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ENSURING CANADIANS
SAFE ACCESS TO
PHARMACEUTICAL PRODUCTS
THROUGH CANADA-CHINA
COOPERATION

Catherine Côté

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ABSTRACT

Canada has a large pharmaceutical industry which is regulated extensively by provincial and federal governments. Yet, the tight regulation of Canada's pharmaceutical industry does not automatically protect citizens from the potential global health threat arising from the entry of pharmaceuticals on the world market from less-well regulated environments, such as China. This paper focuses specifically upon the burgeoning Chinese pharmaceutical industry and the implications for entry and distribution of Chinese products within Canada. It is argued that, as China assumes a more important role in international relations and trade, Canada should look to collaborate more closely with the Chinese government and members of the pharmaceutical industry to ensure Canadians safe access to Chinese pharmaceutical products. Cooperation in the short run on specific projects and confidence-building measures could develop into more comprehensive cooperation in the long run. Collaboration, in particular, should focus upon increasing the quality and safety of Traditional Chinese Medicine as well as combating counterfeiting. More generally, Canada should assist China in its efforts to establish a publicly funded healthcare system.

RÉSUMÉ

Le Canada possède une importante industrie pharmaceutique soumise à une stricte réglementation fédérale et provinciale. Mais aussi rigoureuse qu'elle soit, cette réglementation ne protège pas automatiquement les citoyens contre la menace pour la santé mondiale que peut représenter l'entrée sur le marché international de médicaments issus d'environnements moins strictement réglementés, notamment celui de la Chine.

Cette étude traite précisément de l'essor de l'industrie pharmaceutique de la Chine et de ses répercussions sur l'entrée et la distribution de produits chinois au Canada. Face au rôle grandissant de la Chine dans les relations et le commerce internationaux, elle soutient que le Canada devrait collaborer de plus près avec le gouvernement chinois et les représentants de son industrie pharmaceutique pour assurer aux Canadiens un accès sans risque à ses produits. En collaborant à court terme à des projets ciblés et en adoptant des mesures favorisant un climat de confiance, on jetterait ainsi les bases d'une coopération globale à long terme. La collaboration, notamment, devrait viser l'amélioration de la qualité et de la sécurité des mesures de contrôle du commerce de même que la lutte contre la contrefaçon. Plus généralement, le Canada devrait chercher à soutenir les efforts de la Chine en vue de mettre en œuvre un système de santé public.

ABOUT THE AUTHOR

Catherine Côté graduated from the University of Toronto in 2008, where she majored in Canadian Studies and East Asian Studies. She recently completed a Master of Arts in Asia Pacific Policy Studies at the University of British Columbia. She has developed an expertise in global health issues and the role developed countries, such as Canada, could play in preventing the spread of infectious diseases. Côté currently works in Shanghai for Ivoclar Vivadent, a dental product manufacturer.

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INTRODUCTION

As China assumes a more important role in international relations and trade, Canada should look to collaborate more closely with the Chinese government and members of the pharmaceutical industry to ensure Canadians safe access to Chinese pharmaceutical products. Cooperation in the short run on specific projects and confidence building measures could develop into more comprehensive cooperation in the long run.

Canada's pharmaceutical industry ranks eighth in the world today, accounting for 2 percent of total market sales.¹ Canada has the fourth fastest growing pharmaceutical industry in the world, just behind that of China, the US and Spain. The pharmaceutical industry is also one of the most profitable for the Canadian economy. Although considered to be a risky business, pharmaceutical companies' profits are constantly increasing.² Provincial and federal governments play an important regulatory role. The Therapeutics Products Program, a division of Health Canada, reviews the safety and efficacy data for each new drug submission. Every drug has to be tested and approved by Health Canada before it can be prescribed or dispensed by pharmacies countrywide.³ However, the tight regulation of Canada's pharmaceutical industry does not automatically protect citizens from the potential global health threat arising from the entry of pharmaceuticals on the world market from less tightly regulated environments, such as China.

This paper focuses specifically upon the burgeoning Chinese pharmaceutical industry and the implications for entry and distribution of Chinese products within Canada. It first provides a short description of the Chinese pharmaceutical industry and its regulatory body, the China State Food and Drug Administration (SFDA). Next, this paper examines the changes that have affected the Chinese industry in the past few years, especially since Beijing's accession to the World Trade Organization (WTO), paying particular attention to counterfeit and/or substandard drugs. Then, this paper explores the potential health risks associated with a greater world consumption of pharmaceutical products manufactured in China. Then, this paper turns to the Canadian perspective, focusing mainly on the need for the Canadian government and industry leaders to collaborate with the relevant Chinese authorities to strengthen SFDA's laws and regulations and enforcement mechanisms in order to better prevent the spread of diseases. Two issues are of major interest to Canadians: the presence of counterfeit/substandard drugs in international and Canadian markets and the resulting risks that this could pose including those of infectious disease and, in the extreme, of a world pandemic. These are not simply hypothetical concerns; it is already established that large scale consumption of counterfeit/substandard drugs contributes to the development of resistant forms of infectious agents. Such "super bugs" in turn are transmitted to populations in developed countries through migration and travel.

BACKGROUND

Overview of the Chinese Pharmaceutical Industry

China's pharmaceutical market has been described as one of the world's most exciting.⁴ In recent years a growing population and an increased use of western medicine have made China the fastest growing pharmaceutical market. By 2050 it could be the world's largest.⁵ These market characteristics present some

¹ "Canada Pharmaceutical Industry," Aruvian Research (March 2009), B.

² *Ibid.*, B.

³ Aslam H. Anis, "Pharmaceutical Policies in Canada: Another Example of Federal-Provincial Discord," *CMAJ* 162, No. 4 (2000): 524.

⁴ Faiz Kermani, "China's Pharmaceutical Challenge," *B5*, (2005): 61.

unusual possibilities and challenges to pharmaceutical companies. China's pharmaceutical market has maintained production and sales at a double digit annual growth (some figures suggest an average growth of 10 percent, but others say 28 percent in recent years) since the mid-1980s.⁶ There are over five thousand drug wholesalers, but as Susan Ward states: "mergers and acquisitions (M&As) have become an important means for companies to grow in size, extend into new markets and obtain know-how in the Chinese pharmaceutical industry."⁷ It is also an industry unique in the world by its composition: split almost half and half between chemical and biotech products at 60 percent and Traditional Chinese Medicine (TCM) products at 40 percent.⁸ TCM have been developed through thousands of years of evolution. Modern manufacturing methods and technologies now permit the production of large quantities. The rest of the world is also more receptive to TCM.

"Traditional Chinese Medicine, with its peculiar way of observing life and disease, has the greatest potential for original innovations among all the other academic disciplines in the country," explained Liu Yanhua, vice-minister of Science and Technology.⁹ In fact, the Chinese government believes that the future of their pharmaceutical industry lies in the production and sale of TCM and not other prescription and over-the-counter drugs. To this effect, it has pledged to create several export oriented TCM manufacturing giants in the near future. In 2008, TCM exports reached US\$1.3 billion, up from US\$720 million in 2003.¹⁰

Another feature of the Chinese pharmaceutical market is that it is split between domestic producers (most of them state-owned) and China-foreign joint ventures. Over the past decade or so, imported drugs made up 40 percent of the market.¹¹ Chinese companies are small, as most of them produce a single product. Jiang, Wang and Yan noted that in 2001, "the annual sales of the largest of these companies was only about US\$530 million, just equal to 1% of the annual sales of the US pharma giant Merck."¹² In addition, most of the facilities use outdated equipment and therefore, specialize in the production of raw products with low-tech added value. In addition, competition is fierce since many companies manufacture similar products.

China was the second largest producer of pharmaceutical products in 2001, but its industry lacked investment, innovative capacity and had few proprietary products. Although more recent statistics are not available, industry observers note that the same is still true to a large extent today. Consequently, reliance on foreign pharmaceutical products is a necessity. However, the Chinese market is hard to penetrate, not because of tariffs, but due to the lengthy, complex and opaque registration process with government agencies at multiple levels required to set up operations in China. Companies have to invest significant amounts of time, patience and resources to develop the network required to manoeuvre in the Chinese business environment. According to Minden and Dong, "the result is a reduced role for free market forces, greater inefficiency, and higher prices for Chinese consumers."¹³ Prior to China's accession to the WTO, the government expressed fears over its incapacity to protect its pharmaceutical companies against international competitors. However today, by giving tax breaks and building facilities, the government is bending over backward to convince foreign companies to conduct research and manufacture operations in China.

⁵ Susan Ward, "Demographic Factors in the Chinese Health-Care Market," *Nature Reviews Drug Discovery* 7 (May 2008): 383.

⁶ Xiaofeng Shao and Jianhua Ji, "Reconfiguration of Pharmaceutical Logistics Operations in China: An Empirical Study," *Transportation Journal* (Fall 2006): 53.

⁷ *Ibid.*, 53.

⁸ Yan Jiang, Yongfeng Wang and Xijun Yan, "Chinese Pharmaceutical Companies: An Emerging Industry," *DDT* 6, No. 12 (June 2001): 610.

⁹ Shanshan Wang, "TCM has 'World Potential'," *China Daily* (March 22, 2007).

¹⁰ Fang Yang, "China to Double Traditional Medicine Output in About Ten Years," *Xinhua* (July 1, 2009): 610.

¹¹ *Ibid.*, 610.

¹² S. Yuan, "A Comparison of the Pharmaceutical Industry between China and US," *Med. Economic Inf.* 341 (2001): 25-26.

¹³ Karen Minden and Jeffrey L. Dong, "Dancing with Wolves: Opening the Pharmaceutical Sector in China," in *China's Reforms and International Political Economy*, ed. David Zweig and Chen Zhimin (London and New York: Routledge, 2007), 175.

In the past few years, terms such as 'R&D,' 'strengthen risk control and management,' 'enhance communication and cooperation,' 'standardization,' 'unification,' 'clarification,' among others, have become code words to convince members of the pharmaceutical industry and foreign governments of the Chinese government's commitment to enhance the reliability of its products.¹⁴ To this effect, it has embarked on a series of reforms of the country's drug regulatory agencies.

China's Drug Safety Supervision and Legal System

In July 2007, Zheng Xiaoyu, former head of the State Food and Drug Administration (SFDA), was executed. He was accused of taking some 6.5 million yuan, close to \$1.1 million, in bribes to let medical companies counter the regulatory system.¹⁵ Zheng's case is not unique however, and although significant efforts are made to reform health regulatory agencies, there is still a long way to go before the SFDA can come to par with its North American or European counterparts.

The State Drug Administration was established in 1998 as the first Chinese institution in charge of regulating the pharmaceutical industry. In 2003, it was replaced by the SFDA in accordance with the restructuring plan of the State Council approved by the First Plenary Session of the 10th National Peoples' Congress and the "State Council Notice on Government Structuring" (No.8.2003.).¹⁶ In many ways, this re-structuring came in response to China's entry into the World Trade Organization (WTO). According to Dr. Yin Hongzhang, from the SFDA Department of Drug Registration, "the regulatory system for new drug evaluation and registration in China was gradually developed for better alignment with international standards." Indeed, SFDA's structure mirrors that of the US Federal Drug Administration (FDA).

The SFDA's mandate is to ensure the

administrative supervision and technical supervision over the research, production, distribution and use of drugs (including Chinese crude drugs, prepared slices of Chinese crude drugs, traditional Chinese medicine preparations, chemical drug substances and their preparations, antibiotics, biochemical drugs, radio-active pharmaceuticals, serum, vaccines, blood products and diagnostic agents) and medical devices.¹⁷

The SFDA falls under the direct supervision of the State Council and is headquartered in Beijing. Out of the ten SFDA departments, five deal exclusively with the drug industry.¹⁸ The General Office (Department of Financial Planning) and the Department of Policy and Regulations are in charge of both the pharmaceutical and the food industries.

In addition, according to the government, by the end of 2007 there were 2,692 drug regulatory departments in China, including 31 at the provincial level, 339 at the municipal (prefecture) level and 2,321 at the county level. The provincial regulatory agencies (provincial FDA, local FDA offices and officials) are subject to SFDA oversight. They are responsible for "carrying out field inspections for assessment of

¹⁴ "What's New," State Food and Drug Administration, P.R. China, <http://eng.sfda.gov.cn/eng/> (accessed April 24, 2009).

¹⁵ Chris Buckley, "China Calls Official's Execution a Warning Siren," *Reuters* (July 11, 2007).

¹⁶ "About SFDA," State Food and Drug Administration, P.R. China, <http://eng.sfda.gov.cn/eng/> (accessed April 24, 2009).

¹⁷ "Status Quo of Drug Supervision in China," Government of the People's Republic of China, Beijing (July 2008): 5.

¹⁸ Department of Drug Registration, Department of Medical Devices, Department of Drug Safety and Inspection, Department of Drug Market Compliance, Department of International Cooperation (Office for Administrative Protection of Pharmaceuticals). Source: "About SFDA – Organizational Chart," State Food and Drug Administration, P.R. China, <http://eng.sfda.gov.cn/eng/> (accessed April 24, 2009).

compliance and authenticity of the drug application dossier” and “for the collection of lot release testing samples.”¹⁹ Fifteen other organizations are also affiliated to the SFDA.²⁰ SFDA’s provincial, municipal and county levels subsidiaries are all controlled through a vertical management system, concentrating power under the authority of the State Council.²¹

In short, Chinese institutions in charge of regulating the pharmaceutical industry are numerous, but their respective spheres of influence are not always well-defined. In theory and according to the *Drug Administration Law of the Peoples’ Republic of China*, to be sold on the market, a new drug must be approved for clinical trials (phases I, II and III) and must receive a New Drug Certificate, a New Drug Registration Certificate, as well as a Drug Good Manufacturing Practice (GMP) Certificate. Expert panels review each stage; make recommendations to the SFDA, which then grants approvals.²² However, in practice, many stages are not respected, are sometimes quickly gone over, or worse, are just ignored. The Chinese pharmaceutical industry has grown too fast. The institutional capacity of the SFDA and its subsidiaries remains limited and the legal system “is too weak and insufficiently legitimated to define jurisdictional boundaries in any coherent and consistent fashion.”²³

China’s regulatory system is faced with four major problems. First, the sheer number of small manufacturing companies complicates the monitoring process. There are simply not enough SFDA personnel to ensure proper monitoring of every production facility. Second, the complexity of drug supply chains undercuts the transparency and traceability of pharmaceutical products.²⁴ Since the late 1980s, significant efforts were made to streamline drug supply chains, but the overall process remains complex. Most manufacturers are responsible for warehousing operations and for transporting pharmaceutical products to wholesalers. Nowadays, all enterprises – state, collective and private – are allowed to engage in the pharmaceutical wholesale business. Wholesalers are then charged with distributing drugs to retailers, hospitals and pharmacies. The longer the supply chain, the harder it is for regulatory agencies to ensure the final quality of the pharmaceutical products involved.²⁵

Third, corruption is wide spread. National standards are high, but enforcement is left to local officials. These officials often have to operate under financial constraints. Therefore, local regulatory agencies are more focussed on revenue-generation than drug safety. It is not uncommon for manufacturers to offer bribes in exchange for a good inspection report.²⁶ Observers argue that basic institutional supports for a

¹⁹ Hongzhang Yin, “Regulations and Procedures for New Drug Evaluation and Approval in China,” *Human Gene Therapy* 17 (October 2006): 970.

²⁰ Organizations affiliated to the SFDA: the National Institute for the Control of Pharmaceutical and Biological Products, the Pharmacopeia Commission of the PRC, the Center for Drug Evaluation, the Drug Certification Center, the Center for Drug Re-evaluation, the National Committee on the Assessment of the Protected Traditional Chinese Medicinal Products, the Center for Medical Device Evaluation, the Information Center of SFDA, the Training Center of SFDA, the Center for Qualification of Licensed Pharmacist, the China Pharmaceutical News, the China Medico-Pharmaceutical Science & Technology Publishing House, the China Center for Pharmaceutical International Exchange, the SFDA Southern Medicine Economic Institute and the Chinese Pharmaceutical Association. Source: “About SFDA – Affiliated Organizations,” State Food and Drug Administration, P.R. China, <http://eng.sfda.gov.cn/eng/> (accessed April 24, 2009).

²¹ *Ibid.*, 5. It is interesting to note, however, that Shanghai also has its own regulatory institution called the Shanghai Municipal Food and Drug Supervision Administration (SHFDA). Although still subject to the authority of the State Council, the SHFDA is entitled to “study and draw up the drafts of the local rules and regulations on the safety administration of food, health products and beauty products in light of the actual circumstances of this Municipality”. Source: “Shanghai Municipal Food and Drug Supervision Administration,” Shanghai China – Organizations Directly under the Shanghai Municipality, <http://www.shanghai.gov.cn/shanghai/node17256/node17679/node17704/userobject22ai12433.html> (accessed April 24, 2009).

²² *Op. Cit.*, Yin, 970-971.

²³ Jeremy Paltiel, “The Chinese Domestic Context for Engagement with Canada – Scoping Paper,” Canadian International Council (2008): 2.

²⁴ Chris Ansell, “Holding China Accountable? Protecting Consumers in Global Markets,” Prepared for the 8th Annual Travers Conference on Ethics and Accountability in Government, University of California, Berkeley (10 October, 2008): 7.

²⁵ *Op. Cit.*, Shao and Ji, 53.

²⁶ *Op. Cit.*, Ansell, 12.

successful regulatory system are not in place, that is to say, regulatory developments occur within what remains an authoritarian system. Thus, although China has officially adopted an “independent regulatory commission” system, the SFDA’s independence from the central government is not well established. Furthermore, it remains unclear whether Chinese courts can play an independent adjudicatory role. In short, the large number of manufacturing companies, the complexity of supply chains, corruption and lack of transparency all weaken China’s drug regulatory system.

Pharmaceutical Industries and the Chinese Market:

Why, if the regulatory system is inadequate, are pharmaceutical companies willing, eager even, to enter the Chinese pharmaceutical market? First, Mingwei Wang, director of China’s National Center for Drug Screening, holds that “the combination of desperation outside China and promise within has convinced almost every big pharmaceutical player, including Roche, Novartis, GlaxoSmithKline, Eli Lilly and Pfizer, to collectively invest hundreds of millions of US dollars into research operations there over the past few years.”²⁷

The Chinese market environment is distinctly attractive to these large corporations for several reasons. There are a large number of patients in China, making the country the perfect destination to conduct clinical trials. According to Jean-François Carmier, chief executive officer of Transgene, a French pharmaceutical company, “due to its large population, the Chinese can recruit enough patients for a trial in a short time and can therefore generate statistically significant amounts of clinical data very rapidly.”²⁸ In Europe or in North America, the same trial would last longer since recruitment of suitable patients is harder. In addition, due to the prevalence of diabetes, cardio-vascular diseases, tropical infections and degenerative disorders, China, along with India, is particularly attractive for companies looking to conduct trials.²⁹ In addition, companies are drawn by an increasing talent pool of scientists who trained overseas and are now returning to China.³⁰

Second, what some might see as a problem is seen by others as an advantage. A relatively new system of laws and regulations coupled with a lack of enforcement means that foreign companies are able to employ semi-legal, semi-ethical practices in China as opposed to their own countries where they would be faced with costly lawsuits. In the case of clinical trials, some companies offer financial compensations which amount to more than the participants’ monthly income or by providing medication worth more than their annual salary.³¹ Yet the cost of those compensations remains significantly lower than what it would normally be in the developed world, with strict regulations, elaborate safety measures and small populations.³²

ISSUES OF CONCERN

Up until now, few people have been worried about the potential impacts of the Chinese pharmaceutical industry’s entry into the world market. Yet, the pharmaceutical industry is plagued with many of the same problems as the Chinese food industry while its dangers remain as potent. After all, the State Food and

²⁷ David Cyranoski, “Pharmaceutical Futures: Made in China?” *Nature* 455 (October 29, 2008): 1169.

²⁸ Sue Pearson, Hepeng Jia, and Keiko Kandachi, “China Approves First Gene Therapy,” *Nature Biotechnology* 22, No. 1 (January 2004): 3.

²⁹ Samiran Nundy, M. Chir., and Chandra M. Gulhati, “A New Colonialism? – Conducting Clinical Trials in India,” *New England Journal of Medicine* 352, No. 16 (April 21, 2005): 1634.

³⁰ *Op. Cit.*, Cyranoski, 1170.

³¹ *Op. Cit.*, Nundy and al., 1634.

³² *Ibid.*, 1634.

Drug Administration also regulates the food industry. There are two issues that necessitate particular global attention: the presence of counterfeit/substandard drugs on the international market and the health threat that their consumption poses for their citizens.

Counterfeit/Substandard Drugs

According to the WHO's definition, a counterfeit medicine

is one that is deliberately and fraudulently mislabelled with respect to identity and source. Counterfeiting can apply to both branded and generic products, and counterfeit products may include products with correct ingredients, with wrong ingredients, without active ingredients, with incorrect quantity of the active ingredient, or with fake packaging.³³

In addition, the term "substandard medicines" refers to all counterfeit drugs, but also to "genuine drugs produced by legitimate manufacturers that do not meet the recognized quality and purity standards used by that manufacturer or the regulatory authorities."³⁴ There are at least four common sources of substandard drugs. First, there are batches of drugs that have failed testing, and consequently, should have been destroyed but instead, end up in the hands of unscrupulous people who then sell them on the market. Second, there are drugs that have been improperly stored at elevated temperatures and humidity levels which accelerate the decay of active ingredients. Third, drugs are sometimes sold after their expiration date.³⁵ Finally, there are criminals who intentionally manufacture fake medicine and then manage to infiltrate legal distribution channels.

Counterfeit/Substandard Drugs and China

China's pharmaceutical industry and market exhibits many of the characteristics of other developing countries. The SFDA's regulatory system is very recent and is not supported by a comprehensive health care system. Under such circumstances it is difficult to develop an effective distribution network of drugs. Today in China, hospitals can buy drugs from drug wholesale stations at different levels, pharmaceutical manufacturers, salespersons and so on. These various means for acquiring drugs further increases the likelihood that fake or substandard drugs will find their way into the health care system. Accordingly, drug quality has become an important problem. Indeed, some hospitals consciously choose to purchase low quality drugs in order to earn more through resale. Another consequence of that has been the emergence of illegal drug collectors, "who collect drugs from families at a lower price and then sell them again to low level hospitals or drug retailers."³⁶

There are recognized advantages to the new drug distribution system. It increases competition, which improves the availability of drugs and reduces costs. It also decreases the risk of short supply by diversifying sources. However, the new drug distribution system also negatively impacts the government's capacity to

³³ "Counterfeit Medicines," World Health Organization – Regional Office for the Western Pacific, http://www.wpro.who.int/health_topics/counterfeit_medicines/ (accessed May 4, 2009).

³⁴ Albert I Wertheimer and Jeremiah Norris, "Safeguarding Substandard/Counterfeit Drugs: Mitigating a Macroeconomic Pandemic," *Research in Social and Administrative Pharmacy* 5 (2009): 8.

³⁵ *Ibid.*, 8.

³⁶ Hengjin Dong, Lennart Bogg, Clas Rehnberg, and Vinod Diwan, "Drug Policy in China: Pharmaceutical Distribution in Rural Areas," *Social Science & Medicine* 48 (1999): 783.

successfully regulate the production, distribution and marketing of drugs. First, some factories produce fake or low quality drugs. Second, some physicians under pressure by patients or in order to make more money, prescribe more drugs than necessary.³⁷ Although it is impossible to get exact statistics on counterfeiting, it has been estimated that 192,000 patients were killed by fake drugs in 2001. During the same year, "Chinese authorities closed 1,300 factories while investigating 480,000 cases of counterfeit drugs worth 57 million USD."³⁸ More recent estimates are not available, but despite the SFDA's restructuring and the promulgation of new laws, scientists still identify China as an important source of counterfeit/substandard drugs. In recent years, Chinese authorities collaborated with Interpol and the WHO to arrest large scale counterfeiters, but there is no indication that the scale of the problem is diminishing. Counterfeit drugs do not affect only Chinese people, but are distributed worldwide through an intricate network of drug distribution.

The Global Threat of Counterfeit/Substandard Drugs:

Counterfeit drugs are by no means solely a problem of the developing world, or of those who obtain their drugs through unregulated channels. The growing size and sophistication of counterfeit drug rings has allowed them to penetrate the legitimate drug supplies of developed Western nations, even the United States, which has possibly the most secure drug supply in the world.³⁹

In fact, even the US FDA's most conservative numbers show that there is as much as a one-in-one hundred chance that drugs purchased in a US pharmacy are counterfeit. The WHO even suggests that 5 percent to 7 percent of all drugs in the US do not meet manufacturing standards.⁴⁰ In a market where billions of pills are consumed each year, 1 percent constitutes an impressive number.⁴¹ Most counterfeit drugs are high volume and cost, especially injectable medication, treatments for immunodeficiency virus infection such as AIDS and psychiatric medications. Counterfeiters' methods are so sophisticated than even legitimate producers now have difficulty separating the real drug from the fake without conducting tests.⁴² In addition to legitimate pharmacies, counterfeit/substandard drugs can be easily purchased through the Internet at a lower price.

Although very little research has been done in Canada on the impact of counterfeit/substandard drugs, government authorities are aware of their presence. Over the last few years, Health Canada has posted on its website a series of articles on the risks associated with buying medicine online. It has also been warning consumers against "counterfeit and unapproved avian flu products."⁴³ One of the latest warnings concerning substandard drugs was posted on June 29, 2009 and concerns slimming products called Light Some, Paiyouji, Pearl White Slimming and Reducing Weight Easily. These products are manufactured by Shanghai Chongming Sitai Corporation and are promoted as herbal products used for weight loss. However, they contain undeclared pharmaceutical ingredients and excessive levels of heavy metals, all health damaging.⁴⁴

³⁷ *Ibid.*, 784.

³⁸ Robert Cockburn, Paul Newton, E. Kyeremateng Agyarko, Dora Akunyili and Nicholas J. White, "The Global Threat of Counterfeit Drugs: Why Industry and Governments Must Communicate the Dangers," *PLoS Medicine* 2, No. 4 (April 2005): 303.

³⁹ Wyatt Yankus, "Counterfeit Drugs: Coming to a Pharmacy Near You (Condensed Version)," Prepared for the American Council on Science and Health (August 2006): 4.

⁴⁰ *Ibid.*, 4.

⁴¹ Paul M. Rudolf and Ilisa B.G. Bernstein, "Counterfeit Drugs," *The New England Journal of Medicine* 350, No. 14 (April 1, 2004): 1385. Such brand names like Lipitor, Celebrex and Viagra, available in pharmacies everywhere, were found to be counterfeit.

⁴² *Op. Cit.*, Rudolf and Bernstein, 1385.

⁴³ "Health Canada Advises Consumers against Counterfeit and Unapproved Avian Flu Products," http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2006/2006_12-eng.php (accessed May 4, 2009).

⁴⁴ "'24" Ince, Light Some, Paiyouji, Pearl White Slimming, Reducing Weight Easily," Health Canada Advisories, http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_fpa-ape_2009/2009-110-eng.php (accessed May 4, 2009).

Counterfeit/Substandard Drugs and "Super Bugs"

Potentially the most important threat of large scale consumption of counterfeit/substandard drugs is the development of resistant forms of infectious agents, affecting vast populations and having the potential to develop into a pandemic.

The *Financial Times*, quoting professors of medicine and pharmacology from the Stanford Medical School and Trinity College, stated: "Drug concentrations that are too low can cause the therapy to fail and, equally important, promote the emergence of resistant forms of infectious agent [...] this failure can compromise the response of the patient to other medicines in the future."⁴⁵ Indeed, counterfeit/substandard drugs pose a threat to public health and can quickly become a strain on the health care system, among other ways through their promotion of the emergence of drug resistant diseases. As experts have noted

1) currently available, effective, and relatively cheap drugs will become ineffective, 2) the loss of such drugs will require new drug development, which will be more expensive and will further disadvantage patients in developing countries, 3) the selection of drug resistant pathogens will lead to increased morbidity, mortality and will become a significant burden on developing regions of the world.⁴⁶

It is most alarming that resistance is developing among some of the world's deadliest infectious diseases, such as malaria, tuberculosis (TB) and HIV/AIDS. These drugs are often targeted by counterfeiters because of their high market value. In 2004, a study found that "53% of anti-malarials sold in Southeast Asia contained incorrect levels of the active ingredient."⁴⁷ Earlier in December 2000, "Belgian customs seized 57,000 packs of fake GSK Halfan capsules [...] en route from China to Nigeria."⁴⁸ In fact, if it had not been for the intervention of Belgium's custom agents, 43 tons of 17 brand name counterfeit drugs, from seven international pharmaceutical companies, would have been sold through legitimate channels.

China, however, is not only a source of counterfeit/substandard drugs, but also a consumer. Considering that HIV/AIDS is on the rise and that TB is also frequent, the risks related to the emergence of drug resistant diseases is disturbing. In the past few years, the severe acute respiratory syndrome (SARS) crisis, the avian flu and more recently, the swine flu, have shown how an epidemic outbreak in one country can quickly spread around the globe, not only endangering peoples' health, but also causing major economic losses.

ESTABLISHING CANADA-CHINA PARTNERSHIPS TO INCREASE DRUG SAFETY

In an age when a border is not a barrier, the globalized economy demands nothing less than heightened regulatory interoperability, information exchange, and cooperation, especially on product quality and enforcement matters.⁴⁹

⁴⁵ *Op. Cit.*, Wertheimer and Norris, 5.

⁴⁶ *Ibid.*, 6.

⁴⁷ *Ibid.*, 7.

⁴⁸ *Op. Cit.*, Cockburn, 305. GSK Halfan capsules are antimalarial tablets.

⁴⁹ "FDA Takes Next Step in Establishing Overseas Presence – Agency on Path to Establish Offices in China," FDA News, <http://www.fda.gov/bbs/topics/NEWS/2008/NEW01806.html> (accessed May 4, 2009).

In the decade, the Chinese pharmaceutical industry has grown quickly at the same time as China's 2001 entry into the WTO opened its markets to foreign-owned companies. As China's regulatory system is still in its infancy, and as such, is poorly equipped to ensure proper monitoring of these foreign entities. This rapid growth is seen by companies and governments worldwide as both a threat to peoples' health and for some, an opportunity for collaboration. So far, the Canadian government, in contrast to that of the United States, has perceived the growth of China's pharmaceutical industry more as a threat to its own industry than as an opportunity for cooperation.

The Chinese Pharmaceutical Industry: A Threat from Outside

The link between globalization and infectious disease is well-known. With thousands of people travelling back and forth between China and Canada, the likelihood of contracting and spreading diseases increases. Migration from developing to developed countries facilitates the spread of "non-classical" infectious diseases, which are divided into two categories. First, there are infectious diseases that are more prevalent among a particular immigrant community. The newcomer might unknowingly spread the disease to other people. This is especially dangerous in the case of drug-resistant diseases, like TB. According to the WHO, "the increasing prevalence of this disease in many high-income countries over the past decade has occurred largely as a result of immigration; other examples are hepatitis B and C and *Helicobacter pylori* infection."⁵⁰

The second problem likely to occur is the reappearance in the host country of formerly eradicated or rendered unimportant diseases following vaccination or other health prevention programs. The effects of re-introducing diseases can be disastrous since levels of immunity in the host country are often low or absent. Examples of these infections include measles and diphtheria.⁵¹ Risks of contracting an infectious disease are especially high in confined spaces such as aircrafts. In recent years, "the emergence of MDR-TB and extensively drug-resistant TB (XDR-TB) has raised special concerns in relation to the international spread of particularly dangerous strains of *Mycobacterium tuberculosis*."⁵² These examples show that epidemic outbreaks or development of drug resistant diseases in China inevitably have a negative impact not only on Canada, but on the rest of the world as well.

The Chinese Pharmaceutical Industry: A Threat from Inside

Chinese pharmaceutical imports are divided into two categories: drug products and TCM. To be sold in Canada, manufacturers "must present substantive scientific evidence of a product's safety, efficacy and quality" as required by the *Food and Drugs Act Regulations* and the *Natural Health Products Regulations*.⁵³ No statistics are available on the amount of pharmaceutical imports from China to Canada.

⁵⁰ Lance Saker, Kelley Lee, Barbara Cannito, Anna Gilmore, and Diarmid Capmbell-Lendrum, "Globalization and Infectious Diseases: A Review of the Linkages," UNICEF/UNDP/World Bank/WHO Special Programme for Research & Training in Tropical Diseases (TDR) (2004): 39. "Helicobacter pylori (H. pylori) is a bacterium that causes chronic inflammation of the inner lining of the stomach (gastritis) in humans. This bacterium also is the most common cause of ulcers worldwide. H. pylori infection is most likely acquired by ingesting contaminated food and water and through person to person contact." Dennis Lee, "Helicobacter Pylori," MedicineNet.com, http://www.medicinenet.com/helicobacter_pylori/article.htm (accessed July 31, 2009).

⁵¹ *Ibid.*, 39.

⁵² "Tuberculosis and Air Travel: Guidelines for Prevention and Control," 3rd Ed., WHO (2008): V.

⁵³ "Drugs and Health Products," Health Canada, <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/index-eng.php> (accessed July 30, 2009).

Therefore, it can be inferred that the quantity of drugs imported from China is minimal due to the lack of regulatory oversight on the Chinese side. However, the impact of the growing Chinese pharmaceutical industry on the Canadian market should not be overlooked for two major reasons. First, the percentage of counterfeit/substandard drugs entering the country illegally, but being sold through legitimate channels is increasing. Second, the number of Canadians who turn to natural health products, including TCM, is growing quickly.

The statements by the Canadian Generic Pharmaceutical Association (CGPA) are particularly interesting in this regard. On the one hand, the CGPA posted this statement on its website: "As Canada's Criminal Intelligence Agency has observed, our highly-regulated pharmaceutical system is largely affordable to most Canadians, which 'significantly lessens any potential market for illegitimate supplies of pharmaceuticals in Canada.'"⁵⁴ Yet, in the following sentence, the CGPA expresses concerns over the growing number of counterfeit generic drugs reaching Canadian consumer markets. As for any other illegal activity, reliable data on the scope of the problem is nonexistent. The WHO's International Medical Products Anti-Counterfeiting Taskforce (IMPACT), without providing any estimates, "point to an increase in the prevalence of counterfeit medicines even in developing countries," including Canada. One half of the medicine purchased online is counterfeit.⁵⁵

Another undisclosed health threat is the consumption of substandard drugs, mainly associated with natural health products (NHP). Over 40,000 NHPs are available in Canada, including vitamins, herbal products, homeopathic medicines and TCM. In 2004, the federal government enacted the *Natural Health Products Regulations* (NHP Regulations) to oversee manufacturing, packaging, labelling, storing, importation for sale, distributing and selling of natural products, as well as clinical trials of these products involving humans. Manufacturers, whose products were already on the market, were given until 2010 to comply.⁵⁶ Although the new regulations constitute an important step towards ensuring Canadians' good health, the system still presents significant problems. Several NHP manufacturers have not yet complied with the 2004 Regulations, while other manufacturers just ignore them. Regulatory oversight is not as stringent with NHPs as it is with other prescription drugs. In addition, the Regulations only apply to products destined for commercial sale. NHPs are available directly to Canadians, without any prescription required or medical supervision. A Health Canada survey, conducted in 2005, showed that 71 percent of Canadians use on a regular basis or have used natural health products in the past. Furthermore, findings demonstrate that many users base their decisions on information provided by friends and family (28 percent) or found on the internet (19 percent).⁵⁷

Without a strong commitment from their government to ensure pharmaceutical products' safety and quality, Canadians are at risks of consuming products that are detrimental to their health and that of others. Yet, there can only be significant improvements if the Canadian and Chinese governments work closely together.

⁵⁴ "Anti-Counterfeiting Trade Agreement (ACTA)," Canadian Generic Pharmaceutical Association – Advocacy, http://www.canadiangenerics.ca/en/advocacy/anti_counterfeiting_agreement_i.asp/ (accessed July 30, 2009).

⁵⁵ "Counterfeit Medicines: An Update on Estimates, 15 November 2006," WHO IMPACT, <http://www.who.int/medicines/services/counterfeit/impact/TheNewEstimatesCounterfeit.pdf> (Accessed July 30, 2009).

⁵⁶ Jennifer Farrell, Nola M. Ries, Natasha Kachan, and Heather Boon, "Foods and Natutral Health Products: Gaps and Ambiguities in the Canadian Regulatory Regime," *Food Policy* 34 (2009): 388.

⁵⁷ "Baseline Natural Health: Products Survey Among Consumers," *Ipsos Reid* (March 2005): 19.

Current Level of Canada-China Cooperation

In its July 2008 White Paper titled *Status Quo of Drug Supervision in China*, the Chinese State Council notes: "The Chinese government attaches great importance to and actively participates in various international drug safety activities, constantly broadens the channels and scope of foreign exchanges and cooperation [...]."⁵⁸ In the press releases published on the SFDA's website, certain phrases are used repeatedly, such as "drug safety has become an issue that crosses the borders of individual countries," "to enhance cooperation is the only choice" and "long-term and effective cooperation."⁵⁹ Indeed, the Chinese government is now involved in WHO projects and is adopting pharmaceutical laws and regulations in line with international guidelines. Since 2005, SFDA officials have met with delegates of the European Union, Singapore, Australia and overwhelmingly, with the United States.⁶⁰

China's close collaboration with the US has led to the opening in November 2008 of an FDA office in Beijing, followed by one in Guangzhou and Shanghai respectively.⁶¹ One of this office's goals is "to allow greater access for inspections and greater interactions with manufacturers to help assure that products that are shipped to the United States meet US standards for safety and manufacturing quality."⁶² Their presence in China will also ensure inspectors from the HHS' FDA "better access to Chinese production facilities and on an expedited basis."⁶³ While Americans were negotiating with Chinese authorities to further cooperation in the pharmaceutical sector between their countries, Canada was implementing a new Plan of Action for Cooperation in Health. However, these efforts remained largely unknown by the public.

CANADA-CHINA COOPERATION ON SPECIFIC ISSUES

The government's apparent inactivity in regards to health issues can in part be explained by deterioration in Canada's relations with China since Stephen Harper became Prime Minister in early 2006. However, change is needed. Momentum may have been created by Chinese Foreign Minister Yang Jiechi's visit to Canada in June 2009. At a speech delivered to the Canada-China Business Council in Ottawa, Yang reiterated the importance of learning from each other. Harper visited China in December 2009.⁶⁴ These high-level meetings are significant and provide members of both governments with an opportunity to discuss common issues of concern and ways to tackle problems in a mutually beneficial fashion. Bilateral cooperation should focus on the Chinese healthcare system and TCM. Exchanges and cooperation on counterfeiting should be carried out through WHO's IMPACT.

China's Healthcare System

The Canadian government has an interest in assisting China in the establishment of a public healthcare system. The Chinese Central Government has already committed itself to increase spending on public hospitals, as

⁵⁸ *Op. Cit.*, White Paper, 14.

⁵⁹ *Op. Cit.*, "What's New?"

⁶⁰ *Op. Cit.*, "What's New?"

⁶¹ Deepti Ramesh, "U.S. FDA Opens Office in China; Chinese FDA Supports Efforts," *Chemical Week* 1, No. 8 (December 2008).

⁶² *Op. Cit.*, "FDA News."

⁶³ "Statement by Secretary Mike Leavitt, Secretary of Health and Human Services, On Signing Memoranda of Agreement between the United States and the Peoples' Republic of China to Improve the Safety of Food, Feed, Drugs and Medical Devices," News Releases – U.S. Department of Health & Human Services, <http://www.hhs.gov/news/press/2007pres/12/pr20071211a.html> (Accessed April 24, 2009).

⁶⁴ Fred Edwards, "Back on Track: Chinese Foreign Minister Yang Jiechi's Visit to Canada Bodes Well for Improved China-Canada Relations," *Beijing Review* (July 9, 2009): 10.

well as cut pharmaceutical and treatment costs.⁶⁵ The establishment of a publicly funded healthcare system reduces patients' incentive to purchase and hospitals' incentive to sell counterfeit/substandard drugs. Although Canada and China are very different in terms of population size and paths of economic development, they both have vast landmasses. Canada has developed particular expertise in the delivery of healthcare services to people living in remote areas for example. In recent months, measures have been taken towards closer collaboration so that China could learn about such remote health care delivery systems.

In June 2009, Canada and China renewed their *Plan of Action for Cooperation in Health for 2009-2011*. The newly signed document builds on the 2005 to 2008 Plan of Action which promoted cooperation in several areas, such as timely sharing of information on emerging infectious diseases and a better understanding of regulatory frameworks in the area of therapeutic products and Natural Health Products. The renewed plan "reinforces and broadens work in areas of common concern, such as emerging and re-emerging infectious diseases and food safety."⁶⁶ It is hoped that, through these initiatives, Canada will increase its visibility in the Chinese pharmaceutical market to a level similar to that of the United States and at the same time, increase the number and frequency of Canada-China high-level meetings.

Traditional Chinese Medicine

Strengthening TCM regulatory oversight is a responsibility that both China and Canada should share. On the one hand, it is necessary to work with Chinese authorities to ensure compliance to GMP in the manufacturing of TCM in China in order to increase product quality and safety.⁶⁷ On the other hand, Canadians have many things to learn about TCM's medicinal properties, benefits and usage. TCM constitute the overwhelming majority of Canada's pharmaceutical imports from China. As mentioned above, Health Canada regulates the commercial sale of TCM. However, Canadian policymakers and medical professionals alike often lack the necessary expertise and knowledge to make enlightened decisions on what products to license. Professional exchanges and training programs are but one way in which Canadians and Chinese can learn from each other.

Counterfeiting

Drug counterfeiting is an international problem and as such, it should be tackled mainly through IMPACT. Cooperation between countries, especially trading partners, should include "timely and appropriate exchange of information and the harmonization of measures to prevent the spread of counterfeit medicines."⁶⁸ Another aspect of IMPACT is to create public awareness about the scope of drug counterfeiting and its impact. In Canada, communication and advocacy is particularly important since Canadians are generally unaware of the impact the consumption of counterfeit/substandard medicine in a developing country can have on their health.

⁶⁵ Pliny Han, "Government to Boost Medical Services," *Xinhua* (January 9, 2009).

⁶⁶ "Canada and China Renew Plan of Action for Cooperation in Health for 2009-2011," About Health Canada, http://www.hc-sc.gc.ca/ahc-asc/media/nr-cp/_2009/2009_94-eng.php (accessed August 3, 2009).

⁶⁷ Lui Emk, "Traditional Chinese Medicine Products Research at Canadian Universities: Capacity and Challenge," Prepared for NHPRP, Health Canada (March 13, 2005): 4.

⁶⁸ "IMPACT Activities," IMPACT! International Medical Products Anti-Counterfeiting Taskforce, <http://www.who.int/impact/activities/en/> (accessed August 3, 2009).

CONCLUSION

[...] when used wisely, drugs are a material contribution to the quality of life, human dignity, and self-esteem of individuals, and when successfully used provide employment and a focus for a future orientation, instead of desperation, revolution, and strife.⁶⁹

Although there have been significant improvements of the Chinese regulatory system since 2003, the SFDA's institutional capacity remains limited. In its present state, it is poorly equipped to ensure the proper monitoring of a rapidly growing pharmaceutical industry. Complex supply chains, corruption at the local government level and uncertainty over the SFDA's independence from the central government all contribute to the low quality and reliability of Chinese pharmaceutical products. These inefficiencies also facilitate the production of substandard/counterfeit drugs. Counterfeiters' sophistication eases the exportation of these products to surrounding countries and in some cases, developed countries.

In turn, the consumption of substandard/counterfeit drugs promotes the emergence of drug resistant diseases in developing countries. Migration and travel cause the reappearance in developed countries of formerly eradicated or rendered unimportant diseases following vaccination or other health prevention programs. The effects of re-introducing diseases can be disastrous since levels of immunity in the host country are often low or absent. The risks of a pandemic are thus increased. One way to prevent the spread of diseases is to further Canada-China cooperation.

In fact, as China assumes a more important role in international relations and trade, Canada should look to collaborate more closely with the Chinese government and members of the Chinese pharmaceutical industry to ensure Canadians safe access to pharmaceutical products. Collaboration, in particular, should focus upon increasing the quality and safety of TCM as well as combating counterfeiting. More generally, Canada should look to assisting China in its efforts to establish a publicly funded healthcare system.

The effects of government policies and national practices concerning the manufacture and distribution of drugs and medicines are no longer limited to a specific country, but now have impact all over the world. Thus, Canada has significant interests in closer collaboration with China and accordingly should assume a more proactive stance that it has to date. A default strategy of waiting for the US to take the lead and following on US-China agreements should be avoided, in part because Canadian circumstances may require "Canadian" solutions, and in part because building cooperative relations with China in the pharmaceutical and health care sectors should be an important component of building the overall Canada-China relationship. Cooperation in the short run on specific projects and confidence building measures could develop into more comprehensive cooperation in the long run. This, in turn, is likely to have a positive effect on both China and Canada's political and economic exchanges.

⁶⁹ *Op. Cit.*, Wertheimer and Norris, 14-15.

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THE CIC CANADA-CHINA RELATIONS PROJECT

Bilateral relations between the governments of Canada and the People's Republic of China are a matter of strategic interest to Canada. Recent changes in the frequency of high-level visits, the effective style and content of bilateral communications and perspectives held about each country by various sectors of each other's society all suggest that the Canada-China relationship has changed significantly in recent years. Yet China remains vitally important to Canada for a variety of reasons and in a variety of sectors. Political and diplomatic cooperation on issues of direct bilateral concern and also on issues of global import remains critically important. Commercial and trade ties linking Canada with the world's third largest and fastest growing economy are of obvious importance. Cultural and civil society ties, including immigration patterns and the ancillary effects they generate, are also important. In these and other matters, the Canada-China relationship will likely grow in importance in the years to come. While the diversity of links between Canada and China militates in favour of giving due attention to a multiplicity of commercial, academic and civil society links, bilateral cooperation at the federal/central government level remains important.

In keeping with CIC objectives to advance research and dialogue on international affairs issues of importance and interest to Canadians, the CIC Canada-China Relations Project has focused on supporting research and analysis toward building a policy framework for Canada's relationship with China. The project's activities have been developed along three thematic areas that reflect issues of common concern: a) Chinese domestic institutional and normative contexts for engagement; b) Economic relations; c) Collaboration on global issues such as environment, health and security.

- a) Domestic Context for Engagement: The Canada-China relationship can be most effective when it is grounded on complementarity of interests, which in turn requires mutual understanding of domestic normative and institutional conditions in both countries. Canadian initiatives with China, ranging from WTO compliance and business regulation to human rights, can be effective only if they are designed and implemented in light of China's domestic conditions, ranging from popular norms to governmental structures and policy priorities. Similarly, China's success in nurturing productive relationships with Canada will require appreciation of Canadian domestic conditions. The papers for this thematic area were commissioned and directed by Professor Jeremy Paltiel of Carleton University.
- b) Economic Relations: Economic relations between Canada and China are critically important. Economic relations include bilateral trade and investment relations, and also extend to local effects of economic conditions and behaviour. In the trade area, Canada's strengths match up extremely well with China's needs. In trade and investment relations, efforts to promote normative and institutional accommodation in China for Canadian business objectives are consistent with Chinese development policies and also serve important Canadian interests in the areas of good governance. As well, national economic behavior by the two countries in response to changing economic conditions at the global, regional and local level have important effects on the Canada-China relationship. The papers for this thematic area were commissioned and directed by Yuen Pau Woo, President of the Asia Pacific Foundation of Canada.
- c) Collaboration on Global Issues: The importance of China's responsible participation in systems for addressing global policy concerns in areas such as environment, health and security cannot be overstated. Yet China's participation in the global community can be distorted by its responses to apprehension and competition from other global actors, particularly the United States, the European Union and Japan. Canada has a significant role to play in supporting China's responsible participation, not only through direct bilateral programming but also through our capacity to deploy good offices, legitimation and other soft power resources both bilaterally and globally. The papers for this thematic area were commissioned and directed by Professor Brian Job of the University of British Columbia.

The papers here presented in connection with the CIC Canada-China Relations Project offer informed, non-partisan recommendations for a variety of stakeholders in Canada, including the government and private and public sector institutions and individuals, with a view toward furthering the development of healthy long-term relations between Canada and China. While historical and current conditions may result in disagreement as to how best to manage the Canada-China relationship, China's importance to the world requires our attention. We hope that the papers presented here can further the process of understanding and effective engagement that will strengthen the foundation for productive relations for the long-term interests of both countries.

Dr. Pitman B. Potter

Chair

CIC China Working Group

The Canadian International Council (CIC) is a non-partisan, nationwide council established to strengthen Canada's role in international affairs. With local branches nationwide, the CIC seeks to advance research, discussion and debate on international issues by supporting a Canadian foreign policy network that crosses academic disciplines, policy areas and economic sectors.

The CIC features a privately funded fellowship program and a network of issue-specific Working Groups. The goal of the CIC Working Groups is to identify major issues and challenges in their respective areas of study and to suggest and outline the best possible solutions to Canada's strategic foreign policy position on those issues. The CIC aims to generate rigorous foreign policy research and advice.

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45 Willcocks Street, Box 210
Toronto Ontario M5S 1C7
TEL: 416-977-9000, 1-800-668-2442
FAX: 416-946-7319