Why older, middle-class Canadians will be taking a more active role in paying for the cost of healthcare

And what this means for the pharmaceutical industry

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February 19, 2013 – At a recent pharmaceutical conference we attended in Toronto, there was a discussion about the current difficulties of getting market access for new drugs. "*We developed a comprehensive argument about the value of our therapy for patients*" commented one pharmaceutical delegate, "*but payers were not at all interested; they were only concerned about the price. We didn't know how to communicate the patient-value of our drug to payers!*"

Yet, maybe we should not be too surprised. Tremendous pressures are being placed on healthcare budgets given the needs of aging populations, the extent of current medical innovation and specifically, the number of costly new therapies being developed by the pharmaceutical industry. In this context, public and private payers are looking to negotiate the best price for new drugs in exchange for allowing market access. In reality, whether or not discussed during negotiations, payers will also take account of the health benefit of new therapies, with an overall view about where best to allocate resources. Hard choices are being made, with some patients remaining uncovered for some of the expensive new drug treatments.

Now put yourself in the shoes of a patient with a serious disease, and you will have quite a different perspective. How much would you be willing to pay to save your life? How much to improve your chances of survival, or to significantly improve your quality of life? How much would you lobby your payers to allow you access to the latest drugs if you felt they gave you a better chance? For most of us, there isn't much we wouldn't do in these circumstances!

Internationally, such patient demand can translate into very effective pressure for drug availability. A case in point is with the breakthrough cancer drug, *Gleevec*, which achieved FDA fast-track approval in May 2001. As then-Novartis CEO Daniel Vasella described in his book *Magic Cancer Bullet*, patient pressure was a huge factor in how quickly Gleevec was developed and adopted. The internet plays a big part in this. Pharmaceutical companies have long been constrained about what they can say directly to consumers; yet the internet allows pro-active patients to keep abreast of medical developments, and allow them to connect and collaborate. Gleevec was launched at a worldwide price of US$2,200 a month, with an assistance program designed for less well-off patients.

Over the 10 years since Gleevec was launched, many more therapies for serious diseases have become available – notably, but not exclusively, with growing usage of biotech drugs. They are often very expensive on a per-patient basis, which takes into account the great costs of developing and producing these drugs, and that these costs are often shared by a relatively small number of patients. For pharmaceutical companies, this pricing business model is quite different from one which relies on profits from blockbuster drugs, such as Lipitor or Losec, taken by millions of people.

Another change has been the zeitgeist for patients to take more control over their own healthcare. Such an idea is being popularized by books like Dr. David Agus' *The End of Illness* and Jane Fonda's *Prime Time,* which embrace the idea that if you take responsibility for looking after your wellness, you can live healthily and active throughout life. The *End of Illness* in particular extols the benefits of personalized

medicine, and knowing the risks associated with your own particular genetic make-up. This can make a big difference later in life when we are more vulnerable to serious diseases, or as Dr. Agus puts it '*It's not a coincidence that most cancers emerge after our child-bearing years. In the fourth and fifth decade of life, evolution doesn't have much interest in protecting us anymore... Most of us lose nature's policing, if you will, once we reach middle age'*.

Healthcare systems can vary quite markedly by country and Canadians might be forgiven for thinking that since there is public health care in Canada, consumers generally do not have to worry about the cost of expensive drugs should they require them. Yet Canadians should not be so sanguine given the strategies that public and private insurers currently use to approve drugs and manage healthcare budgets. These strategies can leave consumers exposed to significant healthcare costs – and hard work – to receive the new treatments. Let's first consider the access that Canadians have had for the treatment of colorectal cancer with Avastin (bevacizumab), prior to public coverage for the majority of Canadians.

Intravenous cancer drugs like Avastin, are typically funded publically, but this can involve lengthy approval processes and stringent criteria for coverage. Avastin was approved by Health Canada in 2005 for the treatment of colorectal cancer, yet many Canadians did not have public coverage for the treatment of this disease until 2009. Roche, and physicians affiliated with the Princess Margaret Hospital from the University of Toronto, studied patient access to Avastin from 2006 to 2008, which fell in the period 'post-approval and pre-public coverage'. The results were published in an abstract and poster in the Journal of Clinical Oncology[1] in 2009. The study considered 877 colorectal cancer patients who had applied for Avastin through the Canadian Roche Patient Assistance Program; a program designed to offer patients reimbursement navigation, financial assistance and/or infusion advice. From these 877 patients, around three-quarters had private insurance, and the rest were uninsured. Around half of those with private insurance were still denied coverage with Avastin. In all, 255 patients (29%) elected to pay for Avastin themselves.

This Roche study was concerned solely with understanding access to Avastin amongst patients with an approved condition for the drug – those patients with colorectal cancer. Yet, given the life-threatening dangers of cancer, physicians have a great deal of discretion to prescribe cancer drugs, such as Avastin, for non-approved uses. This is known as 'off-label' usage. Although not speaking specifically to what is happening in Canada, according to Dr. Agus, '*as much as 75% of cancer drug use is of this off-*

[1] Patient out-of-pocket and insurer payment decisions for bevacizumab for metastatic colorectal cancer: A Canadian analysis **S. Yunger, P. Douglas, P. Anglin, M. Crump, S. Lepage, D. Shum, L. Phillips and D. Milliken** Hoffmann-La Roche Canada, Mississauga, ON, Canada; Princess Margaret Hospital, University of Toronto, Toronto, ON, Canada, Journal of Clinical Oncology, 2009 ASCO Annual Meeting Proceedings (Post-Meeting Edition).Vol 27, No 15S (May 20 Supplement), 2009: 6576 - http://meeting.ascopubs.org/cgi/content/abstract/27/15S/6576?sid=37951dcc-23b8-4926-b181-caae07450991

label variety[2]. Canadian patients put in this situation will likely have to work very hard to get coverage given that, according to a 2009 report by the Canadian Cancer Society[3], almost all private insurers and public formularies state that they would not cover off-label usage.

Patient engagement with drugs can also vary quite markedly by disease. With Hepatitis C, two new drugs were approved by Health Canada in 2011 – Victrelis (boceprevir) and Incivek (telaprevir). From a recent conversation with a Toronto-based Hepatitis C nurse, I was told that given the route of transmission, the majority of her Hepatitis C patients are quite disadvantaged. These patients are usually people who had been infected during drug usage, or are immigrants to Canada. Typically they would have few financial resources, little access to information and little understanding about the steps needed to take care of themselves. All this led, in her opinion, to a huge difference between how these disadvantaged people were able to take care of their disease compared to the relatively few middle-class/professional Hepatitis C patients she treated.

Victrelis has publically-funded coverage in Ontario and, with a list price of CAN$1,050 per week, there are well-defined reimbursement criteria for what types of Hepatitis C patients are covered and not covered. Specifically, eligible patients must have evidence of fibrosis, with standard therapy duration of 24 weeks, or have the more severe stage of cirrhosis, where a longer course of 44 weeks applies. Asymptomatic patients are not covered, although for specific cases, the Hepatitis C nurse said she would try and argue for compassionate use of Victrelis.

At the time of the discussion with the Hepatitis nurse in November 2012, Incivek was not publically-funded in Ontario, although patients could get it by paying for it themselves, or if their private insurance covered use of this drug. The nurse said that certain private insurance groups were notoriously difficult at paying for treatments. The situation is dynamic, with ongoing changes as to which provinces are publically-funding Incivek, and for what types of Hepatitis C patients. Further drugs to treat Hepatitis C are anticipated to be launched by 2014.

All these factors suggest that the middle-classes, especially amongst those aged 40+, will be taking a more active role in paying for the cost of healthcare – both in Canada and abroad. In Canada, this will be done directly by pay and co-pay arrangements, in choosing between private insurance companies according to the cover they offer, and by lobbying public-funding authorities effectively. As middle-class people get more acquainted with the costs of treatments and the financial risks they are exposed to, they can more effectively include such costs within their financial planning, and think about how to take care of their health cost-effectively.

For pharmaceutical companies, it means taking a closer look at their value proposition to patients. It is about understanding, through techniques such as Price Volume Optimizer, what the proper course of

[2] The End of Illness (2012), Dr. David Agus, page 88 in the context of a non-approved use of Avastin
[3] Cancer drug access for Canadians, Canadian Cancer Society, August 2009, page 23
http://tinyurl.com/can-offlabel

treatment would be based on individual patient preferences. Such information could help establish patients' willingness-to-pay, and also how to achieve higher treatment completion rates, which in turn could lead to better survival rates and lower costs. Through advances in personalized medicine, there are increasing opportunities to know more about individual medical risk factors and personalized therapy choices. Pharmaceutical companies should also know what strategies healthy people would adopt, and what payment options they would take to manage the risk of catastrophic drug costs.

These kinds of information should make for a more fruitful conversation with payers when it comes to talking about market access.

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