRMA consider the Tufts figure to accurately represent the state of pharmaceutical research today. "The $800 million cited by DiMasi is important confirmatory evidence of the increasingly complex nature of developing an innovative new medicine today," said Raymond V. Gilmartin, chairman, president, and chief executive officer at Merck, in a speech after the release of the latest Tufts study.

He added that this estimate means that a "large and vibrant" drug industry is needed to translate new research into new medicines, and that continued innovation depends upon the ability of the industry to make a profit and protect its intellectual property.

The validity of the Tufts figure aside, the cost of drug development is high compared with R&D costs in other industries. In addition, Tufts has found that it takes between 10 and 15 years to develop and approve a new pharmaceutical in the U.S. "The single largest challenge facing drug developers--both pharmaceutical and biotechnology companies--is to contain R&D costs and reduce development times without compromising clinical test design," Tufts Center Director Kenneth I. Kaitin says.

This article can be found at the following location:
http://pubs.acs.org/cen/coverstory/8004/8004pharmaceuticals.html