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Tufts Drug Study Sample Is Skewed; True Figure of R&D Costs Likely Is 75 Percent Lower

Public Citizen Critiques Tufts Study Pegging New Drug R&D Costs at $802 Million

WASHINGTON, D.C. – A new study claiming that the average cost of developing a new prescription drug is $802 million once again significantly overstates real research and development (R&D) costs, according to an analysis by the national consumer group Public Citizen. The study in question was prepared by the Tufts Center for the Study of Drug Development and was released in Philadelphia on Nov. 30.

The Tufts Center study has two dramatic flaws, according to Public Citizen. First, it is not representative of real drug industry R&D because none of the 68 drugs used in the Tufts study received any government support – a fact admitted by the study's author, Joseph A. DiMasi, at a Nov. 30 briefing on the report. Many, if not most, drugs brought to market receive financial support from the government at some stage in their discovery and development. Therefore, the Tufts study focuses on a skewed sample of drugs and inflates the actual cost of R&D for the average drug.

A National Institutes of Health (NIH) internal document, dated February 2000 and obtained by Public Citizen earlier this year, showed that all the top five selling drugs in 1995 received significant taxpayer backing in the discovery and development phases. Investigations by the Massachusetts Institute of Technology and *The Boston Globe* also have examined samples of medically important and top-selling drugs and found that a vast majority of drugs in each group received government support.

The second major flaw of the Tufts Center study is that it exaggerates the actual R&D expenditures for its sample of drugs. Specifically, the new Tufts Center estimate of $802 million includes significant expenses that are tax deductible and theoretical costs that drug companies don't actually incur. For example, roughly half of DiMasi's estimate ($399 million) is the "opportunity cost of capital" – a theoretical calculation of what R&D expenditures might be worth if they were invested elsewhere. DiMasi calculated actual out-of-pocket R&D costs for drugs in the study at $403 million per new drug.

Those out-of-pocket expenditures are *pre-tax* costs, however. Drug companies can and do deduct 34 percent of their R&D expenses under federal tax law. Therefore, the actual after-tax cash outlay for each drug in the new Tufts study is about $240 million, according to Public Citizen. But it must be stressed that the average R&D cost for each new drug brought to market is significantly less than $240 million because that figure applies only to the drugs used in the Tufts study.

The drug industry's own data show how DiMasi's sample of drugs is skewed toward the most expensive new products. DiMasi puts clinical trial outlays at $282 million per drug, which accounts for 70 percent of his $403 million in total out-of-pocket expenditures.

But according to the drug industry's trade association, the Pharmaceutical Research and Manufacturers of America (PhRMA), clinical trials accounted for only 29 percent of all industry R&D expenses in 1999 (the latest year for which such data is available).

The Tufts Center figure is important because it is used by the drug industry to defend its extraordinary profits and rising prices. In its last study on the cost of developing a new drug, completed in 1991, the Tufts Center – which receives 65 percent of its funding from drug companies – pegged the figure at $231 million. PhRMA used that in its calculations to conclude that the cost of developing a new medicine, including successes and failures, had grown to $500 million. PhRMA then claimed that any attempt by federal or state governments to moderate drug prices would harm R&D innovation.

But Merck CEO Raymond Gilmartin, who attended the Tufts Center event in Philadelphia, contradicted PhRMA's assertion. Gilmartin said there was no direct link between R&D costs and prescription prices. "The price of medicine is not determined by research costs," Gilmartin stated. "Instead, it is determined by their value in preventing and treating disease." Gilmartin's statement clearly undermines PhRMA's claim that prices are connected to R&D costs.

The updated Tufts study used the same methodology as the 1991 study, which also was prepared by DiMasi. In July 2001, Public Citizen published a detailed critique, *Rx R&D Myths*, of the original DiMasi study. It demonstrated that the actual after-tax cash outlay for developing a new drug, including failures, was $110 million – about 75 percent less than PhRMA's $500 million estimate

including failures, was $110 million – about 75 percent less than PhRMA's $500 million estimate. Public Citizen's analysis was based on a major study analyzing the DiMasi report prepared by the congressional Office of Technology Assessment (OTA).

PhRMA commissioned the accounting firm of Ernst & Young to respond to the Public Citizen report. Public Citizen rebutted to the Ernst & Young critique.

Ernst & Young failed to rebut Public Citizen's separate findings that were based on PhRMA data, which showed R&D costs for all new drugs brought to market (including failures) to range between $71 million and $150 million. This analysis (contained in Section II of *Rx R&D Myths*) was not based on the DiMasi methodology but on PhRMA's own claims about how much the industry spends on R&D compared with the number of new drugs approved by the Food and Drug Administration.

Click here for a more detailed critique of the DiMasi report.

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