ECONOMIC PRIZES: A NEW MODEL FOR PHARMACEUTICAL INNOVATIONS

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INTRODUCTION

THE ACCELERATING RATE OF CHANGE IN TECHNOLOGY and globalization of markets requires a change in Canada's innovation policy to improve its international competitiveness. In particular, Canada needs to resolve inefficiencies that afflict key industries by improving its underlying innovation policies.

Despite the use of patents and direct government support for research and development (R&D), the pharmaceutical industry is plagued with market failures. These market distortions prevent sufficient attention on developing cures for diseases that incapacitate the poorest sectors of both domestic and developing nations. Monopolies created by patents also inflate the cost of healthcare at a rate that the government cannot continue to support. Government supported research also creates its own unique market inefficiencies and tends to focus excessively on basic research at the expense of improving Canada's capacity to commercialize on its innovations.

One solution is to redirect Canada's traditional innovation policy, from one which supports research inputs in a diluted manner, to one that proactively directs research and development in areas of greatest need. Offering economic prizes in prioritized areas has the potential to not only increase innovation within that industry, but it could also resolve market inefficiencies. This could result in a more cost-effective use of public funds, saving Canadian citizens money as consumers and as taxpayers.

Although Canada has strong innovative capacity, its ability to commercialize and disseminate successful innovations is weak. Offering a results-based prize could induce inventors to commercialize their innovations faster and more efficiently. Also, offering a reward for innovative applied research could provide the extra incentive for researchers to follow-up on ingenious uses or applications of existing, lower-cost treatments. Economic prizes can provide the additional

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incentive needed to encourage the often overlooked final steps of development and commercialization of socially valuable innovative ideas.

Implementing a new incentive mechanism will also be broadly consistent with the recommendations for improving healthcare and industrial innovation by leading policy experts. It will be congruent with changes in healthcare and innovation policy currently underway in countries such as Ireland, the United Kingdom, Japan, France and Sweden.

Likewise, there is considerable support from economists and innovation experts to implement results-based market incentives to inspire more beneficial innovation. Harvard economist Michael Kremer has been the strongest proponent of the vaccine purchase commitment scheme to encourage development of vaccines for diseases that debilitate developing countries.[1]

However, this paper proposes offering an economic prize to encourage innovation not just for vaccines, but for all pharmaceutical and healthcare innovations that can add significant social value. The wider scope is intended to encourage attention to the creative use of existing medicines, treatments, or other lower cost therapies for applications beyond their originally recognized function. For example, the creative use of Aspirin as a heart disease preventative has provided a much more cost-effective treatment than developing new, expensive drugs. This prize is ground-breaking because it not only addresses patentable innovations that are neglected because of poor commercial viability, but also rewards innovative non-patentable applications not eligible for compensation under any existing private or public mechanism.

A properly structured reward has the potential not only to encourage the creation of needed medicines and treatments, but it can also induce creative approaches to healthcare that are cost-effective, attract foreign investment, and mobilize Canada as an international leader in innovation and global competitiveness.

I. IMPACT OF GLOBALIZATION ON ECONOMIC, HEALTH AND INNOVATION: THREATS & OPPORTUNITIES

TO REMAIN COMPETITIVE WITH GLOBALIZATION OF MARKETS and the rapid rate of technological innovation, Canada needs to update its innovation policies to encourage growth in its science and technology-based industries.[2]

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[1] Michael Kremer & Rachel Glennerster, *Strong Medicine: Creating Incentives for Pharmaceutical Research on Neglected Diseases*, (New Jersey: Princeton University Press, 2004).

[2] "Science, technology and innovation are central to improved economic performance." OECD, *Science, Technology and Industry (STI) Outlook 2004* at 3, online: OECD <http://www.oecd.org/dataoecd/0/60/33998255.pdf> [*(STI)*

However, it is ironic and counter-intuitive to attempt to encourage innovation by relying solely on traditional reward structures. Inspiring greater creativity will require looking beyond current incentives and adopting a more creative approach. The economic prize system proposed in this article is a natural extension of prevailing recommendations by economists to implement results-based incentives. This proposal is ideal because it is progressive and yet complementary to the current system of patents and government supported research and development.

(1) Accelerated Rate of Technological Innovation

The rate of technological innovation is accelerating and markets are increasingly global.[3] This has created a competitive environment where economic growth is spurred by excellence in its knowledge-based industries.[4] The new determinant of economic success is the ability to sustain technological innovation — at both the micro and macro economic levels. Creating a regulatory framework that supports innovation in the technological and scientific industries is crucial to a country's financial sustainability.[5]

Historically, Canada has relied on the sale of its natural resources, such as timber, minerals, fisheries and agricultural commodities, as the source of its economic wealth. However, with the depletion of natural

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Outlook 2004]. Also see *(STI) Outlook 2004* at 4 "More so than before, science, technology and innovation policies need to adapt to the needs of the service sector and increased globalisation." Also see *Annual Innovation Report* (2003): *Trading in the Global Ideas Market*, online: Conference Board of Canada <http://www.conferenceboard.ca>.
The Board emphasized the pivotal role that innovation plays for sustained business success. It recognized that Canada needs to improve its rate of its industrial innovation to gain a competitive edge. The Board also recognized that Canada is already lagging behind other countries in innovative capacity and output.

[3] Government of Canada, "Chapter 3: Moving Forward on Collaborative Science and Technology" in *Federal Science and Technology: The Pursuit of Excellence*, online: Government of Canada <http://www.innovation.gc.ca/gol/innovation/site.nsf/en/in05251.html#top>.
This chapter of the report emphasizes that Canada's science and technology department will have to address the accelerating rate of change in science and technology and the increase in public expectation for government to provide answers to complex challenges, such as cost-effective healthcare. The report also recognizes that Canada needs to improve its international ranking for R&D performance, which necessitates an increase in the volume of innovation in its industries.

[4] Kristian Palda, *Innovation Policy and Canada's Competitiveness*, (Vancouver: The Fraser Institute, 1993) [Palda].

[5] *Ibid.* at 260.

resources and an emphasis on environmental conservation, industrialized economies such as Canada must refocus on building the capacity of its knowledge-based industries to support future economic growth. This requires an innovation policy that adequately rewards inventors, encourages industrial growth and adds to Canada's pool of cutting-edge technological knowledge.

However, a nation's industries must excel not only at technological innovation, but also at the effective and timely commercialization of its innovation. It is, therefore, equally important to provide support for the crucial latter stage of R&D that focuses on researching useful and commercially viable applications derived from basic research. This economic prize is intended to reward socially valuable applied research to counter-balance and complement existing support for basic research.

(2) Increased global competitiveness: all industries and in pharmaceutical industry

As previously mentioned, Canada has historically relied on the sale of its natural resources to create its wealth. In the face of dwindling resources and competition that places a premium on technological innovation, Canada's status as a global competitor is falling.

This fall can be seen in Canada's rankings of Growth Competitiveness made in the World Economic Forum's Global Competitiveness Report. In 2001, Canada ranked 3rd,[6] whereas in 2004, Canada ranked 15th.[7]

Canada's Pharmaceutical Industry in Jeopardy

Similarly, in its pharmaceutical sector, Canada's competitive position is in jeopardy. Although Canada has had a relatively stable coverage of the pharmaceutical market, recent changes in the industry threaten its market share.

Competition from Developed and Emerging Economies

Developing nations such as China and India have emerged as economic powerhouses by focusing on excellence in their knowledge-based industries. These countries are wisely reforming their technology infrastructure and regulatory environment to make their countries more accessible and attractive to foreign investors.

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[6] *Global Competitiveness Report 2001-2003* (New York: Oxford University Press, 2002), online: Oxford University Press <http://www.us.oup.com/us/pdf/reports/gcrexecutivesummary.pdf>.

[7] *Global Competitiveness Report 2005-2006: Policies Underpinning Rising Prosperity*, Table 1: Growth Competitiveness Index Rankings and 2004 Comparisons, (New York: Palgrave MacMillan, 2005) at xvii.

This includes revamping their intellectual property regime to make it easier for foreign investors to apply and be approved for patents in their country.[8] Large pharmaceutical companies are taking advantage of the irresistible allure of the low cost of labour, cutting-edge production facilities and friendly regulatory environment to move their manufacturing to China and India.[9] Given the high cost of investing in a manufacturing facility, once these drug companies have set up manufacturing in low-cost China or India, it would be difficult to convince them to relocate to a higher-cost North American facility. It is, therefore, imperative to attract and retain current pharmaceutical investments in Canada, before they become entrenched elsewhere.

China and India are also competing with industrialized nations for market shares in undeveloped countries, such as in Africa.[10] By establishing themselves in countries that will one day yield consumers with more discretionary income, they are entrenching their brand name and establishing alliances that will be lucrative in the near future. Thus, Canada is also at a disadvantage in establishing a market presence in developing economies.

By offering more progressive innovation environments, emerging economic powerhouses are diverting foreign investment away from Canada. Canada's reliance on outdated regulatory and innovation policies is hampering its ability to compete with other industrialized countries and emerging nations.

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[8] The amended Chinese Patent Law, which brings PRC patent law closer to World Trade Organization (WTO) requirements, took effect on 1 July 2001. The National People's Congress (NPC) passed the second amended Patent Law on 25 August 2000. The major changes in the amended law can be grouped into three categories: new judicial and administrative protections, improved application procedures, and simplified enforcement procedures.
Foreign patent applicants had problems with the time-consuming and complicated filing requirements for procuring patents in China. The new Patent Law addresses these concerns by relaxing the filing requirements for foreign and international applicants, requiring the patent authorities to examine the application within a reasonable timeframe, and removing the limitations on international applications by domestic applicants. Amendments also include simplified enforcement procedures, which will also help large pharmaceutical companies protect their exclusivity rights. See Jiwen Chen, "The Amended PRC Patent Law" (July/August 2001) 28:4 China Business Review 38.

[9] A. Maureen Rouhi, "Asian Competition Gathers Strength: High quality and low cost are a combination that Western firms are finding hard to beat" *Chemical & Engineering News* 82:3 (19 January 2004) 48, online: Chemical & Engineering News <http://pubs.acs.org/cen/coverstory/8203/8203customchemicals3.html>.

[10] United Nations Development Programme, Press Release, "Bold Agenda for Trade on Human Terms in Asia-Pacific" (29 June 2006), online: UNDP China <http://www.undp.org.cn/modules.php?op=modload&name=News&file=article&sid=277&mode=thread&order=0&thold=0>.

"'Economies of large developing countries, among which China is, will surpass many of those of the developed world in the decades ahead. These countries will offer wider market access and services as well as, it is hoped, provide development assistance for least developed countries, especially those in Africa,' according to Zéphirin Diabré, Under-Secretary General of the United Nations and Associate Administrator of the United Nations Development Programme (UNDP)."[11] "Wang Yue, Director General of China International Center for Economic and Technical Exchanges (CICETE) . . . said that the private business in China covers almost every industrial field, and enjoys various advantages such as flexible management and low costs, which meets the needs of the African market."[12] "He noted that the trade volume between China and Africa is rapidly growing. In 1999, it totaled only 2 billion dollars, whilst in 2004 it reached 29.64 billion USD, almost 15-fold over five years."[13] He also said that "[t]his indicates that the trade between China and Africa is growing at an unprecedented speed, and the emerging markets of Africa offer huge investment opportunities to the Chinese private sector".[14]

Compounding the pressure from emerging nations is increased competition from other industrialized nations, as other countries also recognize the threat from the developing world. The European Commission is currently undertaking efforts to harmonize drug approval procedures among its member countries in order to facilitate and encourage investment from pharmaceutical companies.[15]

Canada cannot compete by lowering its cost of labour or relaxing its patent approval process without harming the welfare of its citizens. Canada needs to offer an enticement (to attract drug companies and talented scientists) that differs from other countries.

The economic prize system proposed in this article has the potential to give Canada a competitive edge. Along with the existing R&D tax

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[11] United Nations Development Programme, Press Release, "New Public-Private Partnership to promote Sino-African ties: UNDP, China, and the China Guangcai Programme launch the China-Africa Business Council to promote investment and trade between China and Africa" (17 March 2005), online: UNDP <http://www.undp.org.cn/modules.php?op=modload&name=News&file=article&catid=14&topic=36&sid=92&mode=thread&order=0&thold=0>.

[12] *Ibid.*

[13] *Ibid.*

[14] *Ibid.*

[15] "The European Commission will propose increased centralization of drug approvals, with more new products being submitted to the European Medicines Evaluation Agency in London. It is also seeking new 'fast track' powers to speed approval of medicines aimed at poorly treated diseases." *Financial Times* (18 July 2001), cited in "Section 7 — The Innovation Environment Challenge — Canada's Innovation Strategy," online: Government of Canada, Innovation in Canada <http://www.innovationstrategy.gc.ca/gol/innovation/site.nsf/en/in04162.html>.

credit, it offers drug companies the ability to engage in beneficial R&D and still earn a modest profit. This proposal has the additional allure of providing drug companies with much-needed credible, high-profile positive publicity in place of spending millions on their usual aggressive advertising and marketing campaigns.

Longer Patent Approval Process in Canada

At present, pharmaceutical companies are frustrated with Canada's patent system, finding it overly cumbersome and time-consuming. These companies have stated they prefer to establish manufacturing in countries where the patent approval process is faster and simpler, such as in the U.S. or overseas.[16]

Although Canada has been ranked as among the world leaders in the creation of biotechnology companies, the industry is still considerably less developed than that in the U.S.[17] Canada has internationally recognized research capabilities and promising companies, but like many other countries, it lacks the boasting rights of a major success in the commercialization of one of its (biopharmaceutical) products.[18] One of the main roadblocks is the inability to raise the considerable capital

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[16] The report also states: "Let us consider, for example, Canada's patent system. The process of patent examination, cross-examination, challenge, and opposition in Canada is lengthy. This affects time to market, exposes the invention to the considerable risk of free riding, and undermines companies' ability to attract investment. Given that patenting costs are major determinants of location decisions for patenting, the aforementioned determinants will ultimately make Canada less attractive as a location of first choice. "Patenting in Canada is an afterthought for us," said a focus group participant from industry when speaking about the relatively lower quality and efficiency of the patent examination system in Canada. "We go to the United States because the United States Patent and Trademark Office will typically review the application and provide us with their arguments against patentability." See The Conference Board of Canada, *4th Annual Innovation Report 2002: Including Innovation in Regulatory Frameworks* (2002) at 21, online: Conference Board of Canada <http://www.conferenceboard.ca/boardwiseii/temp/BoardWise2CENFONODCMKPKOBEDLPANMAC200532164952/361-02Report.pdf> [*Innovation Report 2002*]. The report cited that in some cases, the approval process was longer in Canada than in other countries. See "The Biopharmaceutical Industry: Overview, Prospects and Competitiveness Challenges" (2001), Canadian Context, s.1.4, online: SenterNovem <http://www.senternovem.nl/mmfiles/biopharmatechroadmap_overviewprospectse%5B1%5D_tcm24-105268.pdf> [Biopharmaceutical Industry].

[17] Canada was ranked as a world leader in creation of biotech companies relative to its population, as measured by revenues, employees and products in commercialization. Biopharmaceutical Industry, *ibid.*, s.1.4.

[18] Biopharmaceutical Industry, *ibid.*, s. 4.3 at 6, 18-19 & 38.

necessary to finance full product development. In order to capitalize on this huge market opportunity, it is crucial maintain an infusion of capital from multinationals.

The economic prize proposed in this article will demonstrate to multinationals Canada's strong commitment to fostering growth and innovation in its pharmaceutical industry, without hampering patent protection. This will raise confidence in Canada as an investment choice and foster the commercial and technological capacity of its biopharmaceutical industry, when it is still in its formative stages.

A new incentive that provides adequate financial rewards for beneficial healthcare innovation will help Canadian-based drug companies develop their own market base and technology, and be less dependent on large pharmaceuticals. A self-reliant industry will have a revenue base that is less vulnerable to political volatilities or duress from large multinationals.

(3) Global Dispersion of Disease

Globalization also has ramifications on the dispersion of diseases. An increased volume of travel from business and tourism, and international marketing of products and commodities, has resulted in the global spread of harmful viruses and diseases. Diseases previously thought to be isolated to geographically remote undeveloped countries, have damaged the economies and health of industrialized nations.

Canada's recent experience with the SARS crisis is one example of the devastation that "foreign" diseases can cause to an industrialized nation. The Canadian government spent hundreds of millions of dollars to treat SARS victims and to contain further spread of the disease. In 2003 alone, it is estimated that SARS cost Toronto $519 million from lost tourism and foreign investment, and an additional $10 million for an advertisement campaign to counter the negative SARS publicity.[19] Global warming and the rapid-fire rate of mutation of viruses make the threat from potentially pandemic diseases even more imminent.[20]

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[19] "The Economic Impact of SARS" *CBC News Online* (8 July 2003), online: CBC <http://www.cbc.ca/news/background/sars/economicimpact.html>. It is estimated that SARS will cost Toronto $519 million in 2003 and $722 million between 2003 and 2006 in lost potential economic activity. The government of Canada also paid Toronto $25 million to compensate its hospitals for surgical backlogs caused by SARS. The City of Toronto spent $10 million on an ad campaign to counter negative publicity.

[20] " . . . as temperature regimes change, weather patterns will be altered and increased rainfall will facilitate the spread of waterborne and food-borne disease. And increased local rainfall also will make life easier for the insects and animals that carry some human diseases". See "Global warming will bring climate-related health crises," (20 February 2005), online: AZoMed.com

The result is that global diseases can end up costing Canadian taxpayers millions of dollars for the

i. reimbursement for lost or destroyed commodities (ex. destruction of cattle and chickens suspected to carry mad cow disease or the bird flu),
ii. loss of productivity from victims of the disease, which in turn lowers a country's overall Gross Domestic Product (GDP),
iii. cost of treating victims, R&D costs to develop vaccine and efforts to contain spread of the disease, and;
iv. loss of revenue from: decrease in tourism, deterred foreign investment (the effects of which can resonate for years even after the disease has been contained),

adding even more financial pressure to an overburdened healthcare system.

An elite diagnosis, prevention and R&D disease lab is necessary for Canada to protect its citizens and its economy. Canada should not rely on external disease centers, such as the U.S. Centre for Diseases Control, to safeguard its own citizens. A responsive disease relief plan

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<http://www.azomed.com/?id=7848&title=Global%20warming%20will%20bring%20climate-related%20health%20crises>.
"Global warming has the potential to exacerbate water-borne diseases, including cholera, which causes severe diarrhea. Drought enhances water-borne diseases by wiping out supplies of safe drinking water and concentrating contaminants that might otherwise remain dilute . . . 'Aside from causing death by drowning or starvation, these disasters promote by various means the emergence, resurgence and spread of infectious diseases.' Developing countries territories that are especially susceptible to infectious disease — don't have the money or technology to prevent or cure outbreaks. This shortfall has serious implications for the rest of the world, Epstein said. 'In these days of international commerce and travel, an infectious disorder that appears in one part of the world can quickly become a problem continents away if the disease-causing agent, or pathogen, finds itself in a hospitable environment,' Epstein noted. Case in point: the West Nile virus, which showed up for the first time in North America last year."
See Environmental News Network Staff, "Global Warming Spells Health Warning" *CNN* (17 July 2000), online: CNN.com <http://archives.cnn.com/2000/NATURE/07/17/global.warming.enn/>.

requires establishing a state-of-the-art disease center that is funded and located in Canada.

But, an effective disease centre requires the ability to retain top scientific minds that Canada has developed in its universities. Unfortunately, many talented scientists are being lured away by pharmaceutical or commercial labs with deeper pockets, often outside of Canada. Attracting scientific talent with the small budgets of public funded labs is too difficult. A new prize that offers the right combination of economic reward, mastery of a scientific challenge and public acclaim for contribution to a greater good, however, may better attract top scientific talent.

(4) Population Growth & Ageing Demographic

In the final comments of its Global Competitiveness Report, the World Economic Forum identifies two important demographic trends that will affect the relative competitiveness of countries:

i. a population growth in low-income countries, and;
ii. a higher ratio of the elderly population in developed countries.[21]

An increase in the elderly population translates into higher health care costs for the Canadian government. Medical care for the elderly generally entails treatment for acute diseases on a longer term basis and increases the cost of providing for medicines and chronic care. Canada's overly burdened health system will be bankrupt if more cost-effective methods of medical treatment are not soon discovered.

In 2003, persons 65 and over accounted for approximately 50 percent of provincial government hospital expenditure in Canada.[22] The most is spent on seniors between the age of 70 and 84 (31 percent of total).[23] While making up only 12.8 percent of the population, seniors consumed more than 44 percent of all provincial government health spending in 2003.[24]

Thus, any increase in the population of seniors will cause an exponential increase in the cost of healthcare spending. Where will the Canadian government get the money to support its citizens? If the government goes any further into debt, its ability to attract investors in

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[21] G. F. Anderson and P. S. Hussey, "Population Aging: A Comparison Among Countries" *Health Affairs* Vol. 19, Issue 3 (May/June 2000), 191-203 at 192.

[22] Canada, Canadian Institute for Health Information: *National Health Expenditure Trends 1975-*2005 at 26, online: CIHI.ca <http://secure.cihi.ca/cihiweb/products/NHEX_Trends_2005_e.pdf>.

[23] *Ibid.*

[24] *Ibid.* at 29.

the securities market will fall, and the value of the Canadian dollar will also decrease as investors lose faith in the stability of our economy. The other two options are to increase income tax rates or resort to a privatized medicare system. Both of these options will result in much higher healthcare costs to the average citizen.

Population growth in low-income countries will also increase demand for foreign aid, as infectious diseases in those countries spread to a larger population.

Thus, Canada will experience considerable financial pressure both internally, as domestic healthcare costs inflate and externally, to augment its foreign aid contribution. These trends will also exert downward pressure on Canada's debt status and harm its ability to attract investors in the international securities markets.[25]

These implications emphasize the importance of taking a *proactive* approach to addressing healthcare costs in both Canada and developing nations. At present, domestic healthcare and foreign aid takes a *reactive* approach; that is, it focuses on financing the treatment of patients *after* the disease has developed or spread.

It would be more cost-effective to invest in R&D for drugs and treatments that prevent the spread of the disease in the first place. Although this will require an initial investment to finance the economic prize, in the long run, it will save Canadian taxpayers money. Redirecting 10 percent of current government funding for biomedical R&D will provide the initial financing for the proposed reward system.

The proposal in this paper presents a more proactive approach to controlling healthcare costs. This proposal will pre-identify those diseases for which cures or preventative measures are most urgently needed. Researchers who uncover innovative techniques or cures will be awarded proportionate to healthcare cost savings. This will mobilize R&D on priority medical needs in a proactive manner, instead of endlessly financing the treatment of symptoms.

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[25] "Rapidly rising pension and healthcare spending will reduce the debt status of the world's richest industrialized countries to junk within 30 years unless their governments move quickly to balance budgets and reduce outgoings. Standard & Poor's — the credit ratings agency — says that, if current fiscal trends prevail, the cost of ageing populations will fuel downgrades of France, the U.S., Germany and the U.K . . . Without further adjustments either to current fiscal stance or to social and health care costs, the general debt ratios of France, Germany and the U.S. will surpass 200% . . . All big industrialized nations face the problem of large unfunded pension liabilities and rising healthcare costs as populations age. Most have responded with limited moves to make benefits less generous . . . Population ageing is expected to accelerate about 2020." See Paivi Munter, "Major economies' debt may fall to junk status by 2030" *National Post* (21 March 2005) FP2.

Varying the size of the reward in proportion to cost savings will orient researchers to concentrate on new applications of existing or lower cost drugs and therapies. This could save Canada's health system millions of dollars and still provide safe and effective healthcare for its citizens.

Since researchers will be motivated to be the first to claim their prize, beneficial innovations will be commercialized and disseminated much more quickly than with existing incentive mechanisms. Enhancing the pool of scientific knowledge may facilitate subsequent discoveries and the transfer of technology to undeveloped countries. Thus, the sooner undeveloped countries can establish their own healthcare infrastructure, the less reliant they will be on foreign aid.

(5) Enhancing Canada's Foreign Aid & Soft Power: Opening the Doors to Future Markets

Focusing Foreign Aid on Infrastructure Development

In the 2004 Speech from the Throne, Canada vowed to apply its domestic research capabilities to the problems affecting developing countries.[26] A comprehensive study on the burden of global problems ranked combating neglected diseases as the number one priority.[27] The combined implication is that addressing neglected diseases should be the predominant focus of Canada's foreign aid. This focus would also fulfill Canada's commitments to international agreements such the *TRIPS Agreement*,[28] the *Universal Declaration of Human Rights*,[29] the *UN Millennium Development Goals*,[30] and the *African Action Plan*.[31]

The economic prize proposed in this article is entirely consistent with Canada's commitments to the developing world. In fact, because this prize specifically intends to reward innovative treatments for diseases crippling developing countries, it represents a much more directed and

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[26] Canada, *Speech from the Throne to Open the Third Session Thirty-Seventh Parliament of Canada*, online: Parliament of Canada <http://www.parl.gc.ca/information/about/process/info/throne/index.asp?lang=E&parl=37&sess=3> (Delivered by The Right Honourable Adrienne Clarkson, Governor General and Commander-in-Chief of the Canadian Forces).

[27] Copenhagen Consensus Center, online: <http://www.copenhagenconsensus.com>.

[28] *Trade-Related Aspects of Intellectual Property Agreement*, 15 April 1994, art. 26, online: WTO <http://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm> [*TRIPS*].

[29] *Universal Declaration of Human Rights*, GA Res. 217(III), UN GAOR, 3d Sess., Supp. No.13, UN Doc. A/810 (1948) [*UN Declaration of Human Rights*].

[30] UN Millennium Development Goals, online: United Nations Development Program <http://www.undp.org/mdg/abcs.html>.

[31] G8 African Action Plan, online: Government of Canada <http://www.g8.gc.ca/2002Kananaskis/afraction-en.asp>.

proactive approach to foreign aid. Canada's willingness to break away from traditional science management approaches and embrace a new incentive mechanism aimed specifically at the diseases of underdeveloped nations is a powerful demonstration of its commitment to foreign aid.

At present, no other country has been willing to offer a cash prize for the development of solutions for diseases in poor countries. The UK has offered to make a purchase commitment for the development of an effective AIDS vaccine, but its commitment is limited to vaccines for that one disease. This new prize is intended to target all the major debilitating diseases of poor countries and accept all forms of innovation that will advance access to healthcare. This prize is wider in scope of acceptable innovations and yet is more directed, because it pre-specifies which diseases are priorities. Having open-ended technical criteria enables the prize committee to capture truly ingenious inventions which may not conform to an overly rigid or limited vision of possible solutions. Adopting an outcome-based approach also makes this prize consistent with the suggestions of the Organisation for Economic Development (OECD) for improving foreign aid. To improve the effectiveness of Canada's current foreign aid programs, the OECD recommended that Canada take a more results-based approach to manage and measure the use of foreign aid resources.[32]

Although Canada contributed US$2.006 billion in foreign aid last year, it is still criticized for not treating foreign aid as a priority.[33] Canada is under pressure to increase its foreign aid budget from its current level of 0.3 percent of GDP to 0.7 percent, to demonstrate its commitment to the developing world. [34]

Rather than increase the *volume* of its foreign aid budget, Canada should adjust and re-focus its foreign aid policy to ensure the most effective use of this money. A better foreign aid policy should concentrate

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[32] OECD, *Canada Development Co-operation Review 1998: Summary and Conclusions*, online: OECD <http://www.oecd.org/document/15/0,2340,en_2649_34603_2368207_1_1_1_1,00.html>.

[33] According to *The Reality of Aid 2004 Report*, poor countries are losing out to rich countries' as foreign aid is increasingly being seen as an instrument to promote security and combat terrorism. See *Reality of Aid Reports 2004*, *Part VI: World Aid and Donor Reports, Canada: Doubling the budget is just one of the challenge*, online: CCIC <http://www.realityofaid.org/roareport.php?table=roa2004&id=76>, and Canada NewsWire, Press Release, "Special Advisor to UN Secretary-General Calls on Canadians to Take Leadership Role in Fight Against Global Poverty" (6 April 2005), online: ArriveNet <http://press.arrivenet.com/bus/article.php/617147.html> ["Special Advisor"].

[34] "Special Advisor," *ibid.*

on facilitating the development of healthcare infrastructure to enable undeveloped countries to become self-sustaining. In the long run, this is likely to be the most effective use of foreign aid funds and accordingly, the best way to relieve the burden of providing foreign aid in the future.

Alleviating neglected diseases is the necessary first step towards building the economic and political infrastructures of underdeveloped countries. The toll of these diseases includes reduced productivity that delays infrastructural development and eventual economic self-sufficiency for afflicted countries. For every 8 million lives saved, there is a corresponding reduction of 330 DALYs (disability life-adjusted life years). Correspondingly, the economic gain of eliminating these diseases would be $180 million in direct benefits and $180 million in indirect benefits.[35] These benefits significantly outweigh the short-term costs of financing the treatments.[36] Increasing the productivity and welfare of the developing world should reduce their need for foreign aid support. This should free up valuable capital that can be used to increase overall global productivity or aid the development of other countries.

As previously pointed out, the economic prize proposed in this article has the potential to encourage faster development of cures and treatments, as well as faster dissemination of these innovations than current mechanisms are able to provide. The faster the cures and technology are transferred to poorer countries, the sooner they can develop their own healthcare and economies. This prize mechanism will enable Canada to be recognized as a valuable contributor to international development without necessarily increasing its budget.

Visionary Leadership Enhances Canada's Soft Power

Adopting this creative approach to incentive mechanisms should also help increase Canada's "soft power". Soft power is the ability to influence other countries and achieve desired results through persuasiveness and a reputation for strong leadership, as opposed to brute use of force.[37] By implementing a fresh approach to pharmaceutical innovation, with the ability to resolve a key roadblock in the development of underprivileged countries, Canada can greatly increase its soft power.

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[35] WHO, "Investing in Health: A Summary of the Findings of the Commission on Macroeconomics and Health" (2003) at 14, online: WHO <http://www.who.int/macrohealth/infocentre/advocacy/en/investinginhealth02052003.pdf>.

[36] Anne Mills & Sam Shillcutt, "Copenhagen Consensus: Challenge Paper on Communicable Diseases" (February 2004), online: Copenhagen Consensus <http://www.copenhagenconsensus.com/files/filer/cc/papers/communicable_diseases_160404.pdf>.

[37] J. S. Nye Jr., *Bound to Lead: The Changing Nature of American Power* (New York: Basic Books, 1990) at 32.

This reward represents a thoughtful, proactive and results-oriented approach to innovation that integrates concerns about healthcare costs, industrial development and effective foreign aid. As such, it will serve as an impressive example of Canada's ability to resolve a complex issue that overlaps several sectors and government functions, which many other countries are currently struggling to address. Being a leader in developing novel policy solutions to a complicated problem will raise Canada's international esteem and soft power. This will enable Canada to wield greater bargaining power in the negotiation of multilateral trade agreements and international environmental accords, assist the democratization of oppressed countries, and have greater influence over international fiscal and monetary policy.

Opening Markets for Canada's Biotech Industry

A commitment to combat neglected diseases can also benefit Canada's potentially lucrative biotech industry. As previously pointed out, Canada has considerable capacity in its growing biotechnology and bioagricultural industries. However, producers of genetically modified foods have encountered considerable market resistance to their products arising from fear of biotechnology.[38] The use of Canada's biotechnology to cure diseases and improve society will enhance its reputation as a leader in technology and its acceptance by the public. Such positive association may open up domestic and international markets for Canada's genetically modified foods industry.[39]

The economic prize proposed in this article provides a win-win scenario for all stakeholders. This novel approach of specifically targeting developing world diseases with a results-based award enables Canada to fulfill its foreign aid commitments without a sustained increase in the foreign aid budget. It has the potential to facilitate faster development of cures and transfer of technology to developing countries, which should accelerate their ability to be self-sustaining. In the long run, this can reduce the demand for foreign aid support. Taking a visionary approach to innovation management should also improve Canada's reputation as a leader in science and technology, increase its soft power and international influence, and open markets to Canadian-created biotech products.

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[38] Ed Ungar, "Monsanto Pulls Canada wheat plans" *The Scientist* 5:1 (12 May 2004), online: The Scientist <http://www.the-scientist.com/news/20040512/01/>.

[39] Susan R. McCouch, "Is Biotechnology the Answer" in Keith Wiebe, Nicole Ballenger & Per Pinstrup-Andersen eds., *Who Will Be Fed in the 21st Century? Challenges for Science and Policy* (Baltimore: The Johns Hopkins University Press, 2001) at 31.

(6) Innovation Policy on the World Stage: Results-Based Approach to R&D

The OECD recognized, in its *Science, Technology, and Innovation (STI) Outlook for 2004*, a growing trend in countries to reform and strengthen their public research policies to make them more effective and efficient.[40] In particular, the OECD recommends that an improved innovation policy should alter the funding structure of universities and government labs to make them less dependent on institutional (*i.e.* block grants) funding and more reliant on competitively awarded, project financed research.[41]

The report also points out that other countries are recognizing that the government needs to make special efforts to increase support for innovation that will have positive economic and social impacts.[42]

In its Innovation Report (2003), the United Kingdom's Department of Trade and Industry established its national innovation agenda. To improve its government procurement procedures, it recommended the

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[40] "Governments have introduced a range of reforms to strengthen public research systems and to enable them to contribute more effectively and efficiently to innovation. The governments of Denmark, Japan and the Slovak Republic, for example, have increased the autonomy of universities or transformed them into private or quasiprivate institutions and removed obstacles to their co-operation with industry. Funding structures have also been changed in many countries to make universities and government laboratories less dependent on institutional (*i.e.* block grant) funding and more reliant on competitively awarded project funds for research. Many countries have stepped up efforts to evaluate public research organisations, with a view toward improving the quality of teaching and research. Countries are also taking steps to improve technology transfer from public research organisations to industry. New legislation in Denmark and Norway makes technology transfer to industry an explicit mission of universities, and the new University of Luxembourg has been encouraged to stimulate industry interaction through contract research and mobility of students and researchers. Countries continue to reform rules governing the ownership of intellectual property (IP) generated by public research institutions, in most cases granting ownership of IP to the institution in order to facilitate its commercialisation. Norway and Switzerland introduced such changes in recent years, and Iceland and Finland are preparing legislation on the subject. Several countries that have not changed legislation, such as Australia and Ireland, have nevertheless developed new guidelines to encourage commercialisation of research results and provide greater consistency in IP management among research organisations." See *(STI) Outlook 2004*, *supra* note 2.

[41] *Ibid.* at 5.

[42] "Public money is increasingly aimed at scientific and technological fields believed to have great economic and societal value, in particular, ICT, biotechnology and nanotechnology. Several countries, including Denmark, Germany, the Netherlands and Norway have created special funds to finance research in priority fields." *Ibid.*

use of outcome or output-based specifications to produce more effective solutions and capture the creativity of competitors:

> There is an important opportunity to increase innovation through more use of outcome-based regulation, that is regulation which defines the policy objectives, not how they should be achieved. This gives companies greater scope to innovate to comply with the regulations using the most effective technological solutions or business practices.[43]

It was also recognized by Industry Canada, in its *Innovation Strategy* that the government needs to provide clearer stewardship to ensure growth of its innovative capacity.[44] In another Industry Canada report, the *Science and Technology Report*, policy experts recommended that the government should adopt a more integrated approach to federal science management and properly resolve complex national issues that cross traditional departmental boundaries.[45] Equally important, the report

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[43] DTI, "Innovation policies across Government" in *Innovation Report Competing in the global economy: the innovation challenge* (2003) at 81, online: DTI <http://www.dti.gov.uk/innovationreport/>.

[44] *Canada's Innovation Strategy* was launched on 12 February 2002, with the release of two companion documents: *Achieving Excellence: Investing in People, Knowledge and Opportunity* and *Knowledge Matters: Skills and Learning for Canadians*. See online: Government of Canada <http://www.innovation.gc.ca/gol/innovation/site.nsf/en/in04113.html>.
Section 7 of the report recognizes that Canada needs to improve its international recognition as an innovative country in order to attract talent and capital. Also noted is (i) the need for better government stewardship of the nation's innovation through the creation of supportive innovation policies; (ii) increasing global competition for investment and highly qualified people/labour force; (iii) the pace of innovation is accelerating; (iv) Canada faces the challenge of improving its science and technology sectors to be competitive and to ensure the protection of public health and safety. See online: Government of Canada <http://www.innovation.gc.ca/gol/innovation/site.nsf/en/in04162.html>.

[45] This report emphasizes the important changes that Canada's science and technology department will have to address: (i) rapid change in science and technology knowledge and capacity, (ii) aging workforce, (iii) competitive demand for important resources, particularly scientists and researchers, and (iv) an increase in public expectations for government to provide answers to complex challenges including cost-effective healthcare. "The vision was adopted by the deputy ministers of SBDAs has six main elements:

- identify emerging issues important to Canadians and refocus efforts on them;
- mobilize resources to seek solutions;

also emphasizes that science management must be aligned with the priorities of Canadians.

Summary of Global Trends & Reports

- Science & technological innovation is crucial for economic competitiveness
- Canada's declining status in global competitiveness
- Increased competition from developing and developed nations in the pharmaceutical sector
- Global diseases require responsive national lab
- Population growth & aging demographic
- Pressure to increase Canada's foreign aid
- International trend to reform innovation policy
- Opportunity in developing country markets
- Urgent need to improve innovation policy to improve the Canadian competitive edge

The recommendations from innovation policy experts in Canada and internationally can be summarized as follows:

(i) need for the government to provide more specific goals and better stewardship of the direction of innovation in its science and technology sectors;

(ii) increase funding for innovation in fields of science and technology where innovation have high potential economic and social benefits, (such as biotechnology);

(iii) use of outcome-based specifications to improve the efficacy of innovation incentive mechanisms; and

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- integrate across disciplines and departments, with policy and with external partners;
- contribute to better policies and delivery of superior services;
- attract, develop and support outstanding scientific experts; and
- be a prime source of credible, useful and trusted information."

See "Chapter 3: Moving Forward on Collaborative Science and Technology," *Federal Science and Technology: The Pursuit of Excellence* (2003), online: Government of Canada <http://www.innovation.gc.ca/gol/innovation/site.nsf/en/in05251.html#top>.

(iv) need to take an integrative approach in formulating its innovation policies and resolve issues that cross government departments.

The economic prize system proposed in this article incorporates all of the recommendations from these reports. Its structure supports growth in the industrial, health, and science and technology sectors of Canada without compromising their distinct goals.

II. CANADA'S STRENGTHS & WEAKNESSES: INNOVATION POLICY & PHARMACEUTICAL INDUSTRY

(1) Unsustainable Cost of Healthcare in Canada

Statistics show that healthcare costs in Canada are growing at an alarming rate. Total health care expenditures were $123 billion in 2003.[46] Expenditures are forecast to have been $131.8 billion in 2004 and $142 billion in 2005, an increase of 7.2 percent and 7.7 percent, respectively. [47]

The increase in expenditure for drugs has been the most significant factor for this growth in healthcare costs. The Canadian Institute of Health Information (CIHI) found that in 1975 drug costs constituted only 8.4 percent of total health care expenditure, but by 2003, this percentage had almost doubled to 16.4 percent of total health care expenditure ($20.1 billion).[48] This increased spending for drugs is expected to continue, and forecast to grow another 10.9 percent in 2004 to $22.3 billion and by 11 percent in 2005 to $24.8 billion.[49]

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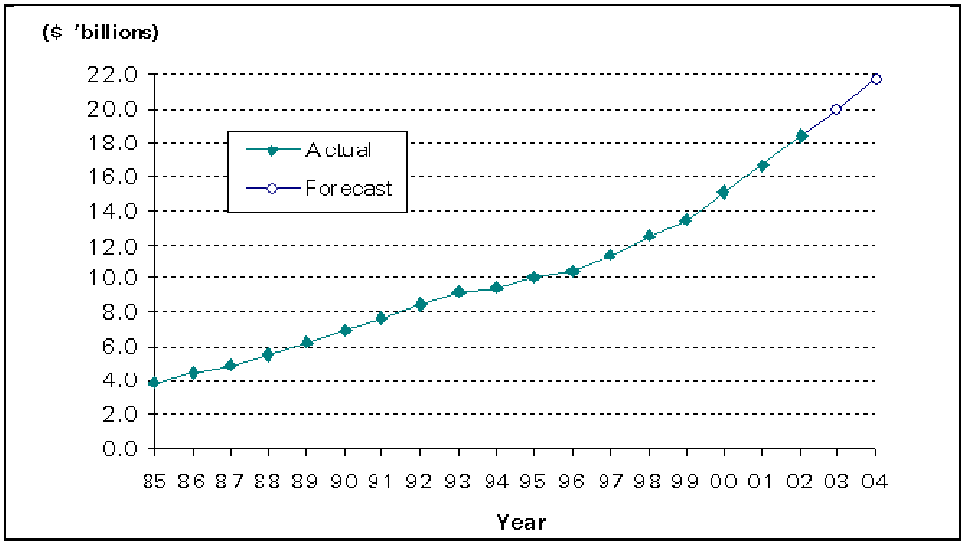
[46] *National Health Expenditure Trends (1975-2005)* (Ottawa: Canadian Institute for Health Information) at 3, online: Canadian Institute for Health Information (CIHI) <http://secure.cihi.ca/cihiweb/products/NHEX_Trends_2005_e.pdf> [*National Health Expenditure Trends*].

[47] *Ibid.*

[48] *Ibid.* at 19.

[49] "Retail sales of prescribed and non-prescribed drugs together constituted the second largest category of health expenditure in 2003 at $20.1 billion, an increase of 9.2% over 2002. Expenditure for drugs has increased more rapidly than total expenditure, with the result that the share of total health expenditure allocated to drugs increased from (a low of) 8.4% in the late 1970s to 16.4% in 2003. Spending on drugs is forecast to have increased by another 10.9% in 2004 to $22.3 billion and by 11.0% in 2005 to $24.8 billion, or 17.5% of total health care spending.
Non-prescribed drugs, which include over-the-counter drugs and personal health supplies, amounted to 18.1% of total expenditure on drugs in 2003." *Ibid.*

Total Drug Expenditure in Canada from 1985 to 2004[50]



The cost of drugs can be broken down into two categories: prescribed drugs and non-prescribed drugs. The majority of the drug care expenditure is attributable to prescribed drugs — amounting to 80.5 percent of total drug care costs.[51] In dollar figures, this amounts to $14.8 billion dollars spent by Canadians and the Canadian government, and this figure is expected to rise to $18 billion by 2004.[52]

In its 2003 Annual Report, the Patent Medicines Price Review Board (PMPRB) listed factors to be addressed to control the cost of drug spending. Along with controlling the price of new drugs, the PMPRB cited the need for a change in the prescribing habit of physicians towards newer more expensive drugs over older, less expensive drugs to treat the same underlying condition.[53]

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[50] Canada, *Report of the Canadian Institute for Health Information: Drug Spending to Reach Almost $22 Billion in 2004*, Figure 1: Total Drug Expenditure, Canada, 1985 to 2004, online: CIHI <http://secure.cihi.ca/cihiweb/dispPage.jsp?cw_page=media_05apr2005_e>.

[51] *Ibid.*

[52] Canada, *Report of the Canadian Institute for Health Information*: *Drug Expenditure in Canada (1985-2004)*, (Table B.7.2 – Part 2) at 89 online: (CIHI) <http://secure.cihi.ca/cihiweb/products/Drug_Expenditure_in_Canada_2005_e.pdf>. Rising healthcare costs are of particular concern to Manitoba, as it has the highest per capita health care cost at $4,406 in comparison to other provinces.

[53] Patented Medicines Prices Review Board, *Annual Report 2003* at 26, online: PMPRB <http://www.pmprb-cepmb.gc.ca/CMFiles/ar2003e30LWY-1062004-5966.pdf>.

A report entitled *Controlling Drug Expenditure in Canada: The Ontario Experience*, cited factors for the growth in drug expenditures on both the supply and demand side. On the supply side, the factors cited were, of course, the price of drugs and the dispensing fees paid to pharmacists for every prescription filled.[54]

The report also recommended that the Ontario government pay only for those drugs where evidence supports their cost-effectiveness, that is, where the benefits substantially outweigh the price of the drugs. Furthermore, it recommends that physicians be better educated and more sensitive to alternative, less costly drug therapies. Lastly, it recommends changes to the means by which pharmacists are compensated via dispensing fees.[55]

The *Final Report on the State of the Health Care System in Canada* (the *Kirby Report*) emphasized the importance of finding new ways to control the rising costs of prescribed drugs, including ensuring that physicians recommend prescription medicines that are safe, yet cost-effective, to ensure access to necessary treatment.[56]

Similarly, in *Building on Values — the Future of HealthCare in Canada — Final Report* (the *Romanow Report*),[57] it stated that the government needs to realign its policies to ensure Canadians have access to prescription drugs they need and that new medicines are integrated in a safe and cost-effective manner.[58]

In a report by the National Pharmaceuticals Strategy (NPS)[59] for Canada, Carl Baltare and William Dempster suggested that the strategy was overly focused on containment of drug costs to the detriment of

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[54] Paul K. Gorecki, *Controlling Drug Expenditure in Canada: The Ontario Experience*, (Ottawa: Minister of Supply and Services Canada, 1992) at 17.

[55] *Ibid.* at 17 & 126.

[56] *Final Report on the State of the Health Care System in Canada*, October 2002 (commissioned by the Standing Senate Committee on Social Affairs, Science and Technology, the Health of Canadians – the Federal Role) (known as the *Kirby Report*), Vol.6, Sec. 7.6 at 143.

[57] Canada, *Building on Values: The Future of Health Care in Canada*, (Saskatoon: Commission on the Future of Health Care in Canada, 2002), online: Health Canada <http://www.hc-sc.gc.ca/english/care/romanow/hcc0086.html>.

[58] *Ibid.*, c. 9.

[59] Anne M. Holbrook *et al.* for the Network Development Committee of the Canadian Prescribing Practices Network Project, "Developing a Canadian prescribing practices network" (1996) 154:9 Canadian Medical Association Journal 1325.

"The National Pharmaceutical Strategy office was founded in 1992 in response to a directive from the provincial ministers of health to 'develop a national strategy for rational and cost-effective development, regulation and use of pharmaceuticals in Canada.'" See online: Library and Archives Canada <http://collection.nlc-bnc.ca/100/201/300/cdn_medical_association/cmaj/vol-154/1325.htm>.

addressing innovation.[60] They recognize it is equally important to address cost containment and innovation policy to effectively manage the healthcare budget, as the two are interrelated problems.

Regarding patient access, if the focus of the NPS Task Force is on cost containment, Canadian patients could face higher co-payments for innovative drugs, and lose access to the newest therapies. Perversely, this leads to underutilization of essential medicines and higher costs to other parts of the health care system.

If the national pharmaceutical strategy focuses exclusively on cost-containment to the detriment of innovation, there will be diminished incentive for international pharmaceutical companies to partner with emerging Canadian biopharmaceutical firms. Canadian inventions will be developed, tested and manufactured overseas or in the United States. The federal and provincial governments are in a strong position to negotiate and implement a balanced national policy that meets both health and economic policy goals, giving patients access to safe and innovative medicines, while at the same time boosting Canadian health R&D investments. This is especially true as the global pharmaceutical policy environment becomes more volatile. Canada's competitors for health R&D investments have already crafted more integrated and balanced approaches. Five years ago, the UK set up the Pharmaceutical Industry Competitiveness Task Force to attract and retain pharmaceutical R&D investments.[61] The European Commission followed suit with the High Level Group on Innovation and Provision of Medicines.[62]

Summary of Recommendations

The consistent theme across healthcare studies, innovation experts, and pharmaceutical industry experts is the need to reform healthcare practices to create a healthcare innovation policy that balances cost-effective access to medical care and yet encourages industrial growth and foreign investment in Canada.

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[60] Carl Baltare & William Dempster, "Will Canada miss national pharmaceutical strategy boat? Commercializing on discoveries requires more than major government grants for researchers" *The Hill Times* (21-27 February 2005) 30. (Carl Baltare is Vice-President, Health and Pharma and William Dempster is a Senior Consultant, Health and Pharma.)

[61] U.K., *Pharmaceutical Industry Competitiveness Task Force – Final Report*, (March 2001) at 4, online: Department of Health: Advisory Bodies <http://www.advisorybodies.doh.gov.uk/pictf/pictf.pdf>.

[62] *Commission pushes for a stronger European-based pharmaceutical industry for the benefit of the patient*, (Strasbourg, 1 July 2003), online: EUROPA <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/03/924&format=HTML&aged=0&language=EN&guiLanguage=en>.

Private Medical Insurance Coverage not Reliable

Access to private medical insurance does not necessarily safeguard citizens from the escalating cost of healthcare either. Whenever a company experiences financial difficulty, one of the first expenditures sacrificed is medical insurance coverage for its employees.[63] Who pays for the cost of providing medical care? Naturally, the government bears this additional burden — further increasing inflationary pressure on healthcare costs. Eventually, this burden is passed on to all taxpayers, including those who are already paying for private medical coverage. Every citizen will be affected by increases in the cost of healthcare — which can take the form of higher taxes, longer waiting lists for crucial procedures or longer waiting periods in the emergency room. This emphasizes again how urgent it is to find ways of controlling healthcare costs by making more effective use of existing products and treatments. It is also worth mentioning again the expected growth in the elderly population in Canada. If the Canadian government recognizes that a looming crisis is evident given the current level of healthcare expenditure, the increased costs of providing drug and long-term care for an even larger elderly population will either bankrupt the government, increase taxes, or result in the privatization of healthcare — any of these options will render Canada less attractive to foreign investment.

Summary of Canada's Internal Strengths & Weaknesses

In an ideal world, the government would have unlimited resources to ensure equal access to comprehensive healthcare, including access to new, more expensive pharmaceuticals. It would also be able to finance all research avenues that could lead to improved health and quality of life for Canadians. Unfortunately, the government has a finite pool of resources, and cannot support an indefinite increase in pharmaceutical expenditures without ultimately passing the costs onto consumers. The dilemma is to strike the appropriate balance between ensuring access to quality healthcare in a manner that is cost-effective and financially sustainable. The key is to *prioritize* funding of R&D projects. The government needs to focus innovation on healthcare issues that are most pressing either because (i) the disease is pervasive and yet ignored by private researchers or (ii) the disease causes a severe financial burden to healthcare. It is, therefore, imperative that the Canadian government find *new* ways to control the cost of pharmaceutical and medical therapies. It has already met with some success in controlling the price of new

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[63] See "Delphi to stop paying retirees' health-care insurance" *National Post* (10 March 2005) FP6.

pharmaceuticals through the creation of the PMPRB — a national regulatory agency that ensures "fair pricing" of patented pharmaceuticals.[64] The government now needs to turn its attention to one of the other key recommendations: ensuring that prescribing practices of doctors include the use of alternative, less costly therapies over patented medicines.

The best way to motivate this change in direction is to encourage applied research, that is, to identify therapeutic benefits from the re-application of existing drugs or treatments in new ways. For example, the revolutionary discovery of the use of Aspirin for the prevention of heart disease has saved millions of dollars in drug treatment and long-term clinical care.[65] This discovery was particularly beneficial, as it uses an off-patent drug that is extremely affordable and thereby accessible to all income levels.

Discovering beneficial uses for existing non-patentable drugs/therapy can save Canadian taxpayers' money in two ways:

i. Savings from use of lower-cost medications or therapies, and;
ii. Foregoing the payment of the pharmacist dispensing fees incurred per prescription filled.

The economic prize system proposed in this article is one policy vehicle available to activate a new approach in prescribing therapies. This proposal will ensure that cost-effective evaluations are woven into decision-making for the allocation of R&D funds. With limited funds, such evaluations are crucial to ensure that only the most viable healthcare research projects are pursued.

More Attention on Applied Research – Reduce Cost of Healthcare

In addition, the scope of this prize includes innovative discoveries of non-patentable applications of existing lower-cost drugs to specifically address the need to find lower-cost treatments for diseases. Unlike basic research, applied research lacks the cachet of being a "breakthrough" discovery worthy of publication in academic journals and is, therefore, often neglected by public lab researchers. However, as in the case of Aspirin, there are enormous healthcare cost savings that could be realized by uncovering beneficial applications of existing lower cost drugs. Private drug companies often forego investing any R&D on new

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[64] *Patent Act*, R.S. 1985, c.P-4 [*Patent Act*] and *Patented Medicines Regulations*, S.O.R./1994-688 [*Patented Medicines Regulations*].

[65] Online: American Heart Association <http://www.americanheart.org/presenter.jhtml?identifier=4456>.

applications of low cost, off-patent drugs because the lack of monopoly protection prevents them from being able to recapture any returns from this type of research. Although finding new uses for low cost drugs will benefit society, because the sale off-patent drugs can be produced en masse at much lower prices by generic producers, there is no direct profit payoff to private drug companies. With limited investment resources, private companies will invest in those ventures with the highest profit potential among a given set of drug development projects. This new prize model will tap into the overlooked but beneficial area of innovative applications of existing drugs and treatments.

Summary of Canada's Internal Strengths and Weaknesses

Strengths

- Quality higher education to develop human resources
- High caliber scientific & technological talent
- Strong industrial infrastructure: new innovation incentive implemented quickly with: minimal additional investment, rapid dissemination of policy to key stakeholders (ex. PMPRB – expand scope)
- Considerable innovative capacity: considerable breadth and depth of knowledge & access to state-of-the-art labs

Weaknesses

- Urgent crisis from rising healthcare costs: over-emphasis on use of new patented drugs, compounded by an aging demographic
- Bill C-9 compulsory licensing: deters pharmaceutical investment
- Complex patent application: deters foreign investment
- Government funded R&D: heavy concentration on basic research with low commercial viability & lack of funding for applied research (Inability to *commercialize* on innovative capacity)
- Limited resources to invest in R&D
- Insufficient development of Canadian-owned pharmaceutical companies (SME)
- Depletion of natural resources

(2) Current Incentives for Pharmaceutical Innovation

The ultimate purpose of innovation is to improve consumer access. This can be accomplished by discovering new developments "that either widens the scope of customer choice (new products) or lowers the purchase price (new processes), or both. Thus, it enhances the economic well-being of the nation."[66]

In its 4th Annual Innovation Report 2002, the Conference Board of Canada also recognized that in order for an intellectual property regime (including patents) to be effective, it must achieve the proper balance between:

a) providing an adequate reward to the inventor which will increase their private return on R&D and promote further innovation, and;

b) promote the interests of society by:

(i) dissemination/diffusion of technology and knowledge, and;
(ii) wider application and public use of invention.[67]

Therefore, the effectiveness of an incentive mechanism can be measured according to how well it meets the previously mentioned definition of innovation.

Let us next evaluate the effectiveness of patents and government supported R&D.

a) Pharmaceutical Patents & Market Failures

Summary of Market Failures from Patents

- Neglects R&D for welfare sectors in both poor and rich countries
- Focus on "me-too" innovations
- Biased research: lack consumer confidence
- Promotes secrecy that hinders subsequent innovation
- Neglects beneficial applied research on non-patentable innovations

The traditional innovation incentive is the legal instrument known as the patent. It awards an inventor the exclusive right to manufacture, use,

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[66] Palda, *supra* note 4 at 1–2.
[67] *Innovation Report 2002*, *supra* note 16 at 26.

and sell their invention to the market for a limited term.[68] This allows the inventor the ability to recoup his original investment in research and development, and ideally, any additional profits will finance subsequent innovations. Thus, the patent mechanism rewards an inventor for his creativity, a new product that adds value to society is created, future innovations are financed, and the economy as a whole is advanced.

However, unique characteristics of the pharmaceutical market create inefficiencies that prevent patents from delivering these benefits. The patent is also considered a "pull" mechanism, as it inspires innovation using profit as the prime motivator to complete development of its products.

The problem arises when a drug company's R&D orientation is "pulled" between two competing interests: profit maximization or social benefit. In order to meet shareholder expectations (and fulfill their fiduciary obligations), drug companies have to focus their investment on products that maximize profits. This makes the pull of profit much stronger than increasing social welfare. This concentrates R&D on innovations aimed at markets with the deepest pockets. Every dollar invested towards more marketable products is one less dollar available for the development of beneficial drugs, regardless of their potential social payoff.

Statistics reveal that patents do result in a proliferation of innovations that are only marginal improvements of existing drugs. This is because such innovations will yield the highest return to the drug companies.

Drug companies allege that it costs about $802 million to bring a drug into development.[69] Although there is debate about the legitimacy of this figure,[70] there is no doubt that drug companies do spend millions of dollars to study diseases, develop possible cures, and run clinical trials. This is a considerable investment by drug companies, even before the drug is considered for approval by the national drug approval agency.

Drug companies allege that they need to charge exorbitant margins on their products in order to recoup R&D costs and finance future

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[68] In Canada, the term for holding exclusivity is 20 years. See *Patent Act*, *supra* note 64.

[69] Tufts Center for the Study of Drug Development, News Release, "Tufts Center for the Study of Drug Development Pegs Cost of a New Prescription Medicine at $802 Million" (31 November 2001), online: TUFTS <http://csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid=6>.

[70] The advocacy group, Public Citizen, has conducted its own study based on overall industry R&D expenditures and the number of drugs approved by the FDA and has reached a much more conservative estimate of $100 million to develop a drug. "Rx R&D Myths: The Case Against the Drug Industry's R&D 'Scare Card'", *The Public Citizen's Congress Watch* (July 2001), online: citizen.org <http://www.citizen.org/documents/rdmyths.pdf> at 1.

innovations which will improve the quality of life. In Canada, the statistics do indicate that the overwhelming majority of pharmaceutical R&D is conducted by private drug companies. The PMPRB reported that more than $504 million had been spent in 2003 on pharmaceutical research and development (including capital equipment costs and allowable depreciation).[71] More than 95.8 percent of this amount originated from the pharmaceutical industry.[72] In 2003, pharmaceutical R&D grew to $1.192 million or $1.192 billion. [73]

However, the concern is not with the magnitude of funds devoted to R&D, but rather with the nature or *quality* of private R&D. Private R&D does not focus on addressing the nation's most pressing health concerns.

The statistics show that drug companies do not use their profits to finance the most beneficial R&D. On the contrary, because the cost of clinical trials on new drugs are so substantial, the drug companies wisely choose to spin off innovations that are almost identical to its existing products.[74] This results in many "innovations" that are chemically distinct but functionally identical to existing products. There are two simple economic reasons for this trend: innovation at minimal additional R&D cost but with maximum profit potential.

First, by focusing on drugs that have already been approved and for which they already have considerable clinical information, drug companies can create "innovative" drugs with minimal additional effort, investment, and clinical risk but a high degree of marketability. Second, as a patented drug nears its expiry, drug companies have found that "me-too" innovations allow them to "extend" their patent exclusivity period. As these "me-too" innovations are still, technically, new chemical inventions, they are entitled to patent protection. With proper marketing and advertising, a drug company can effectively extend patent protection from one expiring product to its derivative product and recapture monopoly profits.

Drug companies justify the importance of "me-too" innovations with two arguments. First, they say that greater competition will lower prices. However, the evidence does not support this claim. On the contrary, because the price of pharmaceuticals is controlled by exclusivity, the drug companies can charge high prices for their new products without

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71 Patented Medicine Prices Review Board, *Annual Report 2003*, online: PMPRB <http://www.pmprb-cepmb.gc.ca/CMFiles/ar2003e30LWY-1062004-5966.pdf> at 31.

72 *Ibid.* at 32.

73 *Ibid.* at 31.

74 An example of a well-known "me-too" innovation is Claritin and Clarinex – where one is a literal regurgitation of the other drug. That is, one is the equivalent of the metabolic product of the other, after digestion by the liver. Marcia Angell, *The Truth About Drug Companies* (Toronto: Random House of Canada Ltd., 2004) at 186-87.

fear of price competition. Also, price is rarely a factor in the decision to purchase by either the consumer or the prescribing physician.[75] Second, drug companies defend that such marginal innovations serve a societal need by meeting the unique needs of individual patients. For instance, they allege that by offering drugs with differences in dosages, frequency of administration, time-release formulations or type of side-effects, they are better meeting society's needs.

However, the drug companies' clinical results cannot support these claims. Patent approval is granted merely upon proving that the new drug is more effective than a placebo, that is, more effective than doing nothing. Therefore, there is no guarantee that taking one drug over a virtually identical drug will alleviate side-effects.[76] Also, it is highly questionable whether the societal value of more drug variations is worth the trade-off of exorbitant profit margins and the resulting inflation in the overall cost of national healthcare. The downside of enhancing product selection at the pharmaceutical counter is particularly steep when it sacrifices the development of truly life-saving innovations, such as a cure for tuberculosis to help our nation's poor.

Even the FDA's associate director of medical policy, Dr. Robert Temple, has said regarding "me-too" drugs, "I generally assume these drugs are all the same unless somebody goes out and proves differently . . . I don't think you lose much if you just always use the cheapest drug."[77]

In short, the supposed benefits from "me-too" innovations do not justify the high cost of the disadvantages.

U.S. Statistics: Focus on Marginal Improvements

In the United States, the National Institute for Healthcare Management (NIHCM) recently conducted a comprehensive report on the quality of innovations produced by the pharmaceutical industry, using statistics gathered from the FDA.[78] The results clearly indicate that the

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[75] *Ibid.* at 89-90.

[76] *Ibid.* at 90.

[77] Gardiner Harris, "2 Cancer Drugs, No Comparative Data" *New York Times* (26 February 2004) C2.

[78] The report analyzes the level of pharmaceutical innovation from 1989-2000. Data available from the U.S. Food and Drug Administration used for this report can be found in the table, *NDAs Approved in Calendar Years 1990-2001 by Therapeutic Potentials and Chemical Types*, online: FDA <www.fda.gov/cder/rdmt/pstable.htm>. See NIHCM Foundation, *Changing Patterns of Pharmaceutical Innovation*, (Washington D.C.: NIHCM Foundation, May 2002) at 24, online: NIHCM Foundation <http://www.nihcm.org/pharm.html> [NIHCM Foundation], and also see *supra* note 74 at 43.

overwhelming majority of innovations from private drug companies have been in name only.

The FDA categorizes applications for new drug approvals (NDAs) as either:

(a) new molecular entity (NME), or
(b) one that is an incrementally modified drug (IMD).

The NME is a new drug that uses active ingredients never before approved by the FDA for the U.S. market. An IMD is a new drug that uses active ingredients that have been approved previously by the FDA or one substantially similar to it.

Each category is further broken down into drugs that are to receive either:

(a) *priority review*: those drugs that seem to offer clinical improvement over existing products in terms of safety, efficacy and convenience, or
(b) *standard review*: drugs that offer no clinical improvement over existing drugs.

Using FDA statistics from 1989 to 2000, NIHCM found that over two-thirds of new drugs approved used active ingredients already available in the market.[79]

Seventy-six percent of new approvals were for standard rated drugs.[80] In other words, three quarters of new drugs approved did not offer any clinical improvement over existing drugs. Put another way, of the billions of R&D dollars that drug companies purport to invest to create beneficial drugs, only a mere 24 percent of this money actually created drugs with a clinical benefit over existing products.[81]

And yet, standard rated drugs (no clinical improvement) were the single most important driver of the increase in retail drug spending. From 1995 to 2000, retail pharmaceutical spending almost doubled from $64.7 billion to $132 billion.[82] Two thirds of this $67.3 billion increase arose from spending on newly introduced drugs; that is, $44 billion or 65 percent of the increase in drug expenditure resulted from spending on new drugs.[83] In simpler terms, new drugs cost a lot more than old drugs.[84]

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[79] NIHCM Foundation, *ibid.* at 7.
[80] *Ibid.* at 8.
[81] *Ibid.*
[82] *Ibid.* at 10.
[83] *Ibid.*
[84] *Ibid.* at 3 & 10.

It appears that this focus on marginal innovations will continue. In 2002, of the 78 new drugs approved by the FDA, only 17 out of the 78 were for NMEs — approximately 21 percent. The remaining 78 percent were drugs using active ingredients already on the market.

Pharmaceutical Innovation in Canada

In Canada, as in the U.S., pharmaceutical innovation consists mostly of the "me-too" quality; that is, they are mostly slight variations of existing patented medicines.

Canada's PMPRB categorizes new medicines submitted for drug approval into three types:[85]

Category 1: New strength of existing drug — also called "line extensions";

Category 2: Provide "breakthrough" or "substantial improvement" over predecessors (either in therapeutic effects or cost savings to the healthcare system);

Category 3: Provide moderate, little or no therapeutic advantage over comparable medicines.

In the five year period between 1996 and 2000, 455 new human drugs were patented in Canada. The proportionate breakdown according to innovation type is as follows:[86]

Category 1: Line Extension: 45 percent

Category 2: Breakthrough: a mere 5 percent

Category 3: Little or No Advantage: 50 percent

Thus, private R&D in Canada is also primarily of the "me-too" variety. These statistics indicate that patents as an R&D incentive inspire superficial innovations geared to raising profits, at the cost of beneficial improvements in the quality of healthcare. A new approach to inspiring truly beneficial innovations to improve healthcare is needed.

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[85] PMPRB, *Compendium of Guidelines, Policies and Procedures,* c. 1, s. 3.2, online: PMPRB <http://www.pmprb-cepmb.gc.ca/english/view.asp?x=654&mid=585#New_v_Existing_Products>.

[86] PMPRB, *Annual Report 2000* at 27, online: PMPRB <http://www.pmprb-cepmb.gc.ca/CMFiles/ar00e812NPN-482003-6735.pdf>.

Neglected Sectors: Developing and Developed Countries

This distorted focus on profitable drug development is reflected in the lack of research to cure diseases that debilitate millions of people in poorer countries. The developing world bears a disproportionate share of the burden of communicable diseases. Infectious and parasitic diseases account for over one-third of the disease burden in poor countries — and for over half of Africa's disease burden.[87]

The three biggest killers are malaria, tuberculosis, and HIV/AIDS. The WHO estimates that 300 million people are infected with malaria every year and 1.1 million die of the disease — most of whom are children.[88] Ninety percent of the victims live in sub-Sahara Africa. Tuberculosis kills about 2 million people every year, 98 percent of them in low-income countries.[89] And more than 42 million people are infected with HIV worldwide, of which 95 percent live in poor countries.[90] In 2002, 3.1 million people died from AIDS and 5 million people were newly infected.[91] Sub-Sahara Africa accounted for 70 percent of the new cases in 2002.[92] It is leading cause of premature death globally and is predicted to orphan over 26 million children by 2010.[93]

From the drug companies' perspective, these low-income sectors are too small and too poor to justify the R&D investment. For example, in 2002, Africa accounted for only 1.3 percent of pharmaceutical sales worldwide.[94] Between 1975 and 1997, only 13 out of 1,233 new drugs licensed worldwide were for tropical diseases, only four of which were developed by commercial pharmaceutical firms.[95] There is a simple economic reason for this dearth of third-world research. Markets in these countries cannot afford to pay high drug prices, so private drug companies do not develop cures for them, regardless of the social payoff.[96]

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87 Michael Kremer & Rachel Glennerster, *Strong Medicine: Creating Incentives for Pharmaceutical Research on Neglected Diseases*, (New Jersey: Princeton University Press, 2004) at 7 [Kremer & Glennerster].
88 *Ibid.* at 12.
89 *Ibid.* at 13.
90 *Ibid.* at 15. See also UNAIDS/WHO, *AIDS Epidemic Update* (2002) at 3-4, online: UNAIDS <http://data.unaids.org/Publications/IRC-pub03/epiupdate2002_en.pdf> [*UNAIDS Epidemic Update*].
91 Kremer & Glennerster, *ibid.* at 15. See also *UNAIDS Epidemic Update*, *ibid.* at 3.
92 *Ibid.* at 15.
93 *Ibid.*, c. 2.
94 United Nations Development Programme, "HIV/AIDS Statistical Fact Sheet," online: UNDP <http://www.undp.org/hiv/docs/olpubs/Barcelona-statistical-fact-sheet-2July02.doc>.
95 Bernard Pécoul, Pierre Chirac, Patrice Trouiller & Jacques Pinel "Access to Essential Drugs in Poor Countries: A Lost Battle?" (1999) 281:4 JAMA 361.
96 *Supra* note 87 at 39.

Even the limited research that is devoted to finding a cure or vaccines for a disease such as HIV is oriented towards the strains common in rich countries, rather than those in sub-Sahara Africa or South Asia, where the great majority of cases exist.[97]

Of the total R&D of $430–470 million devoted to finding an AIDS vaccine (through the International Aids Vaccine Initiative), only $50–70 million comes from private industry. The rest comes from government and non-governmental organizations.[98]

In the U.S., $70 billion is spent every year on health and research development (public and private); only 10 percent is devoted to research for health problems that affect 90 percent of the world's population (known as the 10/90 gap).[99]

In recognition of this market failure, the international community recently implemented changes to intellectual property rights regarding pharmaceutical innovations with the passing of the Doha WTO Ministerial Declaration (the Doha Declaration) on the Trade Related Aspects of Intellectual Property (TRIPS) Agreement and Public Health[100] and the 30 August 2003 decision of the WTO General Council.[101] The Doha Declaration recognized the severity of public health problems affecting less developed countries[102] and how patents increase the price of essential medicines.[103] As such, Doha requires that *TRIPS* not be interpreted or implemented in a manner that prevents public health measures.[104]

Bill C-9 (*The Jean Chrétien Pledge to Africa Act*)[105] was Canada's response in support of the Doha Declaration. It mandates compulsory licensing and exportation of pharmaceutical products to poor countries

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[97] *Ibid.* at 26.

[98] *Ibid.*

[99] See "The 10/90 gap: Now," online: Global Forum for Health Research <www.globalforumhealth.org/Site/003_The%2010%2090%20gap/001_Now.php>.

[100] WTO, *Declaration on the TRIPS agreement and public health*, WTO Doc. WT/MIN(01)/DEC/2 (2001), online: WTO <http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm> [*Doha Declaration*].

[101] WTO, General Council, *Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health*, WTO Doc. WT/L/540 and Corr.1 (1 September 2003), online: WTO <http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm>.

[102] *Doha Declaration*, *supra* note 100, art. 1.

[103] *Ibid.*, art. 3.

[104] *Ibid.*, art. 4.

[105] Bill C-9, *An Act to Amend the Patent Act and the Food and Drugs Act (Jean Chrétien Pledge to Africa)*, 3rd Sess., 37th Parl., 2004, online: Library of the Parliament <http://www.parl.gc.ca/37/3/parlbus/chambus/house/bills/government/C-9/C-9_4/C-9_cover-e.html>.

on the basis of national emergency or other situations of extreme urgency that result in a lack of ability to afford or have access to necessary drugs.

However, despite the implementation of *TRIPS*, the Doha Declaration and Bill C-9, the lack of treatment for diseases in poor countries will continue because compulsory licenses granted under Bill C-9 are only for the *generic* production of existing drugs, and do not affect newly developed treatments or vaccines. So, Bill C-9 does not offer additional motivation for drug companies to create treatments for low-income markets.[106]

High-Income Countries

There is a similar lack of R&D to develop products for diseases that afflict poor sectors in developed countries in North America as well. For example, creating a vaccine for tuberculosis, a disease that primarily affects the poor in North America, is ignored because such ventures are not lucrative enough.

The U.S. *Orphan Drug Act* (1983) creates financial incentives for companies to develop drugs for diseases that affect commercially unviable market sizes of fewer than 200,000 Americans. It provides incentives such as grants and tax credits in exchange for clinical testing and development. The primary incentive is the promise of seven years of market exclusivity.[107] However, as markets in the developing world are too poor to purchase newly developed drugs, this solution leaves unsolved the lack of private R&D to cure diseases in poor nations. An alternative incentive mechanism is needed to fill this gap.

Research Bias

Another market failure arising from patents is the drug companies' ability to control clinical testing conditions. To avoid the lengthy delays associated with public labs, drug companies prefer to use for-profit research companies to run clinical trials. Private drug companies then have free reign to control every aspect of the research, including the collection of data under their specific instructions and publication of results. Also, with public labs feeling the pressure of competition from

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106 Keith E. Maskus, *Intellectual Property Rights in the Global Economy*, (Washington, D.C.: Institute for International Economics, 2000).

107 John Henkel, "Orphan Drug Law Matures Into Medical Mainstay" *FDA Consumer Magazine* (May/June 1999), online: FDA <http://www.fda.gov/fdac/features/1999/399_orph.html>. See also Lisa R. Basara & Michael Montagne, *Searching for Magic Bullets: Orphan Drugs, Consumer Activism and Pharmaceutical Development* (New York: Pharmaceutical Products Press, 1994) at 127-28.

private research companies, they are more willing to accommodate drug companies' control over the entire research process.[108] This creates research bias in *both* private and public labs that are overwhelmingly in favour of their products. According to industry critic Marcia Angell, this makes bias not only possible, but extremely likely.[109] Even the very perception of bias undermines the public's confidence in the integrity of the private drug industry, which is in itself a market failure.

Brain Drain: Losing Top Scientific Talent

The enormous influence that large drug companies have over the industry gives rise to another market failure known as "brain drain." Private research labs and pharmaceutical companies attract top scientific talent away from public research organizations. They offer not only more lucrative pay, access to cutting-edge technology and diagnostic tools, but also freedom from the bureaucratic tedium of submitting annual grant applications.

As previously pointed out, the loss of scientific talent is particularly ominous for Canada, given the importance of qualified labour to develop competitive technology-based industries. The competition for scientific talent will only intensify as other countries are also building their technology-based industries. In particular, as genomic and proteomic sequencing are poised to revolutionize biopharmaceutical innovation, drug researchers will be exceptionally scarce.[110]

Thus, to attract scientific talent, a new incentive mechanism must encompass both economic and *non*-economic rewards to effectively compete with the high salaries offered by private industry. In particular, it should emphasize the freedom to pursue projects for purely creative

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[108] As hospitals lose precious funding to private research contractors, there is greater competition for research contracts sponsored by private drug companies. In 1990, 80 percent of industry-sponsored trials were conducted at academic institutions, but by 2000, this figure declined to less than 40 percent. See *supra* note 74 at 100–101.

[109] Angell concludes that bias is now rampant – a recent survey found that industry-sponsored research was nearly four times as likely to be favourable to the company's product as NIH sponsored research. *Ibid.* at 106. For the survey, see Justin Bekelman *et al.*, "Scope and Impact of Financial Conflicts of Interest in Biomedical Research: a Systematic Review" (2003) 289:4 J.A.M.A. 454. See also Justin E. Bekelman, Yan Li & Cary P. Gross, "Scope and Impact of Financial Conflicts of Interest in Biomedical Research" (2003) 289:4 JAMA 454, and Thomas Bodenheimer, "Uneasy Alliance: Clinical Investigators and the Pharmaceutical Industry" (18 May 2000) 342 New England Journal of Medicine 1539.

[110] Biopharmaceutical Industry, *supra* note 16 at 4-5.

and/or social benefits, which scientists sacrifice when working for private companies.

Backlash Against Drug Companies: Need for Positive Publicity

Market failures associated with patents are no longer quietly tolerated by the public. Pharmaceutical companies are experiencing a severe backlash as the government and citizen groups alike balk at the exorbitant cost of drugs, escalating healthcare costs and an aging demographic.[111] The U.S. government is considering imposing price

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[111] Mary Ellen Egan, "Spin Doctors: Drug companies are [coming] out of the shadows to fight for their reputations — and profits" *Forbes* (29 November 2004), online: Forbes.com <http://www.forbes.com/global/2004/1129/044_print.html>.

" . . . a grand campaign by GSK, the world's second-largest pharmaceutical company, to combat a tide of resentment against its industry. Some U.S. politicians are talking about government cost controls. A lot more are openly advocating the next-worst thing for a vendor of patented medicines, the importation of prescription drugs from cheaper overseas markets. And then there are the tort lawyers, descending on the drug companies with billion-dollar class actions claiming that potentially dangerous drugs like antidepressants and Vioxx have been all too eagerly marketed . . .

Pfizer has a strategy for deflecting criticism: do-goodism. It recently announced a drug discount program targeting uninsured and poor consumers. It offers free Lipitor, the cholesterol-lowering drug, and Viagra, the erectile-dysfunction treatment, among others, to families with incomes under $31,000. Discounts are available for all uninsured families. Bristol-Myers Squibb, meanwhile, is putting media weight behind its commercials with Lance Armstrong, a six-time Tour de France winner and a cancer survivor. The company, which makes Taxol and other cancer-fighting drugs, is also sponsoring an annual cross-country bike relay for cancer survivors, researchers and health professionals. Along the way, company reps tout clinical trials and cancer drug research. The suggestion: Let society pay for Erbitux today and some of the money will fund other cancer treatments down the road.

'Drug companies have finally realized they need to stand up for themselves,' says O. Thomas Hayes, principal at New England Consulting Group in Westport, Connecticut. Will it make a difference? Building awareness of their corporate brands could help the companies sell drugs in the future. But pharmaceutical executives admit they have been too slow to react. 'We were caught off guard by some of the attacks,' says Viehbacher. But the drugmakers' response could also contribute to consumer backlash. GSK, in print ads, insists imported drugs may not be safe or effective. Consumers might not appreciate the scare tactic when they are learning about the problems associated with homegrown drugs, like Vioxx. There's also the chance that consumers, already up in arms about the high cost of drugs, will see the campaign as an expense that will just drive the price of their allergy and cholesterol pills all the higher. GSK's Viehbacher admits an image transformation won't be easy or quick. 'It will take years to rebuild our reputation,' he sighs. 'You don't change perceptions overnight.'"

controls or importing cheaper drugs to combat high prices. Drug companies have been unsuccessful at countering this tide of resentment with their own public relations campaign, as the public regards it as self-serving rhetoric. The public is unconvinced and skeptical of token efforts at "do-goodism" such as providing free Viagra to the poor or sponsoring bike races for cancer survivors.[112] Private drug companies need to associate themselves with more credible recognition from a trustworthy institution.

Our proposal may allow drug companies to develop innovations with high social payoff and yet still be duly compensated. Being awarded a prestigious prize for furthering humanitarian causes will also give drug companies the positive publicity they so desperately need. Marketing-savvy pharmaceutical executives should recognize that any positive brand association will spillover onto their other products. This new reward scheme offers a win-win solution for government healthcare providers, the pharmaceutical industry, and the under-represented poor in society.

Marcia Angell, author and critic of the pharmaceutical industry, recommends raising the innovation threshold for approving pharmaceutical patents. She argues that requiring a higher degree of innovation will force drug companies to be more innovative in their R&D.[113]

However, this article advocates against such a radical change. It would require redefining the very ambit of what patents are intended to protect — inventions. Although "me-too" innovations may not have a measurable medical benefit, they are nonetheless new inventions and as such, should be entitled to patent protection. Also, making it more difficult for pharmaceutical companies to obtain patents will only encourage them to establish manufacturing operations outside of Canada. Canada cannot afford to further discourage foreign investment. Rather than trying to *force* drug companies to engage in more beneficial innovation, it would be simpler to offer an *alternative* reward that will encourage research in desirable areas. This reward would be a complement and not a substitute for existing incentive mechanisms.

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[112] *Ibid.*

[113] *Supra* note 74 at 240–41. In fact, she stresses that this should be the number one priority reform of all of her recommendations: "If I could choose only one of the reforms I am suggesting, it would be this one," in recommending that the FDA require that new drugs be compared with old drugs that treat same conditions and not just placebos in order to be granted patent protection. "The FDA should . . . not approve drugs that on balance offer trivial or no advantages over drugs already available." She believes that, "overnight, that reform alone would force the industry to concentrate on innovative drugs instead of me-too drugs."

Promotes Secrecy: Hampers Overall Rate of Innovation

Protecting patent rights has become so important that private companies tend to hold back on the disclosure of new discoveries in order to be the first to obtain a patent. This slows down the rate of dissemination of beneficial innovations to end-users. It also impedes subsequent innovations which might have been derived from the secreted information.

Government Research Incentives: Push & Pull Programs

Government attempts at filling innovation gaps from pharmaceutical patents have not produced impressive results. *Push programs* subsidize research inputs by providing grants to academics, direct investment in product development, tax credits for R&D investment and government financed laboratories.[114] *Pull programs* operate on the basis of rewarding the inventor only upon the complete development of an innovation; that is, such programs offer rewards only for successful research output.

b) Push Programs:

(i) R&D Tax Credit

As tax credits are only applicable against taxable income, the research and development tax credit is only of benefit to larger profitable drug companies. This mechanism does not encourage innovation or growth for start-up pharmaceuticals. The large drug companies also have an incentive to re-label or exaggerate R&D expenditures to maximize the tax credit. The tax credit mechanism also does not improve the affordability and access to finished products under patent monopoly prices.[115] This incentive mechanism does not provide any additional incentive to create treatments for low-income populations. Professor Kristian Palda, an expert in R&D policy from the Fraser Institute of Canada, concluded that although Canada has one of the most generous R&D tax credit systems of all leading industrial nations, it has "not progressed an iota in its overall research intensity."[116]

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[114] Kremer & Glennerster, *supra* note 87 at 45. Kremer's wording of typical "push" programs.

[115] *Ibid.*

[116] Palda, *supra* note 4 at *x* & 16. See also the rankings from Jacek Warda, *International Competitiveness of Canadian R&D Incentives: An Update*, Report 55-90, (Ottawa: The Conference Board of Canada, June 1990). Rankings of effectiveness of R&D tax credit systems are based on the after-tax cost of $1 of R&D expenditure, divided by one, minus the tax rate.

(ii) Direct Funding of Research

The key problem with push programs is that researchers are rewarded prior to producing successful results.

In determining which projects to finance, informational asymmetry between researchers and grant administrators causes ineffective allocation of funds. Because administrative bodies lack perfect information about the viability of research proposals, they must rely on information submitted by researchers who have a vested interest in exaggerating project success. The result is that too often, precious research funds are wasted on unsuccessful projects.

Difficulty in monitoring the progress of projects also results in considerable waste. Once grant funds have been secured, a lack of accountability engenders complacency by researchers. This can cause inefficient use of grant money, exaggeration of clinical success or even misappropriation of funds.

A dramatic example of how push programs can go awry is the 1980s USAID Malaria Vaccine Program. In 1984, the director of the program stated that a malaria vaccine would be developed within five years — but to this day no such vaccine had been developed. Even after an unsuccessful first round of financing, the project investigator managed to convince the USAID to provide an additional $2.38 million to continue development efforts, which he later transferred into his personal account.[117]

A Canadian example is the government's financing the research and development of the CANDU nuclear reactor.[118] The government spent $10 billion on CANDU, which has still not managed to break-even. It appears that even though the original intent behind CANDU was wise, its commercial viability was overestimated. Consistent with criticism regarding weaknesses in its technology sectors, Canada appears able to excel at technical accomplishments but is less capable of successfully commercializing its innovations.

After reviewing the huge sums of money and energy that have been devoted to encouraging R&D in Canada, Palda found that the results were less than stellar. The resulting degree of technological advancement

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[117] Kremer & Glennerster, *supra* note 87 at 47-48.

[118] See Palda, *supra* note 4 at 176–90 for a full history of the government support for development of the CANDU reactor. Palda relies heavily on Energy, Mines and Resources Canada, *Nuclear Industry Review: problems and prospects 1981-2000* (Ottawa: Energy, Mines and Resources Canada, 1982) and on G. Bruce Doern, *Government Intervention in the Canadian Nuclear Industry*, (Montreal: Institute for Research on Public Policy, 1980).

has not been nearly as impressive as the investment.[119] Palda concludes that Canada's ability to commercialize its innovations is its weakness (*i.e.* weak in relation to the private sector's rate of successful commercialization of its innovations), and yet most of Canada's policy thrust is aimed at R&D support, not commercialization. Economist Michael Kremer agrees that push programs do not support the later stages of innovation that involve commercialization. He reasons that this occurs because government supported researchers are chiefly interested in the pursuit of academic acclaim and publishing in top journals, which concentrates their work on basic or pure scientific research. Academic-oriented researchers tend to lose interest at later stages of development and commercialization of innovations because it is less-intellectually challenging than basic research.[120] As previously mentioned, more attention on inspiring interest in the area of applied research is needed. Applied research is important as it focuses on practical, usable applications of basic research. Rewarding researchers who discover ingenuous new applications for existing drugs and treatments will also be consistent with Canada's urgent need to find alternative, lower-cost medical treatments to help stem escalating healthcare costs. Use of economic prizes is also congruent with recommendations from innovation experts that Canada needs to use results-based incentive programs to facilitate the commercialization of its innovations.

Kremer and Palda agree that government support for purely scientific research is still important, in order to advance scientific knowledge. But they both recognize the value of using market-based results-oriented pull programs to achieve more effective commercialization of innovations.[121] In particular, Palda thinks the government should try to (i) promote conditions for increased competition, (ii) decrease "bail-outs" of the industry with subsidies and government procurements and instead focus on (iii) better ways to pre-identify winners and (iv) facilitate the diffusion of innovation.[122] All of these elements are included in the economic prize system proposed in this article.

Summary of Distortions from Push Programs

- Difficult to identify successful projects/low rate of success

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[119] " . . . government policies, whether by direct subsidy, purchasing schemes, merger encouragement or tax alleviations to encourage innovation have been at best, ineffective." Palda, *supra* note 4 at 101–102.
[120] Kremer & Glennerster, *supra* note 87 at 54.
[121] Palda, *supra* note 4 at 250–51 & 258. See also Kremer, *supra* note 87, c. 6.
[122] Palda, *ibid.*

- Inability to monitor progress/lack of accountability once funded
- Complacency/low motivation
- Research bias/exaggerated findings
- Academic-oriented: focus on basic research
- Tax credit does not alleviate lack of access/affordability
- Slow rate of commercialization
- Appropriate for basic research
- Ignores applied research

c) Pull Programs: Buyouts, Guaranteed Purchase, Economic Prizes

Due to the inefficiencies that arise from push programs, there is growing acceptance of "pull" programs (or reward programs) to encourage pharmaceutical innovation. The appeal of pull programs is they are results-oriented. No reward is paid until the inventor produces a demonstrably successful result; that is, you pay nothing until a viable product is developed. The cost of unsuccessful projects is not financed by taxpayer funds.

Another advantage of an outcome-based reward is that, if properly structured, it enables the government to take a more deliberate and planned approach that directs R&D on priority health issues. As previously pointed out, a key inefficiency of government push programs is that it places the nation's research agenda in the hands of researchers. Not surprisingly, this results in pursuits of mostly academically-oriented research topics, which although scientifically relevant, do not coincide with the nation's most pressing healthcare concerns. Pull programs avoid this inefficient use of taxpayer funds.

Economists Shavell and Van Ypersele (2001) considered the benefits of using rewards to encourage innovation with low profit potential but high social payoff.[123] They concluded that an optional reward system — where an innovator can choose between a reward or intellectual property rights — is superior to a pure intellectual property rights system. They felt a reward system would be particularly effective to encourage drug innovation because it is an industry where social losses due to intellectual property rights are likely to be high. That is, it is an industry where the profit margins are high. They concluded that "in a regime with

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[123] Steven Shavell & Tanguy Van Ypersele, "Rewards versus Intellectual Property Rights" (2001) 44 J. L. & Econ. 525.

rewards, drugs would be far cheaper and more widely used . . . engendering significant increases in consumer welfare."[124]

Two of the strongest proponents of using rewards or market-based mechanisms are Harvard economist Michael Kremer and Rachel Glennerster, as described in *Strong Medicines: Creating Incentives for Pharmaceutical Research on Neglected Diseases* (2004).[125] They believe that the use of pull programs will lead to a "faster, cheaper and more efficient research process that was open to new ideas."[126] In particular, they advocate the use of an "advanced purchase commitment" program as ideal to inspire the development of vaccines for diseases such as malaria, tuberculosis, and HIV/AIDS, that cripple the developing world. The commitment is a legally binding contract to pay a fixed subsidy per vaccine purchased from the developer, provided that the vaccine meets the technical requirements pre-specified by the administrative body. Technical requirements include proving clinical safety and efficacy and delivering the vaccine in market-ready form. This program would encourage innovation on commercially unviable diseases, enable access to the vaccine at a reasonable price, and avoid the waste of financing unsuccessful research endeavors.

This mechanism is being studied and strongly supported by the Centre for Global Development, a Washington, D.C. based think tank. Their working group on the study of APCs is funded by the Bill & Melinda Gates Foundation. The APC has even been recently adopted by the UK. On 1 December 2004, Gordon Brown, Britain's Chancellor of the Exchequer, announced his government's commitment, in cooperation with donors, to purchase an AIDS vaccine when it is developed.[127]

However, one of the limitations of this incentive is that it only encourages innovation for products that have a readily determinable market size and whose technical requirements can be easily described in advance. This suits the development of vaccines, but does not reward other beneficial innovations that cannot be readily foreseen or easily described. In pharmaceutical research, there is enormous potential to benefit from the discovery of new applications of existing drugs or treatments. As previously mentioned, Aspirin is one example of the therapeutic and cost-savings benefits reaped by discovering its use as a heart disease preventative.

Similarly, purchase commitment schemes do not reward inventors whose discoveries are socially beneficial, yet so ingenious and inconceivable that their description is beyond the pre-specified technical requirements of a purchase commitment scheme.

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[124] *Ibid.* at 545.
[125] Kremer & Glennerster, *supra* note 87.
[126] *Ibid.* at 66.
[127] Michael Kremer & Rachel Glennerster, "A magnet for vaccines" *Fortune* 150:13 (27 December 2004) 52.

Awarding Innovations Beyond Vaccines

Potential breakthrough discoveries, as well as important innovations in applied research that have high social value, will be ignored by the private drug companies if they have low commercial appeal. Without an adequate reward mechanism to encourage their full development, the social benefits from such valuable innovations will never be realized. This article proposes the use of economic prizes to tap into this potential. This prize will reward *any* pharmaceutical innovation that adds significant social value or cost-savings to the healthcare system, without pre-specifying the exact technical requirements. The prize will only pre-specify the formula by which the prize amount is calculated and the priority healthcare issues that are eligible.

Kremer himself recommended using purchase commitment to encourage R&D for other drug innovations besides vaccines.[128] In a recent article, economist William A. Masters advocated a similar open-ended prize system to encourage agricultural innovation in low-income countries.[129] And Aidan Hollis, of the University of Calgary, has also proposed a similar prize mechanism to reward drug innovations for developing countries based on their relative incremental social value, using a unique points allocation system.[130] The prize system in this proposal will be similar to the mechanisms proposed by Masters and Hollis, but with a much wider scope of eligible innovations, to include applied research discoveries and drug innovations for under-served sectors in the developed world as well as in poorer nations. The payment

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[128] Kremer & Glennerster, *supra* note 87 at 109-12. Kremer recognized that there may be an advantage to using APC for disease-fighting techniques beyond vaccines, such as drugs and disease diagnostics in order to avoid biasing research towards vaccines at the expense of alternative-disease fighting approaches. He cites the British government's 18th century prize for discovering a method of determining longitude as an example of the benefit of setting prize terms to be more open-ended in order to admit a variety of solutions. One of the difficulties with using APC for innovation beyond vaccines would be the difficulty in specifying the technical requirements in advance, accounting for potential side-effects and encouraging innovations that are only slightly better than existing ones.

[129] William A. Masters, "Research Prizes: A Mechanism to Reward Agricultural Innovation in Low-Income Regions" (2003) 6:1&2 The Journal of Agrobiotechnology Management and Economics 71. Also see William A. Masters, "Research prizes: a new kind of incentive for innovation in African agriculture" (2005) 7:1-3 International Journal of Biotechnology 195.

[130] Aidan Hollis, "An Optional Reward System for Neglected Disease Drugs" (18 May 2005) Department of Economics, University of Calgary; Institute of Health Economics, online: University of Calgary <http://econ.ucalgary.ca/fac-files/ah/optionalrewards.pdf>.

mechanism for this proposal is more akin to the instrument recommended by Masters than the points allocation system advocated by Hollis.

Expanding the scope of the prize to include all types of innovations, including applied research discoveries, is intended to maximize the number of sources of beneficial innovations. The larger the pool of potential discoveries, the more likely it is that discoveries will be made which will benefit Canada's healthcare system. The value of a healthcare discovery should not be measured by its source. Healthcare benefits, whether from new drug formulations, medical treatments, or new applications of existing products and natural substances, should all be fully explored. This prize recognizes that valuable discoveries can come from a variety of sources and intends to be receptive to all the possibilities. For example, the discovery that cinnamon significantly lowers blood sugars and cholesterol makes it a more affordable alternative to more expensive drugs such as statins.[131] But, such discoveries cannot be patented for drug companies to capture any profits, and are, therefore, disregarded or not actively pursued by researchers. Including such discoveries under this prize provides the extra incentive for researchers to follow through or reconsider such applications. The beauty of this open-ended approach is that it does not require any additional financial investment to cast a wider net. No prize money is to be paid unless the inventor is able to produce documentation that their discovery is demonstrably usable and effective. All that is required is to structure the description of eligible prizes to be receptive to all innovations that will benefit the healthcare system. A more detailed description of prize categories is included in the *"Economic Prize: The Mechanism"* section of this article.

III. NEW ERA, NEW INNOVATION POLICY, NEW INCENTIVES

AN EFFECTIVE INNOVATION INCENTIVE MUST ADDRESS the threats that accelerating scientific innovation and global competition present. It must also strengthen Canada's competitive standing in order to capitalize on new market opportunities. Simultaneously, the incentive must be feasible within existing constraints on Canada's resources and take maximum advantage of Canada's current strengths. Therefore, an effective economic prize must meet the following criteria:

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131 Online: U.S. Department of Agriculture <http://ars.usda.gov/is/np/fnrb/fnrb0104.htm#pinch>.

Features of an Effective Economic Rewards System for Pharmaceutical Innovation

- Consistent with priority healthcare needs: encourages innovation on priority healthcare issues
- Self-selecting: encourage private companies to pursue projects that have highest chance for success
- Cost-effective & minimal financial risk: pay only upon successful completion or development of market usable innovations
- Address marginalized diseases overlooked by private industry
- Facilitate faster rate of commercialization of innovations
- Promote knowledge sharing, technology transfer & subsequent innovation development across the industry
- Help retain and attract elite scientific talent to Canada
- Encourage greater focus on applied research
- Encourage R&D on cost-effective applications of existing drugs/treatments to reduce healthcare costs
- Ensure equal access to safe & cost-effective healthcare
- Tap into private drug companies' potential "vault" of disregarded or incomplete developments
- Attract foreign investment from pharmaceutical multinationals

The beauty of the prize proposed in this article is that it incorporates *all* of the previously mentioned criteria. This proposal creates a powerful innovation incentive that addresses global issues, fortifies Canada's vulnerable points, and plays on Canada's strengths. In fact, the use of prizes to inspire novel solutions has a long and successful history.

Brief History of Use of Prizes

In discussing the merits of using rewards to inspire innovation, Kremer recalled several cases where the government's offer of a reward resulted in the successful invention to solve a particular problem.[132] In 1837, it was employed by the French government to invent photography and led to the creation of the Daguerreotype. In more modern times, rewards have been used by the U.S. Patent Compensation Board and the Department of Defense to compensate for innovations of military value

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[132] Michael Kremer, "Patent Buyouts: A Mechanism for Encouraging Innovation" (November 1998) 113:4 The Quarterly Journal of Economics 1137 at 1144-146.

and by the former Soviet Union to reward process innovators with a percentage of cost savings realized from the inventions.[133]

In the early 1900s, hotel magnate Raymond Orteig offered a reward of $25,000 to the first person to fly non-stop from New York to Paris. This resulted in nine different attempts to cross the Atlantic and $400,000 worth of private investment, which, of course, was won by Charles Lindbergh. The prize and attendant competition not only solved a problem left unaddressed by government and private markets, but spawned a revolution in commercial flight that is the basis for today's $250 billion aviation industry.

As previously discussed, the Ansari X Prize is a very recent example of how prizes can be successfully used in today's technologically-jaded society to inspire solutions and spawn commercial activity. It is worth reminding that the offering of a $10 million purse leveraged over $100 million of private investment, revolutionized the idea of low cost commercial spaceflight, and achieved its original purpose — the creation of a commercially viable civilian spacecraft. Despite considerable initial skepticism, the Ansari X prize created value for all stakeholders and advanced society. This was accomplished by overcoming the sociological and psychological barrier that market-based incentives cannot be used to solve a social problem without sacrificing quality or safety.

If a prize can be used to further growth in the spaceflight industry, then the use of prizes to improve access and quality to healthcare is all the more justified. There are few causes more worthwhile and of pressing concern today than improving the health and quality of life of human beings. The main advantage of this prize is that it minimizes financial risk. No prize money is to be paid prior to the production of demonstrably effective results, so unlike other incentives, it involves minimal upfront financial investment. Plus, unlike other government funded research, the burden of assessing project success, monitoring its progress, running clinical tests and commercialization of the final product, lies on the inventor. It induces the inventor to be self-selective and choose only those projects that have the highest likelihood of success.

Economic Prize: The Mechanism

This prize authority will offer to pay a fixed percentage of the *relative* economic value of *any* innovation (in relation to the next best alternative treatment). That is, it will pay a proportion of the incremental therapeutic value of the innovation in comparison to the next, best treatment for the same condition. Or it will pay a percentage of the cost-savings realized from the innovation over using existing treatments. Therapeutic value

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[133] John P. Sinnot, *World Patent Law and Practice*, vol. 2M (New York: Matthew Bender, 1998).

can be measured by impact on health outcomes. An objective measure for health outcomes can be DALYs, as suggested by Kremer, for use in the purchase commitment mechanism. This measure is already used by the World Bank, the World Health Organization (WHO), government healthcare officials, insurance companies, and even drug companies to assess and compare the impact of diseases and the cost-effectiveness of available medical treatments.[134]

The size of the reward shall be between 10 and 20 percent of the cost savings or societal benefit. This will be an amount that is less than gains potentially realized from patent exclusivity, but still sufficient to stimulate research. Annual or periodic reviews of this percentage will allow adjustments to be made to reflect any subsequent changes in therapeutic value. For example, if the innovation results in additional unforeseen side-effects, the percentage shall be discounted. If there are greater than expected cost-savings or therapeutic benefits, the percentage will be increased, similar to awarding a bonus.

Once the innovation is proven to be approved and commercially usable by the administrative body, it will be placed into the public domain. This bypasses the lengthy delays associated with the patent approval process and augments the pool of scientific knowledge more quickly, which will facilitate faster discovery of subsequent innovations.

Offering a share of social value to the innovator will provide the marginal but pivotal extra incentive to spur private or public researchers to complete development of commercially or academically unattractive projects. Another allure of this prize, over pursuing monopoly profits, is that the return of their R&D investment will be immediate. In order to reap profits under patents, the drug company must invest considerable time and money upfront on aggressive advertising and marketing campaigns, and then must wait several months or even years to receive any feedback on success or failure. This not only poses a considerable financial risk to pharmaceutical companies but also entails an opportunity cost. Opportunity cost is the revenue that the company sacrifices by not investing those same funds to earn interest, property, or investment income from other projects.

Financial experts already use such present-value considerations to guide which projects are worth financial investment among a portfolio of projects. It is similar to the old adage that "a bird in the hand is worth two in the bush." Although certain projects initially seem more profitable

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[134] Kremer & Glennerster, *supra* note 87 at 40 & 90 for discussion of use of DALY's in Kremer's purchase commitment program. Also see World Bank, *World Development Indicators (WDI) 2003* (Washington, D.C.: Oxford University Press, 2003) and WHO, "Less-used vaccines against major diseases are cost-effective, researchers conclude" (2000) 78:2 Bulletin of the World Health Organization 274, online: WHO <whqlibdoc.who.int/bulletin/2000/Vol78-No2/bulletin_2000_78(2)_news.pdf>.

and, therefore, more attractive, they are bypassed if the earnings are forecast too far in the future. The longer that valuable capital is locked into a project, the greater the opportunity cost (or foregone income). Also, there is considerable cost in maintaining projects while they are not earning any income, such as the cost of managing and monitoring the project, which also discounts the value of their future revenues. Offering immediate cash rewards allows the drug companies to bypass all of these risks.

This prize is, therefore, consistent with the fundamental business principle that a dollar earned today has a higher present value than the same dollar earned at some future time. By awarding an immediate cash prize and providing a reliable stream of future income, this incentive mechanism has the combined appeal of a higher present dollar value and reduced financial risk — which more than compensates for modest profits.

We also propose that the cash prize be supplemented with other more subtle, but equally powerful, non-economic motivators. This proposal suggests a high-profile announcement of the prize and ongoing promotion that tracks the progress of the competition. Associating the prize with considerable fanfare will not only help raise the profile of the award, but amplify the economic portion of this incentive. A sufficiently high-profile award will satisfy an inventor's desire for academic acclaim and career advancement or peer approval and public recognition. Placing the competition and the awards ceremony in a highly public forum will enhance an inventor's personal sense of accomplishment by highlighting their mastery of a scientific challenge and meaningful contribution to the betterment of society.

To this end, this proposal suggests that the awards ceremony be heavily promoted and include the recruitment of celebrities such as Mandela or Bono and other high-profile members of the political, humanitarian, and scientific community to be awards presenters. At minimal cost, a new journal and website can be used to create additional promotion for the competition and attract private and philanthropic donors. Success attracts success. Potential contributors are always more likely to support an organization with a professional, high-profile appeal.

An example of the successful use of tasteful marketing to further scientific advancement is the Ansari X Prize. The highly promoted Ansari X Prize[135] offered $10 million to the first privately manned space vehicle to orbit the planet twice in two weeks. The X Prize created a high degree of public interest by announcing the competition with black-tie galas and keynote speeches from celebrities such as author Tom Clancy. It also boasts an impressive panel of members and endorsements from well-known celebrities such as Arthur C. Clarke, Dennis Tito, John Glenn,

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[135] Online: X Prize Foundation <http://www.xprizefoundation.com/prizes/xprize_ansari.asp>.

Buzz Aldrin, and Tom Hanks. The results speak for themselves. The $10 million prize resulted in intense competition between 27 teams from 7 countries and leveraged over $100 million in private investment. More importantly, it accomplished what it set out to do. In October of 2004, the first privately-manned spaceflight was launched and revolutionized the idea of low cost civilian spaceflights. Despite initial skepticism, but due to its overwhelming success, the X Prize is now considered the leading model for fostering innovation through competition. The element of healthy competition produced exceptional results, without damaging the integrity of the resulting innovation. Rather, the competition fostered greater awareness, education, and appreciation of science and enhanced the existing pool of scientific knowledge. The prize model in this proposal can bring similar advancement to innovation in healthcare, without compromising its integrity.

After the competition, the website can be used to publish the names of the winners and emphasize the value of their findings. This type of promotion will generate goodwill for both the inventors and improve the government's reputation as a source of knowledge and innovation.

Promotion is a very valuable and powerful reward which has tangible market value. Why else would drug companies devote almost 35 percent of revenues to their advertising and marketing budget?[136] Comprising approximately $54 billion, marketing is the single largest expenditure in their budget, even greater than the amount spent on R&D. Similarly, in 2000, 35 percent of all drug company employees were in their marketing departments. The fact that drug companies are willing to devote billions of dollars to generate promotion indicates how essential and influential a credible public image is to corporate strategy.

Private drug companies should be attracted to this prize because it will benefit their companies in three ways:

> (i) positive publicity will counteract the current tide of anti-drug company resentment. Receiving a prize from a credible, independent body of healthcare and humanitarian experts will lend them much needed credibility (than current self-serving attempts have been);
>
> (ii) positive publicity can provide valuable cross-promotion of other patented products and help boost sales of other products; and

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[136] See *supra* note 74 at 119. See also *supra* note 74 at 115-34 for a detailed analysis of the breakdown of the marketing and advertising budget of the largest drug companies in the U.S.

(iii) positive publicity will also help drug companies entrench their brand names in developing countries, which will be particularly valuable given increasing competition for these markets.

The success of the Ansari X Prize is one example of how prizes and competition can be implemented to encourage innovation in science and technology, promote science education, induce growth of private industry, *and* further the advancement of humanity.

Needs-Driven Approach: Pre-Specify Target Diseases

Placing the research agenda in the hands of the Canadian government instead of researchers will ensure that R&D is directed at resolving the priority healthcare needs of Canadian citizens. Instead of relying on research proposals put forth by researchers, it will be the Canadian government that steers the nation's research efforts directly to the most pressing or overlooked healthcare issues.

Categories 1 & 2: Two Categories for Patentable Treatments for Neglected Diseases:

One category should address priority health issues in Canada and one should address treating diseases in poor, developing countries. For example, the Canadian category could include prizes for innovations which cure diseases that primarily affect the poor and cause pressure on our social welfare system, such as tuberculosis. The Canadian category would also include addressing chronic diseases that are particularly taxing to the healthcare system, such as diseases that affect seniors (arthritis, alzheimer's, high blood pressure), as their health issues comprise the largest portion of healthcare expenditure and will grow as this population expands. The category for the developing world will focus on diseases that are the most widespread and pervasive; a good starting point could be the World Bank's list of priority diseases, as it identifies the diseases that are wreaking the most damage.[137]

Category 3: Innovative Uses/Applications of Existing Off-Patent Drugs & Treatments:

This category will inspire researchers to delve further into discovering beneficial applications of existing drugs and treatments. Since the size of

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[137] Dean T. Jamison *et al.*, eds., *Disease Control Priorities in Developing Countries*, 2nd ed. (New York: Oxford University Press for the World Bank, 2006), online: DCPP <http://www.dcp2.org/pubs/DCP>.

the prize varies with the degree of cost-savings to the healthcare system, it will motivate researchers to focus on new applications of lower-priced medicines that are more widely available to the public and help contain healthcare expenditures. It will also encourage and facilitate the all important commercialization stage of R&D, and contribute to the country's overall economic wealth and competitive standing.

Category 4: Beneficial Applications of Non-Patentable Products/Natural Substance:

Similar to Category 3, this will reward beneficial applications of naturally occurring substances, such as the use of cinnamon extract to lower blood sugar levels or to control cholesterol instead of using more expensive medications such as statins.

Category 5: Innovative Ideas for Cost-Saving Means of Healthcare Distribution or Delivery:

Even once an affordable vaccine has been developed, one of the most common obstacles to implementing the cure in developing countries is the high cost of trying to distribute or deliver the treatment. Delivery of vaccines is expensive because it involves hiring, training, and transporting qualified medical staff, the coordination of vaccine transportation, and the establishment of medical facilities. These costs are particularly high when dealing with the typical widely-dispersed agrarian population of developing nations that lack access to even rudimentary infrastructures such as paved roads, local bus transportation, sanitary running water, electricity, and telephone communication. Therefore, innovative ideas on finding more efficient means on the *administration and distribution of medical treatments* will be extremely valuable.

For example, taking advantage of today's advanced communication technologies and innovative ideas on the use of telemedicine are already being developed.[138] It is based on the novel idea of delivering and monitoring medical care over digital telephone lines as a substitute for traditional on-site visits. It has the potential to be applied to medical diagnosis, remote monitoring of patient conditions, establishment of tele-hospices for the terminally ill and tele-nursing for the chronically ill — with potentially enormous cost-savings on the administration of healthcare. Studies have indicated that it will not only save

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[138] See "Telehome Healthcare," online: *Telemedicine Today: The Health Newsmagazine* <http://www2.telemedtoday.com/articles/telehomehealthcare.shtml>.

administrative costs, but reduce waiting times and back-logs at clinics and emergency centers, improve access to treatments from remote communities, as well as improve the quality of life for the terminally ill.

Such innovative ideas to streamline the delivery or administration of healthcare are absolutely consistent with the government's mandate to encourage cost-effective innovations — and is, therefore, deserving of the type of acclaim and economic recompense available under this reward proposal. As such, similar cost-saving innovative ideas to streamline the administration or delivery of healthcare should be rewarded under this proposal.

Requirements for End-Product: Specific Parameters & Open-Ended Technical Requirements

The eligible innovation must meet specific clinical testing and safety requirements, equivalent to those currently used by the Canadian drug and medical treatment approval administrations. The applicant must submit documentation to verify this clinical testing requirement.

To be consistent with the need for the innovation to be commercially viable, the applicant must submit documentation of the demonstrated usability of the product/treatment. That is, they must provide documentation on the ease of use of product by the actual target market to ensure that the product can be readily administered despite potential infrastructural constraints — such as lack of hygienic water supply, or lack of trained medical staff which limits usability of treatments that require excessively frequent doses or follow-up monitoring.

The prize will be open-ended regarding the specific methodology or type of technology/treatments eligible, so long as it meets the safety and efficacy requirements. An open-ended approach is more inclusive of all types of applications and innovations and taps into a larger pool of creative solutions.

The prize should be eligible to non-scientists in order to tap those ideas for improvement that often come from those with direct interaction with medical drugs and treatments: such as general practitioner physicians, lab assistants, or even consumers. Many worthy inventions have arisen from non-research experts in the past, such as the Wright Brothers — who were actually bike mechanics before they invented the first airplane.

Pre-Specify Payment Formula: Ensures Objective Assessment

The amount of each prize will be proportional to the incremental therapeutic benefit or cost savings to healthcare relative to the next best alternative treatment.

It is recommended that this percentage be 10 to 20 percent of the societal benefit. Awarding a proportion of cost savings will motivate

researchers to focus on innovative applications of existing lower cost treatments as this will increase the size of their prize.

The therapeutic benefit can be assessed by its impact on health outcome as measured using DALYs or QALYs. As previously mentioned, this is a measure that is already widely-used to assess therapeutic value of medical treatments by international health agencies, government healthcare administrators, hospitals, and insurance companies.

There should be annual or periodic review of the efficacy of the innovation to adjust the proportional share of the prize. The percentage can be discounted if additional side-effects are discovered or increased to reward therapeutic benefits greater than initially anticipated.

Make-up of Adjudicating Committee

The decision-making panel should be a Board made up of 8 to 12 members that represent experts in the respective fields of healthcare, pharmaceuticals, and scientific and social development organizations — appointed by senior Canadian healthcare officials. The members could sit for four-year staggered terms to prevent collusion among members or with outside interest groups.

A requirement for members to disclose potential conflicts of interest would be included in the rules to ensure that Board members cannot vote on those prize categories where a member has an affiliation with eligible companies or labs.

Canada has the advantage of looking to the procedures and past decisions of the PMPRB to provide guidance in assessing the relative therapeutic value of eligible innovations. This Board makes similar assessments when it reviews a patented medicine for fair pricing. To come to its decision, it makes comparisons to the cost of clinically equivalent treatments for the same condition, in the same market.[139] Having access to this information will make it easier and faster for the administrators of this new prize to make its assessments. Also, because drug companies are required to disclose their revenues and R&D expenditures to the PMPRB, there is a ready source of information to assist in forecasting sales and usability of submitted innovations.[140]

Finally, the PMPRB provides a ready template from which the administration of this new prize can be developed — without considerable additional research, expense, or delay. It will allow the prize

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[139] PMPRB, *Compendium of Guidelines, Policies and Procedures*, c. 3, online: PMPRB <http://www.pmprb-cepmb.gc.ca/english/view.asp?x=654&mid=587>. See also PMPRB, *Compendium of Guidelines*, *Policies and Procedures*, schedule 2, online: PMPRB <http://www.pmprb-cepmb.gc.ca/english/view.asp?x=654&mid=589>.

[140] *Patented Medicines Regulations*, *supra* note 64, s.5.

to be implemented in a progressive manner, without radical change or expense.

Heavy promotion of prize

As previously mentioned, it is recommended that "celebrities" from scientific and humanitarian sectors be recruited to be presenters at an elaborate awards ceremony (for example, Mandela, David Suzuki, Bono, or other science or humanitarian celebrities) to raise the profile and awareness of the prize, which will help attract top scientific minds and philanthropic interest to the competition.

Similarly, it is also recommended to convince a scientific or humanitarian celebrity to lend their name to the prize — for example, the "Mandela Health Prize" or the "Bono Genius Prize" — to help raise its profile and emphasize that its purpose is the betterment of healthcare and society. Another suggestion is to dedicate a prize to prominent Canadian scientists such as the "Banting and Best Prize" in the Canadian healthcare prize category. Additional promotion can be created via advertising in government press releases, journals, websites, linkages to other science websites, and science and health-related magazines.

Financing of Prize Fund

The prize can be financed by apportioning 5 to 10 percent of the current healthcare budget to this incentive. The category devoted to diseases in developing countries can be funded with five percent of Canada's current foreign aid budget and supplemented with funding from international development agencies such as the WHO or the World Bank. The justification for soliciting funds would be the lower cost of rewarding innovations which proactively cures the diseases in comparison to the higher cost of treating the symptoms over a protracted period. Therefore, it would be wisest to finance cures for developing world diseases and still continue medical aid for those currently infected. It is also recommended that philanthropic organizations such as the Gates Foundation and the Rockefeller Foundation be pursued to contribute funds in a "matching" donation program where the non-profit body would agree to match every dollar the Canadian government has committed to the prize. The non-profit body would also have the right to have the prize category dedicated to their organization.

Benefits of the Economic Prize System

<u>Results-Oriented Reward: Cost-Effective Funding of Innovation</u>

Paying a reward only upon production of a successfully developed and market-ready innovation is the most cost-effective use of R&D funds.

No money is paid in advance, which minimizes the financial risk and avoids wasteful investment in unsuccessful research projects. Since researchers are not paid until the development is complete, it safeguards against inefficient use of resources that can arise with a lack of accountability or avoids the high cost of having to micro-manage projects to monitor their progress. Given an already overtaxed healthcare budget, this mechanism limits investment to those projects which have the highest degree of success and highest degree of social payoff.

Target Neglected Diseases

This mechanism encourages R&D for innovations that have low commercial appeal, but high social value and are, therefore, overlooked by private researchers. Pre-specifying the diseases for which the prize applies provides an additional incentive for drug companies to cure heinous diseases that are crippling citizens and economies of poor countries. It has the combined allure of a moderate profit and substantial positive publicity that will encourage drug companies to reconsider or fully develop research projects discarded because of lack of profit potential. It also taps into unused capacity and encourages faster commercialization of innovations, which will increase overall productivity in the industry.

Build on Existing Knowledge & Tap Unused Capacity

Drug companies already have numerous developments of high therapeutic value sitting in their vault of uncompleted projects, but are ignored because they lack commercial value. The opportunity to gain even a modest profit will provide the marginal incentive for drug companies to fully pursue development of these products or complete clinical evaluations on novel applications of existing products. Drug companies no longer have to choose between profit and pursuit of social betterment — they can have both.

Similarly, in public labs, there are many potential discoveries that are ignored and underdeveloped because they lack academic appeal. This new prize provides additional motivation to reconsider these projects and bring them to fruition. This prize, therefore, has the potential to tap into the unused capacity of both private and public researchers.

Prioritizes Healthcare Issues: Limit R&D Investment to Projects with Highest Added Value

Rewarding innovation for diseases from a pre-specified list will ensure that innovation is aligned with the highest priority medical needs of Canadians. For instance, recognition of an aging demographic should

rank diseases that affect the elderly, such as arthritis, at the top of the list. This intensifies R&D on issues that are either the most prevalent or burdensome to the healthcare budget. Focusing R&D on a select few priority issues at a time improves the likelihood of success, whereas an overly diffuse approach to R&D will result in a lack of success in all areas of concern. Once success has been achieved for higher priority issues, the focus can be shifted to resolving other problems, with greater likelihood of success. Success is guaranteed by focusing on achieving results *one step at a time*. This prize recognizes the value of a more streamlined approach to tackling healthcare concerns.

Focus on Cost-Effective Treatments to Reduce Cost of Healthcare

Rewarding in proportion to *relative* cost savings (relative to the next best treatment) encourages research or completion of research on the therapeutic benefits of existing lower cost drugs/treatments. The goal is to encourage researchers to find that therapeutic uses of existing treatments (or natural substances) can treat a medical condition just as, or more, effectively than expensive, newly patented treatments.

The lower the cost of the treatment used by the researcher, the larger the cost savings and the bigger the prize. In other words, the structure of the prize award makes it in the researcher's best interest to focus on applications of lower cost drugs or treatments. This will concentrate R&D on innovations that are cost-effective and help control rising cost of healthcare in Canada and internationally.

If the innovation is a brand patentable new product or process, it has the potential to provide Canada with a valuable source of revenue by marketing it internationally. This will enable the prize fund to be self-sustaining. It will also enhance Canada's recognition as a primary source of scientific and pharmaceutical breakthroughs.

Encourage Applied Research

The use of an existing medicine beyond its original function, such as the use of Aspirin to combat heart disease, is an excellent example of the benefits of encouraging applied research. A mechanism that rewards innovative applied research allows us to fully explore every facet of existing drugs or treatments.

This is advantageous because it focuses on making maximum use of products for which private industry and the government have already invested considerable money to develop. It builds on the existing wealth of scientific knowledge and taxpayer inputs. A product that is widely-used and already familiar to the public will also be more readily adopted and used for its other therapeutic properties.

Focusing on uses of off-patent or non-patentable products will also enable greater access to affordable healthcare by all income levels, as the products will be less expensive than newer, patented treatments.

Flexible: Adaptable and Responsive to Changes from Globalization

Using a pre-specified list of priority diseases allows the system to be flexible enough to add new potentially pandemic diseases, such as meningitis or the bird flu, should evidence point to their imminent threat. If properly commercialized, the sale of vaccines to other countries will provide Canada with additional revenue, as well as boost Canada's acclaim as a leader in science and technology. As previously mentioned, deforestation and penetration into new ecologies can release new diseases that can rapidly mutate and become a threat to industrialized nations.[141] It is, therefore, important to have an infectious disease centre in Canada that is armed with the best scientific talent to combat new threats.

An important advantage of this prize is that the list of priority health concerns can be adjusted to include new diseases or health threats as they arise. In today's globalized environment, an effective health policy must be adaptable and responsive to frequent and unexpected changes. This prize is structured to be adaptable and responsive to new diseases or other threats that jeopardize the health of its citizens. Responsiveness is the key to providing rapid solutions.

Open-Ended Technical Requirements: Capture Maximum Therapeutic Benefit and Ingenious Discoveries

Another advantage of the open-ended approach of this prize is that it avoids settling for innovations that only meet minimum technical standards. A criticism of the advanced purchase commitment scheme is that by setting rigid technical requirements, inventors are only motivated to meet that minimum standard, as there is no economic benefit to surpassing this threshold. It unnecessarily limits the potential benefits or savings that can be realized from ingenious thought or applications. A scaleable reward motivates researchers to focus on maximizing

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[141] The WHO urges countries to hasten pandemic flu preparations as reports show changes to the H5N1 flu virus circulating in Asia (North Vietnam). The avian virus' genetic makeup is mutating in a way that will allow it to spread more effectively among people and may be showing partial resistance to oseltamivir – the main drug used in wealthy countries to fight the virus.
See Helen Branswell, "Changes to avian flu virus worry scientists" *Globe and Mail* (19 May 2005) A7, online: Globeandmail.com <http://www.theglobeandmail.com/servlet/ArticleNews/TPStory/LAC/20050519/AVIAN19E/TPInternational/?query=branswell>.

therapeutic benefits, which opens the door to unlimited healthcare gains or savings. It enables the prize committee to cull the cream of healthcare innovations and award those discoveries that add the most value to healthcare.

Similarly, having open-ended technical requirements allows the healthcare system to capture fortuitous or truly ingenious discoveries that could never have been anticipated or foreseen. It was the famous inventor, Louis Pasteur, who stated that "chance favors only the prepared mind."[142] Priming the mindset of researchers and scientists (or even end-users) to keep an open mind to all types of innovation, including accidental or fortuitous discoveries, will increase the probability of finding solutions in a shorter time frame.

Compatible with Current Incentives

This system is compatible and complements existing incentives such as patents and public directed research without undermining the functioning of the market. It provides drug companies and public labs with an additional source of income without threatening their current revenue base. Providing an additional source of revenue without threatening their patent protection will help attract foreign investment, scientific talent, and foster growth of Canada's small and medium-sized pharmaceutical companies. Funding for basic research will also be continued and uncompromised by the addition of this new mechanism.

Progressive Reform

The implementation of an economic prize system within the pharmaceutical industry is an ideal starting point for progressive reform of Canada's innovation policies. The persistence of market failures in the drug industry (despite government efforts) points to the need to implement a new approach that does not require radical reform. As already mentioned, the pharmaceutical industry has been cited by economic experts as an ideal environment for the use of optional reward incentives.

Being the first nation to implement a market-based mechanism will also improve Canada's reputation as a *leader* in innovation policy. It will emphasize Canada's ability to find a creative but effective solution to a complex issue that many other countries are currently struggling to resolve, as it involves balancing healthcare provisions and supportive industrial policy.

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[142] Association for Psychological Science (APS), News Release, "Aha! Favors the Prepared Mind" (29 March 2006), online: psychologicalscience.org <http://www.psychologicalscience.org/media/releases/2006/pr060329.cfm>.

Government as a Source of Knowledge

This prize should help improve the public's perception of the government as a source of healthcare innovation and advancing scientific knowledge. Constant worries about the future state and quality of public healthcare in Canada has placed a lot of attention on how the Canadian government intends to resolve this crisis. Being able to produce innovative products or introduce innovative cost-saving measures, at this crucial time, will have the effect of raising the public's confidence in its government as an effective problem solver and manager of the public's funds.

Faster Rate of Commercialization

This prize should also encourage earlier disclosure of innovations than the patent system. The patent system encourages secrecy in order to protect market exclusivity, whereas this system encourages inventors to be the first to apply for the prize and, therefore, disclose their discoveries sooner. This should facilitate faster commercialization of products, faster dissemination of new knowledge, and development of any subsequent innovations that build upon this creativity.

Encourage Technology Transfer

This faster rate of commercialization should enable a faster rate of technology transfer to developing countries. In turn, this should accelerate the rate of their infrastructure development, not only in healthcare, but in all primary sectors that will enable these nations to be fully self-sustaining. Their self-sufficiency should reduce the demand for foreign aid, increase the global rate of productivity, and liberate capital to assist other countries in need.

Attract Foreign Investment & Scientific Talent

This reward offers a combination of modest but immediate profit and positive publicity, which should retain and attract more foreign investment from international pharmaceutical companies. As competition from other countries intensifies, Canada is at risk of losing foreign investment to other countries, such as China and India. Such countries offer lower cost, cutting-edge facilities, faster patent times, and cheaper labor. Although Canada cannot compete on these same bases, this high-profile prize can give Canada the competitive edge to convince multinationals to stay or reinvest in Canada. The allure of creative

freedom and substantial economic payoff should also help retain and attract elite scientific talent to Canadian labs.

The successful production of innovative products or novel applications of existing products will give Canada recognition as the next hotbed for scientific and technological breakthroughs. Being identified as the cutting-edge source for exciting growth — analogous to a Silicon Valley of healthcare innovation — should not only attract investment and talent, but also inspire international respect for Canada as an innovative industrial strategist.

Raise Canada's Foreign Aid Profile & Augment Soft Power

By taking a more proactive, results-based approach to addressing the diseases plaguing developing countries, Canada is demonstrating its commitment to the developing world. Instead of augmenting the size of its foreign aid contributions, this approach simply hones the focus of existing aid resources on the all important first step of curing neglected diseases that hamper infrastructure development. Curing the root cause of the problem will avoid prolonged dependence on foreign aid assistance. At present, no other country has implemented an open-ended cash prize to alleviate diseases in underdeveloped countries. By narrowing its focus, this approach leverages limited foreign aid resources to maximize developmental impact and encourage autonomy.

This proposal also serves as an impressive example of Canada's ability to resolve a complex issue that overlaps key government sectors and functions. It is a clever approach to a widespread problem that many other countries are struggling to address. Developing novel policy solutions to a prevailing international problem can enhance Canada's soft power and authority world wide. Canada could be more influential in settling multilateral trade agreements and disputes, promulgating environmental and human rights accords, and establishing international fiscal and monetary policy. It may also pave the way for Canada's genetically modified foods to be accepted in domestic and international markets.

Potential Drawbacks of Economic Prizes

Requires Deep Pockets: Focus on Late-Stage Products

A results-oriented reward requires that a company invest several years and several millions of R&D dollars to create a fully developed and readily usable product. This may create a bias in favour of richer, private sector multinational companies that have deep enough financial pockets to afford such steep investments. Smaller, start-up companies will not have adequate financial resources to make such long term investments, particularly when it is uncertain whether they will even be awarded the

prize. This may result in a situation where only resource-rich companies can participate in the prize competition and exclude smaller start-up companies. However, in an attempt to be eligible for this prize, smaller start-up companies may be more motivated to form partnerships with angel investors or venture capitalists to finance full product development. This may in fact result in an increase of the overall level of R&D. The effect of this prize model on overall level of R&D is an area that will likely require further study by subsequent researchers.

Ambiguous Prize Value: Highly Subjective

Companies may lack confidence in a prize whose value is not readily determined in advance. If companies cannot ascertain a potential product's payoff, companies may be hesitant to invest heavily to bring a product to full development and actually deter innovations. However, it is believed that workable valuation formulae can be proposed and evaluated by subsequent economic and health academics. The purpose of this paper is merely to consider alternative mechanisms for encouraging innovations and how economic prizes can be used as a complement to existing mechanisms. This paper was not intended to provide the final word on the implementation of economic prizes. The conclusions from this article can be used as a catalyst to ignite discussion among members of the health and economics community to consider how such a valuation formula could be fashioned. In fact, this article recommends conducting further studies to flesh out the precise details of a workable valuation formula, with considerable reference to the work of health economists and their valuation models.

Prize Competition Discourages Information Sharing

Given that this incentive mechanism is predicated on a competition between innovators, with a prize being awarded to only one winner, this mechanism could be criticized as fostering secrecy and discourage information sharing. In the realm of health care, secrecy and hoarding of intellectual capital would be particularly detrimental, as it would hinder or delay the development of subsequent socially beneficial innovations. This drawback can be overcome by making it a condition of the prize to publish their R&D data within three months of the award ceremony. As the prize money and its consequential corporate goodwill is intended to replace the strictly monetary benefits of patent exclusivity, the innovating company has nothing to lose by agreeing to make their R&D data available to the scientific community.

Financing Economic Prize Fund at Expense of Other Push Incentives

This model could also be criticized for suggesting that funding for its prize fund would consist of siphoning 5 percent to 10 percent of funds from the national government's healthcare or foreign aid budget. Thus, it may be suggested this prize's funding would occur to the detriment of valuable basic research conducted in national research labs, hospitals and universities. It should be noted that this is but one suggestion for financing this prize fund. It is not intended to be taken as the ultimate and only recourse for financing this type of prize. As mentioned earlier in this article, the fund may also be financed with contributions from the private sector or from charitable foundations. It also leaves open the possibility for financing using private-public partnerships models, where foundations agree to provide funding on a matching basis with government funding commitments.

The purpose of this article is to open the door to further exploration of this incentive mechanism. This article is not intended to represent the final word on the topic of incentive mechanisms and their application to medical innovations. Rather it is intended to be the first progressive step in the direction of considering alternative mechanisms where the use of conventional incentives have resulted in market distortions that are detrimental to society's overall welfare. It is without question that the advantages and drawbacks of this model need to be explored further by legal and economic experts and academics before it can be implemented by a national government. However, this article can constitute one step in the direction of accepting prizes as an effective incentive mechanism for inspiring socially beneficial innovations.

IV. CONCLUSION

THE ECONOMIC PRIZE SYSTEM PROPOSED IN THIS ARTICLE is an adaptation of market-based mechanisms to encourage innovation that will address the most pressing healthcare issues in Canada and in the developing world. Existing incentives, such as the patent and government funding, have not alleviated these problems and point to the need for a new approach. This prize is intended to be a complement to the existing mechanisms and not a substitute. It will create an additional source of revenue for innovative researchers and advance healthcare and humanity. It offers a win-win scenario that benefits all stakeholders from private industry, to healthcare consumers, to government policy-makers, and healthcare providers.

In addition, this prize will offer the opportunity to introduce progressive reform of Canada's innovation policy in one of its key sectors. An innovation policy that fosters growth in Canada's scientific and technology based industries is crucial to Canada's global

competitiveness. In the near future, this prize can be adapted and re-applied to create growth in its other innovation-based industries. In the long run, building the proper regulatory framework will ensure that Canada has a self-sustaining means of economic growth.

Other nations are already reforming their industrial innovation policies to adapt to rapid technological changes and globalization. Canada needs to try a new approach or risk getting left behind. The hallmark of all successful nations is the willingness to embrace change and strategically position itself to capture the opportunities that change brings. This proposal is a visionary approach to innovation management that has the potential to advance the betterment of society and hone Canada's competitive edge.