The Bizarre World of Health Care (1)

What Price a Drug?

Every drug has its price. It's always $802 million. Reflections on a magic number of doubtful value.

NEW SERIES!

Everybody knows the magic number. The average cost of developing and marketing a new prescription drug is a whopping $802 million. This oft-cited figure is high and very impressive. Whenever a debate about overpriced drugs and excessive company profits arises the major pharmaceuticals start blubbing and wailing and then make hurried reference to their $802 million investments. $802 million per drug to save lives. $802 million per drug to ease the pain of the sick. $802 million gone up in smoke before a new wonder pill even reaches the market. 802,000,000 bucks! Good God, these pharmaceutical welfare companies lead truly perilous, altruistic lives!

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The irritating figure of $802m is the most frequently mentioned in media coverage overall, used not only in reference to drug development but also medical issues in general. But one thing has always bothered me: why in the world does absolutely everyone refer to $802m? Why hasn't this sum increased over the years? By what miracle has it avoided inflation? Why is it trotted out by developers of life-saving cancer drugs as well as by sleeping pill manufacturers and wart salve producers? And, last but not least, why such a precise figure? I have always wondered why nobody ever rounded the magic number down to $800m.

So, the unasked question has to be: where did this $802m originate? Which clever dick discovered, calculated – or invented – the magic number?

This last question can be answered simply. The $802m figure arose in 2003 after Joseph Dimasi's group at the Tufts Center for the Study of Drug Development in Boston, published a wave-making analysis of the cost of drug development (*Journal of Health Economics* 2003, 22(2), 151-85). The scientists used confidential data on 68 new drugs produced by ten pharmaceutical firms to estimate the total pre-approval cost of a new drug. The paper's bottom line was that the magic number of $802m corresponds to "the average pre-tax cost of new drug development". To date, this study (and its forerunner from 1991 (Dimasi *et al., Cost of innovation in the pharmaceutical industry. Journal of Health Economics* 1991, 10, 107-142) has been cited again and again, many thousands of times.

In their 2003 analysis, Dimasi *et al.* stated that the average cost of discovering and developing a new drug, including those that do not make it to market, had risen from $231 million in 1987 to $802 million in 2003. The Tufts Center researchers included the high cost of failed research programmes as well as the drug companies' 'opportunity cost of capital' (meaning the diminishment of the expected return due to a bypassing of other potential investment activities). They stated that costs had "continued to skyrocket" (according to Tufts Center Director, Kenneth Kaitin).

So much for the theory. And now for something completely different. In practice, Dimasi's findings are disputable. Firstly, the source of his data stinks. They were provided by drug manufacturers who were, of course, interested in increasing Dimasi's cost estimate. Secondly, the Tufts Center is part-funded by pharmaceutical companies, implying possible conflicts of interest. Thirdly, the Tufts scientists neglected to consider public research grants and tax reimbursements. And, finally, they only included new chemical entities (NCEs) in their study, which are by far the costliest to develop.

But the problem is deeper and more pernicious than this. Pharmaceutical companies have a clear interest in producing higher estimates of drug development costs, so it is hardly astonishing that they are keen to shout findings like Dimasi's from the rooftops. In policy debates, high development costs are the perfect justification for slapping high prices onto the resulting drugs (not to mention providing a watertight excuse for a good whinge). A recent paper, published by Donald Light, Professor of Comparative Health Care at the University of Pennsylvania, criticises the fact that the data used by Dimasi's team cannot be verified independently (D.W. Light *et al.*, *Extraordinary claims require extraordinary evidence. Journal of Health Economics*, 2005, 24(5), 1030-1044).

Other authors claim considerably lower drug development costs. In 2001, the Global Alliance for TB Drug Development published a comprehensive, 168-page report on estimating development costs for a new anti-tuberculosis drug (*www.tballiance.org/pdf/Economics%20Report%20Full%20(final).pdf*). In conclusion, the total cost (including failure costs) was estimated to range from $115 million to $240 million – slightly cheaper than Dimasi's $802 million.

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In any case, such studies are naïve fallacies. Is it really advisable to put entirely different drug development projects in a huge basket and – abracadabra! – pull out a magic figure like $802m for each of them? It would make more sense to measure apples and bulbs in order to calculate the typical size of a hen's egg.

By the way, Dimasi and colleagues continue to work on apples and bulbs. Recently they published an extension of their 2003 paper on pharmaceutical drugs. This time they calculated the average cost of developing a new biotechnology product (*http://csdd.tufts.edu/NewsEvents/NewsArticle.asp?newsid=69*). It is $1.2 billion, they say.

Gripping stuff.

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