

Drug R&D costs queried

A new report estimating the cost of developing a medicine has been attacked by the United States consumer group Public Citizen for being an over-calculation. The report, released by the Tufts Center for the Study of Drug Development, Boston, estimates the expense at \$802 million in FY00 dollars—a major increase on their last estimate in 1991 of \$231 million in FY87 dollars. Public Citizen claims today's costs are closer to \$240 million.

The Tufts data was compiled from a survey of 10 pharmaceutical companies. The analysis ranged from the cost of preclinical research to the expense of clinical studies using a sample of randomly selected investigational compounds. However, Bob Young, Research Director at Public Citizen, claims that the drugs chosen were not "...representative of new drugs because none received any support from government during development." He says that most drugs receive some government backing if only at the basic disease research stage.

Young also claims that the clinical costs are overblown. "This report puts them at \$282 million after tax whereas congressionally mandated research shows that clinical trials cost \$75 million on average. And according to the drug industry's own trade association, the Pharmaceutical Research and Manufacturers of America, clinical trials accounted for only 29% of all industry R&D expenses in 1999, the latest year for which such data is available," he says.

Ken Kaitin, the director of Tufts, responds that Public Citizen is basing its assessment of clinical costs "on an old report that harps back to orphan drug trials, which are much smaller than the regular trials." He adds, "The bigger the trial, the more expensive the clinical aspect, and these days much R&D involves multicenter trials." The clinical research phase has seen the biggest increase in costs since the last Tufts study a decade ago and Kaitin points to more expensive monitoring equipment and expanded regulatory requirements

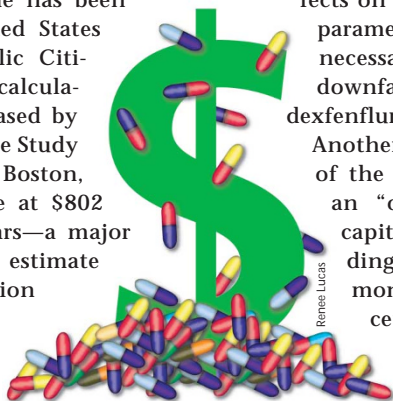
such as the determination of drug effects on long QT syndrome, a parameter which it has been necessary to record since the downfall of the diet drug, dexfenfluramine.

Another criticism is that half of the \$802 million sum is an "opportunity costs of capital" factor, corresponding to the amount of money that pharmaceutical manufacturers have tied up in R&D that could be invested to make money. Kaitin's reply is that all busi-

nesses prepare financial statements in this way and that they also use pre-tax figures—Young argues that companies are able to deduct 34% tax from their R&D costs.

The Tufts Center is affiliated with Tufts University. It receives 65% of its funding in the form of unrestricted research grants from the pharmaceutical industry. Kaitin emphasizes that this is a no-strings-attached funding system and that industry does not direct the group's research agenda. A copy of the Tufts report can be seen at <http://www.tufts.edu/med/csdd/Nov30CostStudyPressRelease.html>.

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RAE reveals drastic improvement in UK research

Biomedical researchers working in British universities were given a gold star for effort late last year when the results of the 2001 Research Assessment Exercise (RAE) were published in December. All but 4 of the 22 institutions that entered their biomedical research staff in the exercise were judged to have improved the quality of their research since the last review in 1996. But universities will become the victims of their own success if funds are capped to meet the increased payout due for achieving more widespread higher-ranking scores.

The 2001 RAE is the fifth to run since the scheme began in 1986, when 1,000 departments were asked to supply their 5 best academic publications for grading. Carried out every five years, its results are used by funding councils to selectively distribute a billion pounds of government money for research infrastructure. The RAE is designed to channel the most money to the best people, so departments with the highest scores receive the most funding, and those performing poorly get no money.

The latest RAE is the biggest yet with 60 subject panels assessing the work of almost 50,000 researchers. In addition to published research papers, the evalua-

tion panels analyzed other factors including the number of postgraduate students, external research income and invitations to international conferences to score each research department on a 7-point scale. The top 5 and 5* grades are reserved for departments where a significant proportion of staff are judged to carry out research rated as internationally excellent.

For biomedical research, more than three-quarters of the departments entering the 'Clinical Laboratory Sciences' (CLS) subject review in 2001 were awarded one of the top two grades—up from about a quarter in 1996. The CLS division encompasses a range of fields including molecular and cellular pathology, immunology, virology and medical physics. Neuroscience, infection and immunology, cardiovascular medicine and

cancer studies were investigated separately by four sub-panels. The improvement within biomedical research mirrors a rise in grades across the research board. Some 55% of UK re-

searchers now work in university departments rated as 5 or 5*, up from 31% in 1996.

The Higher Education Funding Council for England calculated that giving out money this time around—based on the 1996 formula—would leave it

