Rebuttal: Are drugs too expensive in Canada?

YES

Joel Lexchin, MD, MSC, CCFP (EM)

When used properly, drugs can deliver value for money, but only about 10% of the drugs brought to market offer any substantial therapeutic value over existing medications. For example, for treating uncomplicated hypertension, older diuretics at pennies a day have proven just as good as, if not superior to, angiotensin-converting enzyme inhibitors and calcium channel blockers that cost more than $1 a day.1

Companies do not reflect the relative value of drugs in the prices they set. For new patented drugs marketed in Canada, prices are typically set at the level of the most expensive product in their therapeutic group, regardless of whether they offer any incremental therapeutic value.2 Companies charge what they think the market will bear, not what it costs to produce the drug.3 When people are ill, cost takes second place; witness the fight to get trastuzumab (Herceptin) covered despite its $35 000 price tag.4 When drugs come off patent and generic products appear, brand-name companies still refuse to engage in price competition.5

The pharmaceutical industry typically ignores costs associated with the side effects of medications. Although there are no Canadian figures, estimates from the United States suggest that more than 100 000 deaths a year are associated with adverse effects of medications.6 Many of these problems could stem from aggressive promotional practices. When the heavily promoted cyclooxygenase-2 (COX-2) inhibitors were introduced in Ontario, hospital admissions for gastrointestinal bleeding actually rose7 despite the COX-2s' alleged gastrointestinal protection. The situation with COX-2 drugs and antihypertensives illustrates the problem of relying on simplistic, uncontrolled analyses of cost savings,8 such as that of Lichtenberg referred to by Mr Williams.

Mr Williams mentioned pharmaceutical companies’ investment in research and development, but neglected to point out that, as a percentage of sales, investment steadily dropped from 12.9% in 1997 to 8.5% in 2004.9 When basic research that actually discovers new drugs is looked at separately and tax credits are factored in,

NO

Russell Williams Jean Marion, PhD

When discussing the therapeutic value of new medicines, industry critics refer to the entry of new active substances in the second category established by the Patented Medicine Prices Review Board (PMPRB) (ie, 10% of new active substances introduced from 1999 to 2004). During the same period, 32% of new active substances (including biologics—such as immunizing agents; drugs obtained by recombinant DNA procedures; drugs other than antibiotics prepared from microorganisms; and products derived from animal and human fluids, tissues, and organs) approved by Health Canada and 45% of new molecular entities (including certain biologics starting in 2004) approved by the Food and Drug Administration's Center for Drug Evaluation and Research, had priority review status,1,6 meaning there was substantial evidence for significant improvements or effective treatment when no other drug had been approved.

Health Canada considers priority review status in the context of serious, life-threatening, or debilitating illnesses. We wonder, then, to what extent the PMPRB number reflects the therapeutic value of new active substances.

While complex and costly, pharmaceutical research and development (R&D) can offer important benefits when successful in yielding new medicines and vaccines. The approach used to estimate the cost of discovering and developing an approved new drug, $802 million (in 2000 US dollars or more than $1 billion Canadian),6 has been criticized. The analysis, published in 2003, builds on a similar 1991 study7 by the same group, and the authors responded to criticism in the second paper. More recently, this estimate has been verified using information from a large publicly available data set.8 This analysis yields an average cost per new drug of $868 million (US), although the estimate can vary widely depending on the therapy or the developing firm. Pharmaceutical R&D has a highly skewed distribution of returns.8 Ongoing research investment depends on the few drug products that recover or surpass their development costs, about 3 new approved compounds out of 10.9

These rebuttals are responses from the authors who were asked to discuss, “Are drugs too expensive in Canada?” in the Debates section of the May issue (Can Fam Physician 2006;52:573-6). In these rebuttals, the authors refute their opponents’ arguments.
the investment works out to less than 1 cent for every sales dollar.

The industry claims it costs about $1 billion Canadian to produce a new drug, but that $1 billion is worldwide costs. Canada represents about 2% of the world drug market, so a Canadian subsidiary should contribute about $20 million to development costs. Does $20 million justify the prices that companies charge?

Mr Williams says, “Prescription patented medicines purchased from manufacturers account for about 7 cents of each health care dollar,” but this is a distortion of what drugs really cost the health care system. Brand-name companies also sell off-patent medications and even generic drugs, and there are ancillary costs, such as transportation and dispensing fees, that should be factored in. Without these costs, no drugs would ever reach patients. In total, drugs now account for more than 16% of each health care dollar, well above the amount spent on doctors.10

Drugs that are the most effective treatments should be available to patients at reasonable prices. That recommendation should be made by impartial experts relying on the best available evidence, not by people who frequently have commercial ties to the companies whose products they are recommending.11

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References

Promotional activities are important, as they communicate information to health care providers and to some extent the public. Simply extrapolating the promotional costs from the United States to Canada is inappropriate. There are differences in market conditions and regulations between the 2 countries. All our members adhere to the Rx&D Code of Conduct10 and thereby agree to follow the Pharmaceutical Advertising Advisory Board’s Code of Advertising Acceptance and the guidelines of the Canadian Association of Medical Publishers.

The retail value of clinical evaluation packages or samples is included under promotional expenditures. We believe that these packages are useful to health care providers and beneficial to patients when used in accordance with the rules set out by the Food and Drugs Act and Regulations and the requirements of our Code regarding distribution, storage, disposal, and inventory audit. These packages can be dispensed by health care professionals only, and their main use is to begin immediate treatment, when needed.

How the business climate in Canada compares internationally also matters. Many countries are involved in the development of new medicines and vaccines that can contribute to improving patients’ health and well-being. For Canada to maintain or augment its participation, we need to develop and implement coherent policies that provide a more attractive environment for investment in pharmaceutical R&D as we compete with other jurisdictions for these investments. We should foster in Canada a culture that encourages greater collaboration in pharmaceutical R&D between researchers from industry and academic and hospital settings, recognizing the expertise and professionalism of all groups.

Mr Williams is President of Canada’s Research-Based Pharmaceutical Companies (Rx&D). Dr Marion is Director of Scientific Affairs for Rx&D.

References

Accessed 2006 April 27.