## Cost of drug patent changes exaggerated

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Canada is being asked to bring intellectual-property protection for medicines up to international standards as part of the trade agreement being negotiated with the European Union.

The changes might increase what we'll have to pay for medicines in the future. Experts writing in the Post are sharply divided on the possible impacts.

Brett Skinner of the Canadian Health Policy Institute pointed out that prescription drugs accounted for only 9% of government spending on health care in 2010 and that this percentage had declined over time.

His conclusion was: "Don't blame the drugs." However, government spending is only part of the story.

Over half the pharmaceutical bill in Canada is paid for by employer drug plans and by patients themselves.

In contrast to Mr. Skinner, John Greiss, a pharmacist, claims the drug bill could rise by 22%, a \$2billion to \$3-billion annual increase. Who is right and what could the impacts really be?

Most of the gains in intellectual-property protection for brand-name drugs would come from "Patent Term Restoration" (PTR). This measure is designed to compensate firms for the loss of patent lifetime caused by lengthy regulatory review processes.

To arrive at a 22% increase in drug prices, you need to assume that all eligible drugs are awarded PTR.

However, European experience shows that only about half such drugs receive PTR. In this scenario, the cost increase could be in the order of 11% and would likely be less given that Canada is very abstemious in awarding and protecting intellectual-property rights.

What's more, any extra protection would be applied only to drugs that come to market after the agreement is signed in 2014. Given the way that intellectual-property rights work, the increased costs would first be seen in 2022.

Between now and 2022, the pharmaceutical market will change dramatically. Many blockbuster drugs such as Crestor, Singulair, and Plavix have recently either lost market exclusivity or will do so in the next couple of years. Patients will expand their use of less expensive, generic versions of brand-name drugs.

Indeed, provinces and major private insurers such as Sun Life and Great West Life are strongly encouraging generic dispensing. Let's also not forget that intellectual-property protection is not iron-clad and patents are often overthrown for arcane reasons.

Viagra recently lost patent protection when the Supreme Court determined that information about the active ingredient was not properly disclosed. Overturned patents open the door to more generic drugs and lower costs.

On the other hand, some pharmaceutical costs will increase between now and 2022. The drug-development pipeline has many drugs for diseases affecting small patient populations.

These include advanced cancer treatments. Given that the R&D cost has to be amortized over small numbers of patients, these drugs will necessarily be more expensive than the norm. In short, predicting what will happen to the drug bill by 2022 is fraught with uncertainty.

Bringing intellectual-property rights up to international norms makes sense. It establishes Canada as a serious player in a lucrative high-tech industry. In a worse-case scenario, we might be looking at increases in drug costs of a size that can be counterbalanced by the discounts and rebates routinely negotiated between suppliers and payers.

What should we do? The obvious approach is to finalize the trade deal, bring our intellectual-property protection up to international norms, use generic drugs where appropriate, and for payers to negotiate effectively on brand-name pharmaceutical pricing.

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