

Economic Prizes: Filling the Gaps in Pharmaceutical Innovation (2005)

Abstract

This paper identifies the importance of creating a strong innovation policy to support industrial growth and strengthen Canada's competitiveness in a globalized marketplace. This paper summarizes market failures in the pharmaceutical industry that inflate the cost of healthcare in Canada and hinder research and development for treatments of diseases that primarily affect welfare sectors. This paper proposes a system of cash prizes to reward researchers upon production of demonstrably effective and tested products (or processes) that will improve healthcare. The prize authority would pre-specify diseases for which treatments are a priority and offer to pay a cash prize in proportion to the relative social value (cost savings) of *any* innovation that offers a solution, without pre-specifying the technical requirements. This approach is particularly innovative as it encompasses any type of healthcare innovation, patentable or non-patentable - thereby tapping into the enormous potential of overlooked but highly valuable innovations. In the long run, such a system will help control the high cost of healthcare in Canada, assist the economies of developing countries and improve Canada's international standing as a leader in industrial innovation and foreign aid policy.

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, 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.

The 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 will not only increase innovation within that industry but

resolve market inefficiencies. This will result in 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 will induce inventors to commercialize their innovations faster and more efficiently. Also, offering the reward for innovative applied research will provide the extra incentive for researchers to follow-up on ingenious uses or applications of existing, lower-cost treatments. It provides the additional 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 “guaranteed purchase commitment” scheme to encourage development of vaccines for diseases that debilitate developing countries.

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 will not only encourage creation of needed medicines and treatments, it will also induce creative approaches to healthcare that are cost-effective, attract foreign investment, and mobilize Canada to be 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 industries¹.

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 global². This has created a competitive environment where economic growth is spurred by excellence in its knowledge-based industries³. The new determinant of economic success is the ability to sustain technological innovation – at both

¹ Organization for Economic Development, *Science, Technology and Innovation Report (2001)*, p.1 “science, technology and innovation are central to improved economic growth”
p.1 “more so than before, science, technology and innovation policies must adapt to meet the needs of globalization”.

Innovation Report (2004), Conference Board of Canada.

http://www.conferenceboard.ca/inn/abstracts/annual_innovation.html

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.

² <http://www.innovation.gc.ca/gol/innovation/site.nsf/en/in05251.html#top> *Federal Science and Technology: The Pursuit of Excellence*, Dept. of Industry Canada,. Last date accessed April 18, 2005. *Chapter 3: Moving Forward on Collaborative Science and Technology*. 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.

³Kristian Palda , *Innovation Policy and Canada’s Competitiveness* (1993) (© The Fraser Institute)

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 sustainability⁴.

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 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 innovation⁶. 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 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.

In its Global Competitiveness Report (1991), the World Economic Forum pointed out Canada's declining status, from 10th in 1991, down to 16th in 2003. In 2004

⁴ IBID, p.260 and OECD footnote 39.

⁶ The Science Council of Canada (1990), Research project outline, p.8.

<u>Global Competitive Status</u>	
Year	Canada's Rank
1991	10 th
2003	16 th
2004	15 th

Source: Global Competitiveness Reports from World Economic Forum

Canada had made a marginal improvement to 15th place⁷.

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 country more accessible and attractive to foreign investors.

This includes revamping their intellectual property regime to make it easier for foreign investors to apply and be approved for patents in their country⁸. Large

⁷ www.weforum.org/site/homepublic.nsf/Content/Global+Competitiveness+Programme%5CGlobal+Competitiveness+Report

This ranking is based on performance of three components: technology, public institutions (infrastructure) and macroeconomics (current sustainable level of productivity). Wealth in a country is created at microeconomic level by individual companies – therefore, success of various components will create success to country's performance.

⁸ The amended Chinese Patent Law, which brings PRC patent law closer to World Trade Organization (WTO) requirements, took effect on July 1, 2001. The NPC passed the second amended Patent Law on August 25, 2000. The major changes in the amended law can be

pharmaceutical companies are taking advantage of the irresistible allure of the low cost of labor, cutting-edge production facilities and friendly regulatory environment to move their manufacturing to China and India⁹. 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 Africa¹⁰. 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.

“ ‘ 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

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.

Jiwan Chen, *The Amended PRC (People's Republic of China) Patent Law*, The China Business Review (2001) Issue: July/ August 2001

⁹ January 19, 2004 Volume 82, Number 3, CENEAR 82 3 pp. 48-50.
ISSN 0009-2347, *ASIAN COMPETITION GATHERS STRENGTH High quality and low cost are a combination that Western firms are finding hard to beat* A. MAUREEN ROUHI, C&EN WASHINGTON.

¹⁰ Press Releases: New Public-Private Partnership to promote Sino-African ties
Posted Mar 18, 2005 - 01:37 PM. Online source:
<http://www.undp.org.cn/modules.php?op=modload&name=News&file=article&sid=277&mode=thread&order=0&thold=0>

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).

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.

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 in five years.

' This 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,' he said. "

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, to facilitate and encourage investment from pharmaceutical companies¹¹.

Canada cannot compete by lowering its cost of labor 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 will give Canada a competitive edge. Along with the existing R&D tax 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

¹¹ "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." Source: [Financial Times](#), July 18, 2001

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 US or overseas¹².

US Threatens to Block Canadian Internet Pharmacy Sales

Canadians benefit from the fair pricing regulation enforced by its Patent Medicines Price Review Board. This agency is unique to Canada. It monitors the price of patented medicines to ensure that prices are fair and reasonable. There is no comparable body in the United States and the cost of identical drugs are considerably higher in the US than in Canada. This has created a tremendous demand for medicine in America via Canadian internet pharmacies.

However, the Canadian pharmaceutical industry should not rely solely on American-based sales. In March of 2005, under tremendous pressure from pharmaceutical-backed lobbying groups, the US government threatened to block shipments of drugs from Canadian internet dispensers from entering America¹³. In an attempt to prevent Canadian suppliers from providing their drugs at lower prices to the American market, large pharmaceutical companies such as Pfizer have also threatened to cease supplying Canadian internet pharmacies altogether.

¹² 4th Annual Innovation Report 2002 by Conference Board of Canada
(<http://www.conferenceboard.ca/boardwiseii/temp/BoardWise2CENFONODCMKPKOBEDLPA NMAC200532164952/361-02Report.pdf>), p.27, p.32.

p.27 "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."

p.32 "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 also *The BioPharmaceutical Industry: Overview, Prospects and Competitive Challenge* (2001), p.4 and section 1.4. *The Canadian Context*: The report cited that in some cases, the approval process was longer in Canada than in other countries. Online source: http://www.senternovem.nl/mmfiles/biopharmatechroadmap_overviewprospectse%5B1%5D_tcm24-105268.pdf. (Last date accessed April 14, 2005.)

¹³ March 10, 2005 – Financial Post – John Greenwood, National Post, page FP1 and FP7, "FDA Targets Online Drugstores."

The implication is that the Canadian pharmaceutical business cannot rely solely on sales to the American market for long-term financial viability. The Canadian pharmaceutical industry relies heavily on large pharmaceutical companies for financing and access to the latest technology and state of the art labs. Although it is important to form these strategic alliances with multinationals, it is equally important to develop the business capacity of Canadian-owned pharmaceutical companies. One of the key ways of building sustainable business growth is provide economic rewards to compensate startup companies for their inventiveness. This will help finance the future growth of Canadian-owned drug companies and raise their international profile as sources of innovation in their own right.

In particular, breakthrough discoveries in recombinant DNA and genetic manipulation have earmarked biopharmaceuticals to revolutionize the direction of innovation in new drug development¹⁴. Unlike the orally delivered small molecule drugs that underpin the traditional pharmaceutical industry, biopharmaceuticals are complex macromolecules that are usually administered by subcutaneous, intravenous, or intramuscular injection.

Although Canada has been ranked as among the world leaders in the creation of biotechnology companies¹⁵, the industry is still considerably less mature than the US. Canada has internationally recognized research capabilities and many promising companies, but like many other countries, it lacks the boasting rights of a major successful in the commercialization of one of its (biopharmaceutical) products¹⁶. One of the main roadblocks is the ability to raise the considerable capital 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, while still in its formative stages.

¹⁴ Biopharmaceutical Report
http://www.senternovem.nl/mmfiles/biopharmatechroadmap_overviewprospectse%5B1%5D_tcm24-105268.pdf. (Last date accessed April 14, 2005.) at page 2.

¹⁵ IBID, at p. 4, 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.

¹⁶ IBID, at p. 9.

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 dependant 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 a "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 millions of dollars from lost tourism and foreign investment and an additional \$10 million for an ad campaign to counter the negative SARS publicity¹⁷. Global warming¹⁸ and the rapid-fire rate of mutation of

¹⁷ *The Economic Impact of SARS*, CBC News Online, Updated July 8, 2003. Online source: <http://www.cbc.ca/news/background/sars/economicimpact.html>. (Last date accessed, March 27, 2005.) 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.

¹⁸ Medical Science News, Sunday, February 20 , 2005 , "Global warming will bring climate-related health crises. "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 also: *Global Warming Spells Health Warning*, CNN. July 17, 2000 or <http://archives.cnn.com/2000/NATURE/07/17/global.warming.enn/Web> posted at: 12:17 p.m. EDT (1617 GMT). By Environmental News Network staff.

“ ‘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.

viruses makes the threat from potentially pandemic diseases even more imminent.

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

- (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 an external disease centers, such as the US Centre for Diseases Control, to safeguard its own citizens. A responsive disease relief plan 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 the 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, will attract scientific talent.

(4) Population Growth & Ageing Demographic

In the final comments to the Global Competitiveness Report, the World Economic Forum identifies two important demographic trends that will affect the relative competitiveness of countries²⁰:

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.' "

²⁰ See footnote 5, pg.11 of Executive Summary.

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

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 bases, 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 2002, persons 65 and over accounted for approximately 50% of provincial government hospital expenditure in Canada²¹. The most is spent on seniors between the age of 70 and 84 (31% of total). While making up only 12.7% of the population, seniors consumed more than 44% of all provincial government health spending in 2002²².

Thus, any increase in 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 the securities market will fall and the value of the Canadian dollar will also decrease as investors lose faith in stability of our economy. The other two options are to increase income tax rates or resort to 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 spreads 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

²¹ National Health Expenditure Trends (1975-2003) , Canadian Health Institute of Health Information, p.25

Online source:

http://secure.cihi.ca/cihiweb/dispPage.jsp?cw_page=download_form_e&cw_sku=NHEXTREND_S04PDF&cw_ctt=1&cw_dform=N. (Last date accessed April 1, 2005.)

or Drug Expenditure in Canada (1985-2003) , CIHI.

Online source:

http://secure.cihi.ca/cihiweb/dispPage.jsp?cw_page=download_form_e&cw_sku=DRUGEXP850_3PDF&cw_ctt=1&cw_dform=N. (Last date accessed April 1, 2005.)

²² IBID, at p.28.

status²³ and harm its ability to attract investors in the international securities markets.

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 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% of current government funding for biomedical R&D will provide the initial financing for the proposed reward system

Our proposal will be consistent with a more proactive approach to controlling healthcare costs. Our 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 the symptoms.

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 will 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 will facilitate subsequent discoveries and the transfer of technology to undeveloped countries. The sooner that undeveloped countries can establish their own healthcare infrastructure, the less reliant they will be on foreign aid.

²³ Paivi Munter, *Major Economies Debt May Fall to Junk Status by 2030*, National Post, March 21, 2005, FP2 (Fin. Post),

“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 and Poor – the credit ratings agency – if current fiscal trends prevail, the cost of ageing populations will fuel downgrades of France, the US, Germany and the UK. Without further adjustments either to current fiscal stance or to social and healthcare costs, the general debt ratios of France, Germany and the US 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”.

(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 countries²⁴. A comprehensive study on the burden of global problems ranked combating neglected diseases as the number one priority.²⁵ 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 agreement²⁶, the UN declaration of human rights²⁷, the UN millennium goals²⁸ and the African Action Plan²⁹.

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 pro-active 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 also more directed by clearly identifying the research goals. 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.

²⁴ Canada, "2004 Speech From the Throne" online: Prime Minister of Canada Website < http://www.pm.gc.ca/grfx/docs/sft_fe2004_e.pdf > [hereinafter Speech From the Throne]

²⁵ Online: Copenhagen Consensus website <http://www.copenhagenconsensus.com/>.

²⁶ ²⁶ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, article 26. online: World Trade Organisation Website < http://www.wto.org/english/docs_e/legal_e/27-trips.doc >. [hereinafter TRIPS]

²⁷ *Universal Declaration of Human Rights*, GA Res. 217 (III), UN GAOR, 3d Sess., Supp. No. 13, UN Doc. A/810 (1948). [hereinafter UN Declaration of Human Rights].

²⁸ UN Millennium Development Goals, online: United Nations Development Program Website: <http://www.undp.org/mdg/abcs.html>.

²⁹ G8 African Action Plan, online: Government of Canada website: <http://www.g8.gc.ca/2002Kananaskis/afraction-en.asp>.

Adopting an outcome-based approach also makes this prize consistent with the suggestions of the Organization for Economic Development 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 resources³⁰.

Although Canada contributed \$2.6 billion in foreign aid last year, it is still criticized for not treating foreign aid as a priority³¹. Canada is under pressure to increase its foreign aid budget from its current level of 3% of GDP to .7%, to demonstrate its commitment to the developing world. However, with the implementation of new national security measures, (in response to the 9/11 bombings) and ballooning healthcare costs, it is unrealistic to expect Canada to double its foreign aid.

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 on facilitating the development of healthcare infrastructures to enable undeveloped countries to become self-sustaining. In the long run, this will be the most effective use of foreign aid funds and 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 is reduced productivity that delays the country's infrastructural development and eventual economic self-sufficiency. For every eight million lives saved, there is a corresponding reduction of 330 DALY's. Correspondingly, the economic gain of eliminating these diseases would be \$180 million in direct benefits and \$180 million in indirect benefits³². These benefits will significantly

³⁰ *Canada Development Co-operation Review: Summary and Conclusions* by the OECD. Online source: http://www.oecd.org/document/15/0,2340,en_2649_34603_2368207_1_1_1_1,00.html (Accessed March 21, 2005).

³¹ Poor countries are losing out to rich countries' priorities as foreign aid is increasingly being seen as an instrument to promote security and combat terrorism according to Reality of Aid (2004). http://www.ccic.ca/e/docs/002_aid_roa_2004-08_network_update.pdf (Accessed March 21, 2005) and

Special Advisor to UN Secretary-General Calls on Canadians to Take Leadership Role in Fight Against Global Poverty. Canada NewsWire, April 6, 2005. Online source: <http://press.arrivenet.com/bus/article.php/617147.html>. Last date accessed April 7, 2005.

³² "Investing in Health: a summary of the findings of the Commission on Macroeconomics and Health" (2003) online: Commission on Macroeconomics and Health website: <<http://www.who.int/macrohealth/infocentre/advocacy/en/investinginhealth02052003.pdf>>

outweigh the short-term costs of financing the treatments³³. Increasing the productivity and welfare of the developing world will reduce their need for foreign aid support. This will 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 will encourage faster development of cures and treatments and the faster dissemination of these innovations than with current mechanisms. 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 valuable contributor to international development without necessarily increasing its budget.

Visionary Leadership Enhances Canada's Soft Power

Adopting this creative approach to incentive mechanisms will 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 force³⁴. Implementing a fresh approach to pharmaceutical innovation, with the ability to resolve a key roadblock in the development of underprivileged countries, will greatly increase Canada's soft power.

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 will 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

³³ A. Mills & S. Shillcutt, "Copenhagen Consensus: Challenge Paper on Communicable Diseases" online: Copenhagen Consensus website http://www.copenhagenconsensus.com/files/filer/cc/papers/communicable_diseases_160404.pdf.

³⁴ J. S. Nye Jr., *Bound to Lead: The Changing Nature of American Power* (New York: Basic Books, 1990), at 32.

considerable market resistance to their products arising from fear of biotechnology³⁵. The use of Canada's biotechnology to cure diseases and the betterment of society will enhance its acceptance by the public and Canada's reputation as a leader in technology. This positive association will open markets for Canada's genetically modified foods in domestic and international markets³⁶.

The economic prize proposed in this article provides a win-win scenario for all stakeholders. The 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 will facilitate faster development of cures and transfer of technology to developing countries, which will accelerate their ability to be self-sustaining. In the long run, this will reduce the demand for foreign aid support. Taking a visionary approach to innovation management will 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.

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

The Organization for Economic Cooperation and Development (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 efficient³⁷. In particular, the OECD

³⁵ "Monsanto Pulls Canada Wheat Plans" (2004) online: The Scientist website at <http://www.biomedcentral.com/news/20040512/01/>.

³⁶ S. R. McCouch, "Is Biotechnology the Answer" in K. Wiebe, N. Ballenger & Per Pinstrup-Andersen eds., *Who Will Be Fed in the 21st Century* (Baltimore: The Johns Hopkins University Press, 2001) at 31.

³⁷ *Science, Technology, and Innovation (STI) Outlook for 2004*, OECD, Page 1. Online source: http://www.oecd.org/document/63/0,2340,en_2649_34273_33995839_1_1_1_1,00.html or www.oecd.org/dataoecd/0/60/33998255.pdf (Last date of access: April 11, 2005)

p.5/6. " 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

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 research³⁸.

The report also points out that other countries are recognizing that the government needs to make special effort to increase support for innovation that will have positive economic and social impact³⁹.

“a growing trend in countries...to be less dependent on institutional (i.e. Block grants) funding and more reliant on competitively awarded project financed research.”

Source: The OECD 2004 Report on Science, Technology, and Innovation (STI) Outlook, p.4.

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 use of outcome or output based specifications to produce more effective solutions and capture the creativity of competitors⁴⁰,

“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.”

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.”

³⁸ IBID, page 4. (OECD, STI Report).

³⁹ IBID, page 4 “ 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.”

⁴⁰ *Innovation Report (2003)*: United Kingdom, Dept of Trade and Industry <http://www.dti.gov.uk/innovationreport/>.

Chapter 5: Innovation Policies Across Government, p.81.

It was also recognized by Industry Canada, in its *Innovation Strategy* (2002) that the government needs to provide more clear stewardship to ensure growth of its innovative capacity⁴¹. In another Industry Canada report, the *Science and Technology Report* (2003), 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 boundaries⁴². Equally important, the report also emphasizes that science management must be aligned with the priorities of Canadians.

⁴¹ *Canada's Innovation Strategy* (2002), Industry Canada. *Canada's Innovation Strategy* was launched on February 12, 2002, with the release of two companion documents: *Achieving Excellence: Investing in People, Knowledge and Opportunity* and *Knowledge Matters: Skills and Learning for Canadians*.

Online source: <http://www.innovation.gc.ca/gol/innovation/site.nsf/en/in04162.html> (Last date accessed March 31, 2005)

Section 7 of Innovation Strategy: Innovative Environment Challenge

Report recognizes that Canada needs to improve its international recognition as innovative country in order to attract talent and capital. Also noted: (i) the need for better government stewardship of nation's innovation through creation of supportive innovation policy (ii) increasing global competition for investment and highly qualified people/labour force (iii) the pace of innovation is accelerating (iv) Canada faces challenge of improving its science and technology sectors to be competitive and ensuring protection of public health and safety.

⁴² *Federal Science and Technology: The Pursuit of Excellence* (2003), Industry Canada. *Chapter 3: Moving Forward on Collaborative Science and Technology*. Online source: <http://www.innovation.gc.ca/gol/innovation/site.nsf/en/in05251.html#top> (Last date accessed April 18, 2005.) 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 an (iv) increase in public expectation for government to provide answers to complex challenges including cost-effective healthcare.

The vision agreed upon by the deputy ministers of various science bodies and department has six main elements:

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

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 Pharmaceutical Sector
- Population Growth & Ageing 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 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),
- (ii) the use of outcome-based specifications to improve the efficacy of innovation incentive mechanisms, and
- (iii) the 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 \$114.0 billion in 2002. Expenditures are forecast to have been \$123.0 billion in 2003 and \$130.3 billion in 2004, an increase of 7.9% and 5.9%, respectively⁴³.

Increase in expenditure for drugs has been the most significant factor for this growth in healthcare costs. The Canadian Health Institute of Health Information found that in 1975, drug costs constituted only 8.4% of total health care expenditure but by 2002, this percentage had almost doubled to 16.1% of total health care expenditure (\$18.4 billion)⁴⁵. This increased spending for drugs is expected to continue, and forecast to grow another 8.7% in 2003 to \$20.0 billion and by 8.8% in 2004 to \$21.8 billion⁴⁶.

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% of total drug care costs⁴⁷. In dollar

⁴³ National Health Expenditure Trends (1975-2003) , Canadian Health Institute of Health Information, p.3.

Online source:

http://secure.cihi.ca/cihiweb/dispPage.jsp?cw_page=download_form_e&cw_sku=NHEXTREND_S04PDF&cw_ctt=1&cw_dform=N. (Last date accessed April 1, 2005.)

or Drug Expenditure in Canada (1985-2003) , CIHI.

Online source:

http://secure.cihi.ca/cihiweb/dispPage.jsp?cw_page=download_form_e&cw_sku=DRUGEXP850_3PDF&cw_ctt=1&cw_dform=N. (Last date accessed April 1, 2005.)

⁴⁵ IBID. p.19 National Healthcare Expenditure Trends (1975-2003).

⁴⁶ IBID, p.19 “ Retail sales of prescribed and non-prescribed drugs together constituted the second largest category of health expenditure in 2002 at \$18.4 billion, an increase of 10.5% over 2001. 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 16.1% in 2002. Spending on drugs is forecast to have increased by another 8.7% in 2003 to \$20.0 billion and by 8.8% in 2004 to \$21.8 billion, or 16.7% of total health care spending.

Non-prescribed drugs, which include over-the-counter drugs and personal health supplies, amounted to 19.5% of total expenditure on drugs in 2002.”

⁴⁷ IBID.

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 2003⁴⁸.

In its 2003 Annual Report, the Patent Medicines Price Review Board, listed factors to be addressed to control the cost of drug spending. Along with controlling the price of new drugs, the Board 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 condition⁵⁰.

“change in the prescribing habit of physicians towards newer more expensive drugs over older, less expensive drugs to treat the same underlying condition”

Source: 2003 Annual Report, the Patent Medicines Price Review Board.

A report commissioned by the Ontario government, “Controlling Drug Expenditure in Canada: The Ontario Experience” (1992), 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 filled⁵¹.

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.

⁴⁸ Rising healthcare costs are of particular concern to Manitoba as it has the highest per capita health care cost at \$4,406⁴⁸ in comparison to other provinces

⁵⁰ IBID.

⁵¹ Gorecki D: *Controlling Drug Expenditure in Canada: the Ontario Experience*, Economic Council of Canada and Ontario Ministry of Health, Ottawa, 1992.

“recommends that physicians be better educated and sensitive to alternative, less costly drug therapies”

Gorecki, *Controlling Drug Expenditure in Canada* (1992)

In the *Final Report on the State of the Health Care System in Canada*, (October 2002), (known as 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 treatment⁵².

Similarly, the Commission on the Future of Healthcare in Canada, *Building on Values – the Future of HealthCare in Canada – Final Report* (Nov 2002)⁵³ (known as the Romanow Report) highlighted 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 manner⁵⁴.

Even the Ontario Bar Association recognized the need to improve prescribing practices of physicians to ensure the most cost-effective use of drugs and treatments to partially help control the cost of drugs⁵⁵.

In a criticism of a report by the National Pharmaceuticals Strategy (NPS⁵⁶) for Canada, Carl Baltare and William Dempster⁵⁷ felt that the strategy was overly

⁵² 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, p.143.

⁵³ Romanow R.J. *Building on values: the future of health care in Canada*. Saskatoon: Commission on the Future of Health Care in Canada; 2002. Online source: www.healthcarecommission.ca. (Last date accessed: April 1, 2005).

⁵⁴ IBID, “Directions for Change”, Chpt 9 – Prescription Drugs.

⁵⁵ Martin Campbell, p13 – April 28, 2003: *Issues in Pharmaceutical Industry Drug Benefits: Provincial Issues*, Ontario Bar Association, Health Law Section

⁵⁶ *Developing a Canadian prescribing practices network* (1996) by Anne M. Holbrook, MD, PharmD, MSc, BScPhm, FRCPC; Stuart M. MacLeod, MD, PhD, FRCPC; Paul Fisher, PhD; Mitchell A.H. Levine, MD, MSc, FRCPC; for the Network Development Committee of the

focused on containment of drug costs to the detriment of addressing innovation. 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.

Canadian Prescribing Practices Network Project , *Canadian Medical Association Journal* 1996; 154: 1325-1331.

Online: http://collection.nlc-bnc.ca/100/201/300/cdn_medical_association/cmaj/vol-154/1325.htm Accessed March 17, 2005. 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." In response to rising healthcare costs, the First Ministers agreed to strike a new F/P/T Task Force and report back by June, 2006 with a strategy to implement a long list of pharmaceutical initiatives, including:

- national catastrophic drug coverage;
- a national drug formulary;
- accelerating drug approvals for breakthrough therapies;
- improving drug safety;
- bulk buying of pharmaceuticals;
- education on optimal drug use for health professionals;
- broadening the use of e-prescribing and the Electronic Health Record;
- accelerating access to (and achieve lower prices of) less costly generic drugs; and
- improving drug cost and best practices policy analysis.

⁵⁷ Carl Baltare and William Dempster, “*Will Canada Miss Its National Pharmaceutical Strategy Boat?*”, Published in *The Hill Times* - February 21, 2005. (Carl Baltare is Vice-President, Health and Pharma and William Dempster is a Senior Consultant, Health and Pharma.)

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. The European Commission followed suit with the High Level Group on Innovation and Provision of Medicines. Japan, France, and Sweden have also implemented holistic strategies that consider both the health and industry portfolios as complementary. "

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.

Private Medical Insurance Coverage not Reliable

Access to private medical insurance does not necessarily safeguard citizens from escalating cost of healthcare either. Whenever a company experiences financial difficulty, one of the first expenditures that is sacrificed is medical insurance coverage for its employees. Who pays for the cost of providing medical care? Naturally, the government bears this additional burden – increasing again inflationary pressure on healthcare costs. Eventually, this burden is passed onto 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 treatments⁵⁸.

It is also worth mentioning again the expected growth in the elderly population in Canada. If the Canadian government recognizes that a looming crisis 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 privatization of healthcare – any of these options will render Canada less attractive to foreign investment.

⁵⁸ "Delphi to stop paying retirees' health-care insurance." National Post, page FP7, March 10, 2005. Source: Cox Newspapers, with a file from Bloomberg News.

Summary of Canada's Internal Strength & 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 pharmaceuticals through the creation of the Patent Medicine Price Review Board – a national regulatory agency that ensures “fair pricing” of patented pharmaceuticals⁵⁹. The government now needs to turn its attention to one of the other key recommendations: ensure that prescribing practices of doctors includes use of alternative, less costly therapies to 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 prevention of heart disease⁶⁰, has saved millions of dollars in drug treatment and long-term clinical care. This discovery was particularly beneficial as it uses an off-patent drug that was extremely affordable and thereby accessible to all income levels.

Discovering beneficial uses for existing non-patentable drug/therapy can save Canadian taxpayer's 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 the perfect policy vehicle to activate a new approach in prescribing therapies. This proposal will ensure that cost-effectiveness evaluations are woven into the 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.

⁵⁹ *Patent Act*, R.S. , C.P-4 and Patent Medicines Regulations, 1994 (SOR/94-688).

⁶⁰ <http://www.americanheart.org/presenter.jhtml?identifier=4456>. Accessed April 2, 2005.

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 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 of 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 Report Findings

- Crisis in Rising National Healthcare Expenditure
 - private medical coverage unreliable
 - aging demographic
- Better control over cost of prescription drugs
- More cost-effective use of drugs: old vs. new drugs
- Improve prescribing practice of doctors: focus on alternative lower-cost therapies to drugs.

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 Aging Demographic
Bill C-9 Compulsory Licensing: Deter Pharmaceutical Investment
Complex Patent Application: Deter Foreign Investment .
Government Funded R&D: Heavy Concentration on Basic Research with Low Commercial Viability & Lack 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

Missing Ingredient?

Supportive Innovation Policy to Effectively Mobilize Resources and More Needs-Based and Results-Oriented Approach to Healthcare R&D

(2) Current Incentives for Pharmaceutical Innovation

The ultimate purpose of innovation is to improve consumer access. This can be accomplished by discovering a new development that will “either widen the scope of customer choice (new products) or to lower the purchase price (new processes) or both. Which will in turn enhance the economic well-being of a nation⁶¹.

⁶¹ K. Palda, *Innovation Policy and Canada's Competitiveness* (1993) The Fraser Institute, Vancouver British Columbia, Canada, p.1 and p. 2.

Purpose of Innovation

“the ultimate purpose of innovation is to either:

- (i) widen scope of customer choice (new products),***
- (ii) lower the purchase price (new processes, or***
- (iii) both.***

Which will in turn enhance the economic well-being of a nation.”

Source: K. Palda, *Innovation Policy and Canada’s Competitiveness* (1993).

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

- a) providing an adequately reward to the inventor: which will increase their private return on R&D, and promote further innovation, and;
- b) promote interests of society by:
 - (i) dissemination / diffusion of technology and knowledge, and;
 - (ii) wider application and public use of invention⁶².

Therefore, the effectiveness of an incentive mechanism can be measured according to how well it meets the previously mentioned definition of innovation. Let us evaluate the effectiveness of patents and government supported R&D.

⁶² Concluding remarks from the 4th Annual Innovation Report 2002, Conference Board of Canada, p.32.

a) Pharmaceutical Patents & Market Failures

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 Applications

The traditional innovation incentive is the legal instrument known as the patent. It awards an inventor the exclusive right to manufacture, use and sell their invention to the market for a limited term⁶³. This allows the inventor the ability to recoup their 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” by competing: 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.

⁶³ In Canada, the term for holding exclusivity is 20 years. See *Patent Act*, R.S.C 1985. c.P-4. The definition of a patent on medicines includes: “active ingredients, processes of manufacture, for particular delivery system or dosage form integral to the delivery of medicines..” includes vaccines, anesthetics and diagnostic products but not include medical devices.

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 development⁶⁴. Although there is debate about the legitimacy of this figure⁶⁵, there is no doubt that drug companies do spend millions of dollars to study diseases, develop possible cures and running 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 it needs to charge exorbitant margins on its products in order to recoup R&D costs and finance future innovations which will improve the quality of life. In Canada, the statistics do support that the overwhelming majority of pharmaceutical R&D is conducted by private drug companies. The Patented Medicines Prices Review Board reported that more than \$504 million had been spent in 1993 on pharmaceutical research and development (including capital equipment costs and allowable depreciation). More than 97% of this amount originated from the pharmaceutical industry⁶⁶. In 2003, pharmaceutical R&D grew to \$1,192 million or \$1.192 billion.

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 products⁶⁷. 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 already been approved and for which they already have considerable clinical information, drug companies can create

⁶⁴ Economists from Tufts Centre – Study for Drug Development.

⁶⁵ 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.

⁶⁶ PMPRB Annual Report 2003 – Section 7.5 “Analysis of R&D Expenditures”. Online source: <http://www.pmprb-cepmb.gc.ca/english/view.asp?x=302&mid=293> – accessed March 31, 2005.

⁶⁷ An example of a well-known “me-too” innovation is Claritin and Clarinex – where on 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.

“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 fear of price competition. Also, price is rarely a factor in the decision to purchase by either the consumer or the prescribing physician⁶⁸.

Secondly, 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, better meets societies needs.

However, the drug companies own 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-effects⁶⁹. 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 of 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 drugs⁷⁰.”

⁶⁸ Marcia Angell, M.D, *The Truth About Drug Companies* (2004), Random House of Canada Ltd, Toronto, Canada, p.89/90 .

⁶⁹ IBID, p. 90.

⁷⁰ Gardiner Harris, *2 Cancer Drugs, No Comparative Data*, New York Times, February 26, 2004, C1.

"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 drugs."

Source: FDA's associate director of medical policy, Dr. Robert Temple, said of "me-too" drugs.

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

US Statistics: Focus on Marginal Improvements

In the United States, the National Institute for Healthcare Management recently conducted a comprehensive report on the quality of innovations produced by the pharmaceutical industry, using statistics gathered from the FDA⁷¹. The results clearly indicate that the overwhelming majority of innovations from private drug companies have been in name only.

The FDA categorizes applications for new drug approvals (NDA's) as either :

- (a) 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 US 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.

⁷¹ *Changing Patterns of Pharmaceutical Innovation*, NIHCM Foundation, May 28, 2002, p. 24 . Online at <http://www.nihcm.org/pharm.html> (Accessed March 21, 2005). 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, *NDA's Approved in Calendar Years 1990-2001 by Therapeutic Potentials and Chemical Types*, found at www.fda.gov/cder/rdmt/pstable.htm. and (see also p.43 of *The Truth About Drug Companies*).

If placed on a continuum of degree of innovativeness, starting with the most innovative:

Ranking Innovativeness Using FDA Criteria	
<u>Category of NDA</u>	<u>Degree of Innovation</u>
Priority NME	Most Innovative
Standard NME	
Priority IMD	
Standard IMD	Least Innovative

Using FDA statistics from 1998 to 2000, NIHCM found that over two-thirds of new drugs approved used active ingredients already available in the market⁷².

Seventy-six percent (76%) of new approvals were for standard rated drugs. 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 invest to create beneficial drugs, only a mere 24% of this money actually created drugs with a clinical benefit over existing products⁷³.

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. Two thirds of this \$64.7 billion increase arose from spending on newly introduced drugs. That is, \$44 billion or 65% of increase in drug expenditure resulted from spending on new drugs. To put it even more simply, new drugs cost a lot more than old drugs⁷⁴.

⁷² IBID. p.7.

⁷³ IBID, p.8.

⁷⁴ IBID, p.3 and p.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 “new molecular entities” (NME’s) – approximately 21%. The remaining 78% were drugs using active ingredients already on the market.

Pharmaceutical Innovation in Canada

In Canada, as in the US, pharmaceutical innovation consists mostly of the “me-too” quality, that is, are mostly slight variations of existing patented medicines.

Canada’s Patented Medicines Price Review Board categorizes new medicines submitted for drug approval into 3 types:

Canada’s Classification of New Patent Medicines: 3 Degrees of Innovation

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.

Source: Patent Medicine Price Review Board: Pricing Guidelines (<http://www.pmprb-cepmb.gc.ca/english/view.asp?x=230&mid=204>)

In the five year period between 1994 and 1998, 408 new human drugs were patented in Canada. The proportionate breakdown according to innovation type is as follows⁷⁵:

Category 1: Line Extension: 52%
Category 3: Little or No Advantage : 42%
Category 2: Breakthrough – mere 6%

⁷⁵ Patent Medicine Price Review Board, Annual Reports. See online source at: <http://www.pmprb-cepmb.gc.ca/english/View.asp?x=91&mp=68>. (Last date accessed: April 14, 2005)

In 2001, this pattern continued, of 82 new patent drugs introduced, the breakdown consists of:

- Category 1: Line Extension: 49%
- Category 3: Little or No Advantage: 45%
- Category 2: Breakthrough: 6%

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

Neglected Sectors: Developing and Developed Countries

This distorted focus on profitable drug development is reflected by 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 disease burden in poor countries – and for over a half of Africa’s disease burden⁷⁶.

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. Ninety percent of the victims live in sub-Saharan Africa. Tuberculosis kills about 2 million people every year, 98 percent of them in low-income countries. And more than 42 million people are infected with HIV worldwide, of which 95 percent live in poor countries. In 2002, 5.1 million people died from AIDS and 5 million people were newly infected. Sub-Saharan Africa accounted for 70 percent of the new cases in 2002. It is leading cause of premature death globally and is predicted to orphan over 26 million children by 2010⁷⁷.

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

⁷⁶ Michael Kremer and Rachel Glennerster, *Strong Medicines, Creating Incentives for Pharmaceutical Research on Neglected Diseases*, (2004), Princeton University Press, Princeton, New Jersey, p.7.

⁷⁷ *IBID*, Chapter 2: *Health in Low Income Countries*.

For statistics, see also: World Health Organization (2001) *World Health Report 2001 and 2002*, WHO *Global Tuberculosis Report 2002*, Geneva: WHO. UNAIDS, *AIDS Epidemic Update*. December.

accounted for only 1.3% of pharmaceutical sales worldwide⁷⁸. Between 1975 and 1997, only 13 out of 1,233 new drugs licensed worldwide were for tropical diseases⁷⁹. Only four of which were developed by commercial pharmaceutical firms. 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.

“The drug industry has little incentive to spend money on research to develop medicines that will be of enormous benefit to public health if it offers little prospect for commercial gain⁸⁰.”

Even the limited research that is devoted to finding a cure or vaccines for a disease such as the HIV virus 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 exist⁸¹.

Of the total R&D of \$430 to 470 million devoted to finding an AIDS vaccine (through the International Aids Vaccine Initiative), only \$50 to 70 million comes from private industry. The rest comes from government and non-governmental organizations⁸².

In the US, \$70 billion is spent every year on health and research development (public and private), only 10 percent is devoted to research into health problems that affect 90 percent of the world's population (known as the 10/90 gap)⁸³.

In recognition of this market failure, the international community recently implemented changes to intellectual property rights regarding pharmaceutical innovations with the passing of DOHA & the TRIPS Accord. TRIPS stands for the Trade Related Aspects of Intellectual Property (TRIPS) agreement and Public Health⁸⁴ and the Aug 30, 2003 decision of the WTO General Council.⁸⁵ The

⁷⁸ [www.undp.org/hiv/docs/ Barcelona-statistical-fact-sheet-2July02.doc](http://www.undp.org/hiv/docs/Barcelona-statistical-fact-sheet-2July02.doc) – UNDP United Nations Development Programme

⁷⁹ Pecoul, Bernard, Pierre Chirac, Patrice Trouiller, and Jacques Pinel. (1999) “*Access to Essential Drugs in Poor Countries: A Lost Battle?*” *Journal of the American Medical Association* 281(4): 361-67.

⁸⁰ See footnote 51, at p.48 (*The Truth About Drug Companies*, M. Angell).

⁸¹ See note 59 at p.26 *Strong Medicines* by Kremer

⁸² *IBID.*

⁸³ Global Forum for Health Research, 2002

⁸⁴ “Declaration on TRIPS and Public Health”, Doha WTO Ministerial Conference, 2001. [Doha Declaration] online World Trade Organisation website:

<http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm>

⁸⁵ WTO General Counsel, *Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health* online: WTO website

<http://www.wto.org/english/tratop_e/trips_e/t_news_e.htm> [hereinafter Decision on TRIPS]

Doha declaration recognized the severity of public health problems affecting less developed countries⁸⁶ and how patents increase the price of essential medicines.⁸⁷ As such, Doha requires that TRIPS not be interpreted or implemented in a manner that prevents public health measures⁸⁸.

Bill C-9 (*The Jean Chretien Pledge to Africa Act*)⁸⁹ was Canada's response in support of the Doha declaration. It mandates compulsory licensing and exportation of pharmaceutical products to poor countries, on the basis of national emergency or other situation of extreme urgency that results lack of ability to afford or have access to necessary drugs.

However, despite the implementation of TRIPS, DOHA 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 does 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 markets⁹⁰.

High-Income Countries

There is a similar lack of R&D to develop products 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 US *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 exclusivity⁹¹. 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.

⁸⁶ Doha Declaration, *supra* note 26 art. 1.

⁸⁷ *Ibid* art. 3.

⁸⁸ *Ibid* art. 4.

⁹⁰ *Intellectual Property Rights in the Global Economy*, Keith E. Maskus © Institute for International Economics (2000) Washington D.C.

⁹¹ Henkel, John 1999 "Orphan Drug Law Matures Into Medical Mainstay" FDA Consumer Magazine, May-June. Available online at http://www.fda.gov/fdac/features/1999/399_orph.html. and also, L. R. Basara & M. Montegue, *Searching for Magic Bullets: Orphan Drugs, Consumer Activism and Pharmaceutical Development* (New York: Pharmaceutical Products Press, 1994) at 128.

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 whether to even publish results. Also, with public labs feeling the pressure of competition⁹³ from private research companies, they are more willing to accommodate drug company's control over the entire research process. This creates research bias, in *both* private and public labs, that are overwhelmingly in favor of their products. According to industry critic Marcia Angell, this makes bias not only possible, but extremely likely⁹⁴.

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 labor to develop competitive technology-based industries. The competition for scientific talent will only

⁹³ See footnote 51 at p.100/101 (Truth About Drug Companies): As hospitals lose precious funding to private research contractors, there is greater competition for research contracts sponsored by private drug companies. (In 1990, 80% of industry-sponsored trials were conducted at academic institutions, but by 2000 this figure declined to less than 40%).

⁹⁴ See footnote 51 at p.100 (Truth About Drug Companies). Angell concludes that bias is now rampant – recent survey found that industry-sponsored research was nearly four times as likely to be favorable to the company's product as NIH sponsored research.

See also Kevin A. Shulman et al., "Scope and Impact of Financial Conflicts of Interest in Biomedical Research," *Journal of the American Medical Association*, Jan 22-29, 2003, 454. and Thomas Bodenheimer, "Uneasy Alliance: Clinical Investigators and the Pharmaceutical Industry," *New England Journal of Medicine*, May 18, 2000, 1539.

⁹⁶ *The BioPharmaceutical Industry: Overview, Prospects and Competitive Challenge* (2001), p.4/5.

intensify as other countries are also building their technology-based industries. In particular, as genomic and proteomic sequencing are poised to revolutionize biopharmaceutical innovation⁹⁶, drug researchers will be exceptionally scarce.

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 and/ or social benefits, both of 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 demographic⁹⁷. The US government is

⁹⁷ Spin Doctors, Mary Ellen Egan, 11.29.04 “ Drug companies are coming out of the shadows to fight for their reputations--and profits. “ Forbes.com. Online source: http://www.forbes.com/global/2004/1129/044_print.html. Date accessed March 24, 2005.

“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

considering imposing price 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 survivors⁹⁸. Private drug companies need to associate themselves with more credible recognition from a trustworthy institution.

Our proposal will 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&D⁹⁹.

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 in countries 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.

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."

⁹⁸ IBID.

⁹⁹ See footnote 51 at p. 240/241: "In fact, she stresses that this should be the number one priority reform of all of her recommendations, (p.241) "If I could choose only one reform, 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. (p240) "The FDA should not be allowed to approve drugs that offer merely trivial or no advantages over existing drugs." She believes that, "overnight, this reform alone would force the industry to concentrate on innovative drugs instead of me-too drugs (p241)".

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 laboratories¹⁰⁰ (definition from Kremer p.45). *Pull programs* operate on the basis of rewarding the inventor only upon the complete development of an innovation, that is, such programs reward 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 product under patent monopoly prices¹⁰³. 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 one iota in its overall research intensity¹⁰⁴”.

¹⁰⁰ See footnote 59, at p.45 (Strong Medicines): Kremer’s wording of typical “push” programs.

¹⁰³ See footnote 59 at p.45.

¹⁰⁴ See footnote 1, at page (x) of Introduction and p.16 of Palda. See also the rankings from the report *International Competitiveness of Canadian R&D Incentives: An Update*, Report 55-90, Ottawa: The Conference Board of Canada, June 1990 by Jacek Warda – by the federal department of Industry, Science and Technology). Rankings of effectiveness of R&D tax credit systems are based on after-tax cost of \$1 of R&D expenditure, divided by one minus the tax rate.

(ii) Direct Funding of Research

The key problems 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 1980's 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 account¹⁰⁵.

A Canadian example is the government's financing the research and development of the CANDU nuclear reactor¹⁰⁶. 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 less capable of successfully commercializing on its innovations.

¹⁰⁵ See footnote 59 at p.47 to 49.

¹⁰⁶ See footnote 1, at p.176 to p. 190 of Palda for full history of the government support for development of CANDU reactor. Palda relies heavily on Energy, Mines and Resources Canada, *Nuclear Industry Review – Problems and Prospects 1981-2000*, Ottawa: 1982 and on G. Bruce Coern, *Government Intervention in the Canadian Nuclear Industry*, Montreal: Institute for Research on Public Policy, 1980.

“government directed push programs are well-suited for basic research”

Source, Kremer, *Strong Medicines*, p.3.

After reviewing the huge sums of money and energy that has been devoted to encouraging R&D in Canada, Palda found that the results were less than stellar. The resulting degree of technological advancement has not been nearly as impressive as the investment¹⁰⁷

Palda concludes that Canada’s ability to commercialize on its innovations is its weakness (ie. weak in relation to the private sectors rate of successful commercialization of its innovations). And yet most of Canada’s policy thrust is aimed at R&D support and lacks support for commercialization. Economist, Michael Kremer agrees that push programs do not support the latter stages of innovation that involves commercialization. He reasons that this occurs because government supported researchers are chiefly interested in 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 latter stages of development and commercialization of innovations because it is less-intellectually challenging than basic research¹⁰⁸. 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 ingenious 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 to continue, 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 innovations¹⁰⁹. 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

¹⁰⁷ Footnote 1, at p.101/102, “government policies to encourage innovation (whether by direct subsidies, purchasing schemes, merger encouragement or tax alleviations have been at best, ineffective”.

¹⁰⁸ See footnote 1 at p.260 (Palda) and footnote 59, at p. 54 (Kremer’s *Strong Medicines*, Chpt 5: Role of Push Programs).

¹⁰⁹ See footnote 1 at p.250/251 and p.258 and footnote 59 at Chapter 6: The Potential Role of Pull Programs.

winners and (iv) facilitate the diffusion of innovation ¹¹⁰. All of these elements are included in the economic prize system proposed in this article.

*“most effective means of government to promote technology ..is to promote conditions for increased competition..”
agrees with the recommendation for “the government to restrain from bail-outs’ of companies including ‘subsidies and guaranteed procurements’”*

Source: K. Palda, *Innovation Policy and Canada’s Competitiveness*, (1993), p.258.

Quoting: BIAC, *Principles for the Promotion of Science, Technology and Industry – A View from the Industry*, Paris, February 23, 1990. (BIAC – Business and Industry Advisory Committee of the OECD.)

Distortions from Push Programs

- Difficult to Identify Successful Projects/ Low Rate of Success
- Inability to Monitor Progress/ Lack of Accountability once Funded
- Complacency / Low Motivation
- Research Bias / Exaggerated Findings
- Academic-Oriented: Focus on Basic Research
- Tax Credit not alleviate Lack Access/ Affordability
- Slow Rate of Commercialization
- Appropriate for Basic Research
- Ignores Applied Research

¹¹⁰ See footnote at, p. 250/251 and p.258.

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 developed. The cost of unsuccessful projects are 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 pursuit 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 payoff¹¹¹. 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 rewards, drugs would be far cheaper and more widely used.....engendering significant increases in consumer welfare.¹¹²”

“ In a regime with (economic) rewards, drugs would be far cheaper and more widely used...engendering significant increases in consumer welfare...from enhanced incentives to innovate..”

Source: See footnote 93 at p.545, *Rewards vs Intellectual Property Rights*, Shavell and Van Ypersele (2001).

¹¹¹ Steven Shavell and Tanguy Van Ypersele, *Rewards versus Intellectual Property Rights*, *Journal of Law and Economics* (2001), v.44, 525.

¹¹² *IBID*, at p.545.

One of the strongest proponents of using rewards or market-based mechanisms is Harvard economist Michael Kremer and Rachel Glennerster, as described in *Strong Medicines: Creating Incentives for Pharmaceutical Research on Neglected Diseases* (2004)¹¹³. They believe that the use of pull programs will lead to a “faster, cheaper and more efficient research process open to new ideas¹¹⁴”. In particular, they advocate the use of an “advanced purchase commitment” program as ideal to inspire 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 strongly supported by the Centre of Global Diseases, which is funded by the Bill & Melinda Gates Foundation, and has even been recently adopted by the UK. On December 1, 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 developed¹¹⁵.

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.

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

¹¹³ See footnote 59.

¹¹⁴ See footnote 59, at p.66.

¹¹⁵ *Fortune*, New York, December 27, 2004. Vol.150, Iss.13;p.52. © *Time Incorporated*.

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 vaccines¹¹⁶. In a recent article, economist William A. Masters (2003) advocated a similar open-ended prize system to encourage agricultural innovation in low-income countries¹¹⁷. 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 system¹¹⁸. 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 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 discoveries are likely to 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,¹¹⁹ makes it a more affordable alternative to more expensive drugs

¹¹⁶ See footnote 59, at p.109.

¹¹⁷ W.A. Masters (2003), *Research Prizes: A Mechanism to Reward Agricultural Innovation in Low-Income Regions*, The Journal of Agrobiotechnology Management and Economics, Vol.6, Number 1&2, Article 14, 71-74. A longer and more detailed version is forthcoming in the International Journal of biotechnology, and is available by download from AgBioForum at www.earth.columbia.edu/cgsd/masters-news. (Last date accessed April 15, 2005).

¹¹⁸ *An Optional Reward System for Neglected Disease Drugs*, Aidan Hollis, Department of Economics, University of Calgary; Institute of Health Economics. See on line version at : <http://econ.ucalgary.ca/fac-files/ah/drugprizes.htm> or <http://econ.ucalgary.ca/fac-files/ah/optionalrewards.pdf>. Last date accessed May 31, 2005.

¹¹⁹ Online: U.S. Department of Agriculture website: <http://ars.usda.gov/is/np/fnr/fnr0104.htm#pinch>.

such as statins. 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:

Features of an Effective Economic Rewards for Pharmaceutical Innovation

- Consistent with Priority Healthcare Needs: Encourages innovation on priority healthcare issues.
- Self-Selecting: Encourage private companies to pursue projects where 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
- Enhance Canada's Overall Industrial & Economic Growth

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, fortify Canada's vulnerable points and plays to 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 problem¹²¹. In 1837, it was employed by the French government to invent photography and led to the creation of the daguerrotype. In more modern times, rewards have been used by the US Patent Compensation Board and the Department of Defense to compensate for

¹²¹ Michael Kremer, *Patent Buyouts: A Mechanism for Encouraging Innovation*, (1998) *The Quarterly Journal of Economics*, 113(4): 1137-67, at p. 1144-1146.

innovations of military value and by the former Soviet Union to reward process innovators with a percentage of cost savings realized from the inventions¹²².

In early 1900's, 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 in today's time 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. Unlike other government funded research, the burden of assessing project success, monitoring its progress, running clinical tests and commercial development 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 can be measured by impact on health outcomes. An objective measure for health outcomes can be DALY's (disability life-adjusted

¹²² Sinnot, John P., *World Patent Law and Practice*, Volume 2M (New York: Matthew Bender, 1998).

life years), as suggested by Kremer for use in the purchase commitment mechanism. This measure is already used by the World Bank, the World Health Organization, government healthcare officials, insurance companies and even drug companies to assess and compare the impact of diseases and the cost-effectiveness of available medical treatments¹²³.

The size of the reward shall be between 10 to 20% 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. Whereas, 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 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

¹²³ See footnote 59 at p.40 and p.90 for discussion of use of DALY's in Kremer's purchase commitment program. Also see World Bank (2003) *World Development Indicators*. Washington, D.C.: Oxford University Press and WHO(2000) *Less-used Vaccines against Major Diseases Are Cost-Effective, Researchers Conclude*, Bulletin of the World Health Organization 78(2):274.

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 recruit 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 Prize¹²⁴, 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, 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

¹²⁴ See website for Ansari X Prize at: <http://www.xprize.org/home.php>.

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% of revenues to their advertising and marketing budget¹²⁵? 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% 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 will be attracted to this prize because it will benefit their company 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,

(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 & technology, promote science education, induce growth of private industry *and* further the advancement of humanity.

¹²⁵ See footnote 51, at *Chapter 7: The Hard Sell...Lures, Bribes and Kickbacks* for a detailed analysis of the breakdown of the marketing and advertising budget of the largest drug companies in the U.S.

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.

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

one to address priority health issues in Canada and one to treat 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 affect system, such as diseases that affect seniors (such as 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 damage¹²⁶.

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 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, coordination of vaccine transportation and establishment

¹²⁶ World Bank (1993) *Disease Control Priorities in Developing Countries*. New York: Oxford Medical Publications, Oxford University Press for the World Bank.

of the 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, telephone communication etc... So 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, innovative ideas on the use of telemedicine¹²⁷ are already being developed. 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 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 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. Therefore, 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.

¹²⁷ *Telemedicines Today, The HealthNews Magazine* or see online source at : <http://www2.telemedtoday.com/articles/telehomehealthcare.shtml> (Last date accessed April 30, 2005).

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 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 next best alternative treatment. It is recommended that this percentage be 10 to 20% 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 impact on health outcome as measured using DALY's or QALY's . 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 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 member 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 Patent Medicine Price Review Board 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 market¹²⁸. 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 PMPRB¹²⁹, there is a ready source of information to assist in forecasting sales and usability of submitted innovations. 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 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 (ex. Mandela, David Suzuki, Bono, or other science or humanitarian celebrities...) to raise 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 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% of the current healthcare budget to this incentive. The category devoted to diseases in developing countries can be funded with 5% 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 Foundations, Rockefeller Foundation, etc... be pursued to contribute funds in “matching” donation program where the non-profit body would agree to match every dollar the Canadian

¹²⁸ Compendium of Guidelines, Policies and Procedures (of Patent Medicines Price Review Board). Online source: <http://www.pmprb-cepmb.gc.ca/english/View.asp?x=135&mp=73> at Chapter 3: Scientific Review Process and Schedule 2: Therapeutic Class Comparison Test.

¹²⁹ Patented Medicines Regulations, 1994 (SOR/94-688), s.5 (Revenues and Research and Development Expenditures) or online source: <http://laws.justice.gc.ca/en/P-4/SOR-94-688/161444.html#rid-161474>.

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 Economic Prize

Results-Oriented Reward: Cost-Effective Funding of Innovation

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 up front, 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 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 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. Given the opportunity to gain even a modest profit will provide the marginal incentive for drug companies to full 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 taps 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 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 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 researchers 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

Creativity has been defined as "the making of unexpected connections between things that are already known". 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, 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 nations¹³⁰. 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

¹³⁰ *Changes to Avian Flu Virus Worry Scientists* by Helen Branswell, Toronto, Globe and Mail, Thursday, May 19, 2005, A7, Canadian Press. Or see Globe and Mail online at: <http://www.theglobeandmail.com/servlet/ArticleNews/TPStory/LAC/20050519/AVIAN19E/TPInternational/?query=branswell>. (Last date accessed May 20, 2005).

The WHO urges countries to hasten preparation pandemic flu preparations as releases report of changes to H5N1 flu virus circulating in Asia (North Vietnam). The avian virus' genetic makeup is altering to spread more effectively among people and possibly showing partial resistance to oseltamivir – the main drug used in wealthy countries to fight the virus.

the potential benefits or savings that can be realized from ingenious thought or applications.

A scaleable reward motivates researchers to focus on maximizing 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 the prepared mind”. 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) point 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 *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 provision and supportive industrial policy.

Government as a Source of Knowledge

This prize will help improve the public’s perception of the government as 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 will 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 will 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 will enable a faster rate of technology transfer to developing countries. In turn, this will 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 will 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 will 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 will 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 – will not only attract investment and talent, but 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 a novel policy solutions to a prevailing international problem will enhance Canada's soft power and authority world wide. Canada will be more influential in settling multilateral trade agreements and disputes, promulgating environmental and human rights accords, and establishing international fiscal and monetary policy. It will also pave the way for Canada's genetically modified foods to be accepted in domestic and international markets.

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 stakeholder: 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 will advance the betterment of society and hone Canada's competitive edge.