motions of the fingers), dry eyes, carpal tunnel syndrome, migraine headaches, repetitive stress injuries, sleep deprivation, disregard of hygiene and nourishment, social isolation, family discord, divorce, academic failure, job loss and debt. Wieland's survey of scientific literature on the incidence, symptomatology and treatment of IAD also indicated cognitive–behavioral therapies, self-help groups and psychopharmacological solutions like selective serotonin re-uptake inhibitors are among the most common interventions. — Compiled by Wayne Kondro, *CMAJ*

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Pulse

## Brand-name drug companies fail to meet R&D commitments

When the federal government enhanced patent protection for drugs roughly 2 decades ago, critics feared the end result would be soaring drug costs and conversion of the Canadian industry into little more than a re-packager of import bulk chemicals.

It appears those concerns were justified as the latest report of the Patented Medicine Prices Review Board (PMPRB) indicates Canadian spending on brand-name drugs continues to grow while company outlays for research and development (R&D) remain lower than promised.

The PMPRB's 2005 annual report indicates that overall drug sales rose by 1.3% to $16.1 billion, as patented drugs continued to gobble up an ever larger share (71.4%) of the overall drug pie, rising 5.5% to $11.5 billion.

Canadian spending on patented drugs had hovered around $2 billion per year, or about 43% of the pie, after the federal government passed Bill C-22 in 1987, giving new drugs protection from compulsory licensing for 7 to 10 years. But outlays began to increase after 1992, when Ottawa passed Bill C-91 extending patent protection for all brand-name drugs to 20 years. In exchange for the extended protection and essentially jettisoning the compulsory licensing regime, which had allowed generic firms to more readily make knock-offs, brand-name drug makers committed to increasing basic R&D spending to 10% of sales.

They got off to a rocky start by reducing manufacturing output in Canada and expanding outlays primarily in the areas of marketing and sales, arguing that was a necessary function of globalization. But as federal reports indicated the brand-name industry was failing to achieve the promised goal, Rx&D, (Canada's Research Based Pharmaceutical Companies then known as the Pharmaceutical Manufacturers Association of Canada) began aggressively campaigning to include all clinical trials in the calculation. This has since become the norm.

Yet even including all clinical trials (phase I to IV), as well as other non-basic R&D outlays, such as costs for drug regulation submissions and bioavailability studies, PMPRB's 2005 report indicates brand-name drug makers have an R&D-to-sales ratio of 8.8% in Canada. After a 2-year decline in overall R&D spending, outlays rose 5.5% to $1.234 billion, but for the third consecutive year the R&D-to-sales ratio fell below 10%.

The basic R&D picture is even gloomier. Outlays dropped 3% to $215.1 million and now constitute but 18.2% of brand-name company R&D expenditures in Canada (Fig. 1). Spending on applied R&D (primarily clinical trials) constituted 62.4% of outlays, while that on other qualifying research, like drug regulation submissions, was 19.5%.

In short, the promise to spend 10% of sales on basic R&D actually translated into something on the order of 2% in 2005.

Rx&D declined all comment other than a formal statement from President Russell Williams, which asserted the shortfall is a direct function of deficiencies in federal intellectual property law and likely wouldn't change until the federal government created an internationally competitive "innovation and commercialization environment."

But Williams was encouraged by proposed amendments to drug regulations "that would provide 8 years of data protection for pharmaceuticals, and additional 6 months of data protection for medicines that have been the subject of clinical trials in children. These amendments will impact future life sciences innovation in a significant way. Therefore, Rx&D urges the federal government to implement these important changes immediately." Williams offered no comment on whether the changes might compel significantly larger basic research investments by member firms. — Wayne Kondro, *CMAJ*

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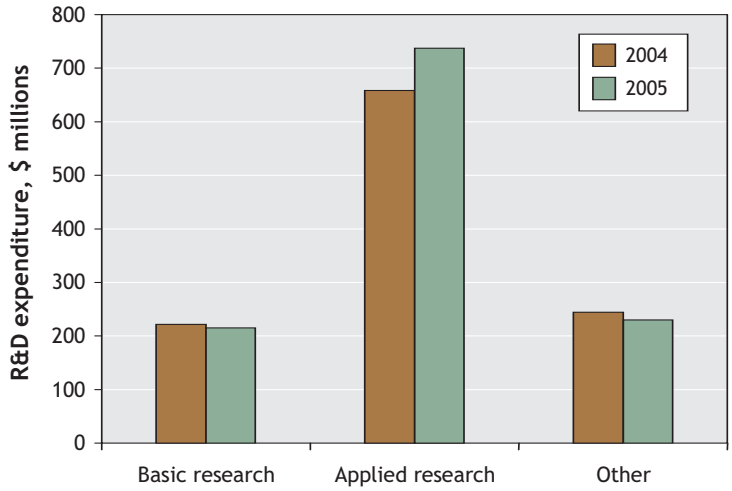


Fig. 1: Brand-name pharmaceutical company spending by category of research. Source: PMPRB