

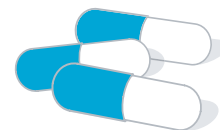


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How should the value of new drugs be determined?



The amounts spent on drugs in the Canadian health care system have risen sharply over the last few years. In this context, the cost of new patented drugs is a source of controversy. According to an increasingly widespread view, most patented drugs, other than a few truly innovative products, are just "me-too" copies, with no value added, that cost less to produce than we are told. How much are new drugs really worth? And who should end up deciding whether their use is justified?

Figures called into question

Those opposing new drugs use two main arguments aimed at challenging their added value.

1. The pharmaceutical industry is accused of exaggerating the costs of researching and developing new active substances, which were laid out in a series of studies conducted by J.A. DiMasi and his colleagues at the Center for the Study of Drug Development (CSDD) at Tufts University in Boston.¹ Costs in the United States prior to approval by the Food and Drug Administration (FDA), recalculated in 1993 by the Office of Technology Assessment (OTA) of the U.S. Congress and later by other researchers, have been estimated at about US\$500 million (in 2000 dollars). This is the figure most often cited in this controversy.

This number is challenged, however, by opponents of new drugs. According to the consumer-advocacy organization Public Citizen, which used the same data as the study by DiMasi *et al.* (1991), costs are closer to US\$110 million² in 2000 dollars. The Public Citizen estimates differ from the CSDD estimates essentially on two points. They do not take account of the cost of capital used throughout the process (lasting about 12 years), amounting to about half of R&D costs, and they assume that R&D costs should be calculated on an after-tax basis since R&D spending, like all other spending, is deductible from corporate income taxes.

2. Opponents assert that the great majority of drugs are just duplicates of existing drugs, with minimal or zero value added. Public Citizen cites an FDA classification according to which 53% of new drugs approved in the U.S. between 1982 and 1991 represented little or no therapeutic improvement and only 16% represented a major therapeutic improvement. In Canada, opponents of new drugs suggest that the public authorities should refuse, or at least limit, the availability of copies to patients by rejecting their inclusion on provincial lists of drugs paid for by the public system.

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Arguments that remain ignored

Opponents of new drug are ignoring several arguments in their evaluations, however.

1. Their R&D cost estimates, found in sources such as the Public Citizen report, are based on a methodology that "deviates from standard methodologies adopted by previous research and the financial and accounting communities."³ The cost of capital is taken into account by all investors when evaluating an investment project, and this cost rises with the risk and duration of

¹ The main study is J.A. DiMasi, R.W. Hansen, H.G. Grabowski & L. Lasagna (1991), "Cost of innovation in the pharmaceutical industry," *Journal of Health Economics*, 10 (2), pp. 107-142.

² Public Citizen (2001), "Rx R&D Myths: The case against the drug industry's R&D 'scare card'," available at <http://www.citizen.org/publications/release.cfm?ID=7065&secID=1078&catID=126>.

³ Ernst & Young (2001), "Pharmaceutical Industry R&D Costs: Key Findings about the Public Citizen Report," *Ernst & Young LLP*, p. 1, available at <http://www.phrma.org/mediaroom/press/releases//2001-08-11.277.pdf>.



an investment. Because of this, it is illogical not to factor in these costs and to pretend that tying up capital for more than a decade is cost-free.

In addition, it is arbitrary and unjustified to calculate R&D costs after taxes in reflecting the resources that companies put into new drugs. Corporate income tax is a tax on profits and “deductions for R&D and other business costs are the means used to approximate the appropriate base for the tax (revenues minus costs),”⁴ thereby avoiding double taxation. As a result, “the pre-tax value of pharmaceutical R&D expenditures more accurately reflects the true value of the resources that must be devoted to this activity.”⁵

As the OTA confirms, the R&D cost estimates by DiMasi *et al.* (1991) “are reasonably accurate.”⁶ A more recent study by the same team using the same methodology evaluates these costs at US\$802 million in 2000⁷ and at about US\$900 million altogether if the costs of post-approval tests required by the FDA are included.

2. By its nature, the process of

innovation results mostly in incremental improvements, whatever the area of technology. According to Wertheimer *et al.*, “the history of pharmacology is characterized by incremental improvements in the safety, efficacy, selectivity, and utility of drugs.”⁸

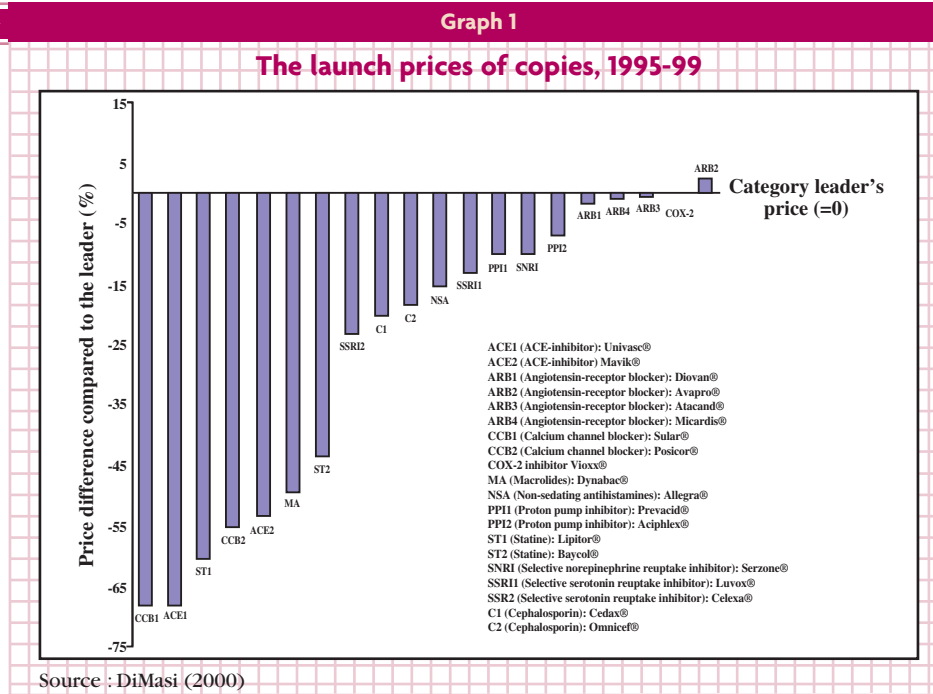
Once approved and used on a large scale, breakthrough drugs

often show failures. From a medical standpoint, the fact that several copies are available offers advantages over the existence of a single pioneering drug. In case the latter is withdrawn or a treatment fails, doctors are able to replace it with another drug providing a similar treatment. Moreover, each patient reacts differently to drugs, and the existence of various active substances for the same illness allows for treatment to be personalized.

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Copies also have economic advantages. Incremental improvements may lead to major improvements in the well-being of patients. For example, a reduction in side-effects (vertigo, vomiting, digestive problems, etc.) or pain can enable people with illnesses to lead normal lives and become productive again more quickly. Consumers (but also employers) may be willing to pay more for an improved version of an older drug.

Copies offer greater choice to consumers and to third-party payers (governments as well as insurance companies), and they strengthen competition. They are usually introduced at lower prices to gain market share at the expense of existing products. In the United States, a study⁹ on 20 new drugs launched between 1995 and 1999 concluded that



⁴ J.A. DiMasi, R.W. Hansen & H.G. Grabowski (2003), “The price of innovation: new estimates of drug development costs,” *Journal of Health Economics*, 22 (2), p. 174.

⁵ Ernst & Young (2001), *op. cit.*, p. 3.

⁶ Office of Technology Assessment (1993), “Pharmaceutical R&D: Costs, Risks and Rewards,” p. 66, available at http://www.wws.princeton.edu/~ota/ns20/alpha_f.html.

⁷ J.A. DiMasi, R.W. Hansen & H.G. Grabowski (2003), *op. cit.* In *The \$800 Million Pill* (University of California Press, 2004), M. Goozner challenges these estimates but without bringing any new arguments to the debate.

⁸ A. Wertheimer, R. Levy & T. O’Connor (2001), “Too many drugs? The clinical and economic value of incremental innovations,” *Investing in Health: The social and Economic Benefits of Health Care Innovation*, Vol. 14, p. 80, available at <http://www.npcnow.org/resources/PDFs/toomanydrugs.pdf>.

⁹ J.A. DiMasi (2000), “Price trends for prescription pharmaceuticals 1995-1999,” A background report prepared for the Department of Health and Human Services’ Conference on Pharmaceutical Pricing Practices, Utilization and Costs, available at <http://aspe.hhs.gov/health/reports/Drug-papers/dimassi/dimasi-final.htm>.



every copy except one was marketed at prices up to 70% lower than the category leader (see Graph 1). This had the effect of containing drug spending. These drugs accounted for more than half of prescription drug sales in 1999. Moreover, their presence made buyers better able to obtain discounts from producers.

Copies can sometimes be more expensive on a unit basis, but the overall treatment may cost less and require less additional care. In addition, copies ensure a steady income stream for pharmaceutical companies since “no mature industry can sustain itself on income from breakthrough innovation alone.”¹⁰ Any policy that artificially limits the market entry of copies would have the perverse effect of raising risk in the industry and making new pioneering drugs – whose therapeutic and economic value is challenged by nobody, not even by opponents of new drugs¹¹ – even more expensive.

Individual preferences

In any discussion on the value of drugs, it is essential to take account of the individual preferences of patients, who are the ultimate beneficiaries of new products. Modern economic analysis holds that the value of a good or service is determined not by costs (including R&D) but rather by individual satisfaction, which consumers are willing to make sacrifices to obtain. In this regard, economist John Calfee emphasizes that “the basic criteria for the value of new drugs should be the benefits to consumers rather than the benefits to governments or other providers of health care.”¹²

Consequently, in determining the value of a new drug, it is necessary to let patients decide, directly or indirectly, whether or not the benefits exceed the costs of new drugs. These decisions depend on a broad variety of therapeutic and economic factors, and patients make these decisions based on many sources of information, including information provided by their doctors. Such decisions obviously imply that patients assume, in one way or another, the costs of their drug use, either by

paying for drugs directly or by paying insurance premiums based on their preferences. The drug and insurance markets are thus closely linked.

The involvement of public authorities in Quebec and elsewhere in Canada, as well as in most other developed countries, has come increasingly to take the place of individual choice in drugs. In 1997, the Quebec government set up a compulsory drug insurance plan by extending public coverage to all people not covered by private insurance. At least some of these people – who until then could make individual evaluations of the costs and benefits of drugs and who covered their spending personally where required – were forced to join the public plan. This public insurance plan places a growing burden on Quebec taxpayers. Drug spending by the public plan rose on average by about 17% per year between 1997 and 2003.¹³

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The determination of public authorities to hold back this explosive increase in spending shows itself in particular in the restrictions on the number of drugs reimbursed, as listed in Quebec’s drug formulary, the *Liste de médicaments* (similar restrictive mechanisms exist in other provinces). This formulary – “the primary instrument for controlling demand”¹⁴ – specifies which drugs, from among those authorized in Canada, must be covered by public insurance as well as by all private insurance plans.

The listing of new drugs is a difficult exercise: they must be examined in terms of both therapeutic and budgetary value by the *Conseil du médicament du Québec* or by similar government bodies in other provinces. In seeking to reduce costs, however, public authorities risk underestimating the benefits of new drugs. Even if the *Conseil’s* membership consists of doctors, pharmacists and experts in health economics, its

¹⁰ A. Wertheimer, R. Levy & T. O’Connor (2001), *op. cit.* pp. 108-9.

¹¹ On the economic benefits of pioneering drugs, see F. Lichtenberg (1996), “Do (More and Better) Drugs Keep People Out of Hospitals?,” *American Economic Review*, Vol. 86, Issue 2, which finds that each additional dollar spent on new drugs reduces other expenses by US\$3.25. See also the study by the Analysis Group/Economics (2002), “The value of pharmaceuticals in Canada,” UQAM, available at http://www.canadapharma.org/Media_Centre/Special_Reports/The%20Value%20of%20Pharmaceuticals%20in%20Canada%20-%20Full%20Report.pdf.

¹² John E. Calfee (2000), *Prices, Markets, and Pharmaceutical Revolution*, AEI Press, p. 35, available at http://www.aei.org/publications/bookID.196,filter./book_detail.asp.

¹³ Data from the *Régie de l’assurance-maladie du Québec*; calculations by the author.

¹⁴ Montmarquette Report, or *Rapport du Comité sur la pertinence et la faisabilité d’un Régime universel public d’assurance médicaments au Québec*, “Pour un régime d’assurance médicaments équitable et viable,” (Report of the Committee on the suitability and feasibility of a universal public drug insurance plan in Quebec, “For a fair and viable drug insurance plan”), December 2001, p. 25, available at <http://206.167.52.1/fr/document/publication.nsf/4b1768b3f849519c852568fd0061480d/d858bba2a48916fb85256b1f006c7078?OpenDocument>.



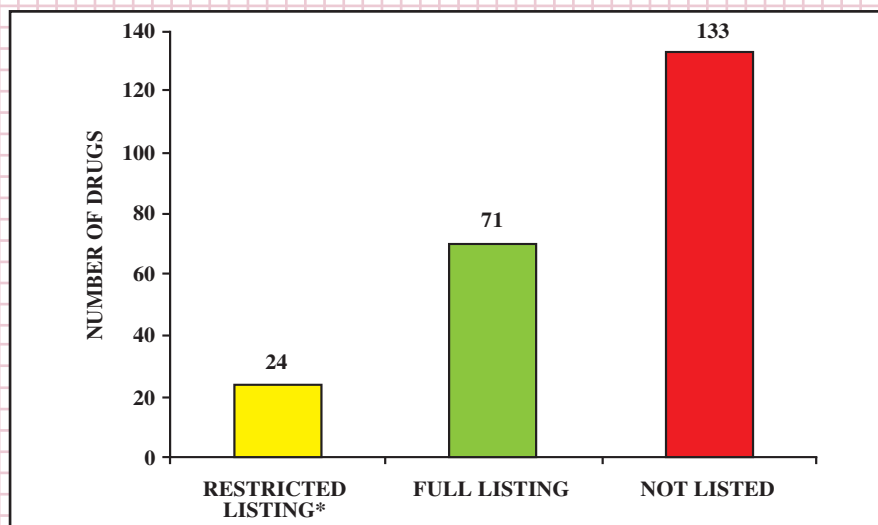
decisions can never replace, nor even reflect fully, the medical opinions of all health professionals or the economic choices of patients. It is impossible for it to determine the value of drugs on a scientific basis because the collection and centralization of the pertinent information forces it to make numerous arbitrary judgments on a great number of variables.

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In the case of private insurers' drug formularies - where they exist - it is clear that the people covered by insurance, acting with advice from their doctors, end up deciding whether or not to validate these judgments. With Quebec's compulsory formulary, nothing of the sort is possible, and there is no option allowing the *Conseil's* evaluation to be called into question. The *Conseil* takes the place of patients in deciding if the price of a new drug is too high and whether its use is economically justified. It also takes the place of health care professionals in judging where a drug is sufficiently effective in therapeutic terms. In Quebec, which nonetheless has one of the most complete formularies among the Canadian provinces, 133 drugs were rejected between 1995 and 2000 (see Graph 2). Cost control policies can only accentuate this trend.

Graph 2

Listing in Quebec of drugs launched between 1995 and 2000



*Drugs available on an exceptional basis with prior authorization from the public insurance plan.

Source : Rx&D, Canada's Research-Based Pharmaceutical Companies, *Quebec Drug Benefit Plan*, available at: http://www.canadapharma.org/Patient_Pathways/Drug_Plans/QC_e.html.

Conclusion

The drug formulary creates an obstacle to learning the true value of new drugs and facilitating their use by people covered under the public insurance plan. For these people to be able to obtain the full therapeutic benefits they consider valuable, it will be necessary to set up a drug insurance system that allows more room for individual choice.

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