THE PATHOGENS FOR PEACE INITIATIVE:

EXPANDING RESOURCES TO ADDRESS NEGLECTED DISEASES, PROMOTE ECONOMIC DEVELOPMENT, AND SUPPORT SUSTAINED SCIENTIFIC ENGAGEMENT

Final Report, Business Plan, and Proposal

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EXECUTIVE SUMMARY

When Canada hosted the G8 Summit in Kananaskis in 2002, it brought to the table a long and innovative history in the fields of foreign assistance and public international health that, if leveraged, could produce significant advances to the dual threats of neglected diseases and biological weapons proliferation. By integrating Canada's public health investments in vaccine/therapeutic drug development and foreign assistance to developing countries with Ottawa's financial and programmatic commitments under the "Global Partnership Against the Spread of Weapons and Materials of Mass Destruction," new funding streams could aid the fight against neglected diseases and promote sustainable development all while ensuring the nonproliferation of sensitive weapons know-how.

Bio-Proliferation

After more than a decade of effort to eliminate an urgent threat to global security, both anecdotal and empirical indicators suggest that there is a continuing risk of "brain drain" proliferation from the states of the former Soviet Union. While proliferation threats emanate from across the spectrum of WMD specialties, former biological weapons specialists pose a particular challenge owing to the inability of current regimes to detect and prevent the development of weaponized pathogens. Moreover, evidence suggests that the aging community of researchers that have previously raised the most concern do not represent the only proliferation challenge. According to recent analyses, young bioscientists throughout the former Soviet Union with modern laboratory skills that have direct access to biological materials at the erstwhile weapons institutes, as well as strong financial ambitions, pose equally daunting challenges to international security.[1] Like many developing states, the scientific community of both generations in the FSU has not been adequately absorbed into global research networks. This failure not only neglects new scientific knowledge, approaches, and capacities in the region, it sustains an environment in which brain drain proliferation can thrive and flourish.

Neglected Diseases

Scientific advances in vaccine development and other advanced therapeutics have dramatically altered the course of human history. By exploring the frontiers of science, new knowledge has been tapped to conquer diseases that once killed millions of people each year. But while scientific breakthroughs have all but eliminated the threat of life-threatening infectious disease among children in the developed world, we have yet to produce vaccines against most diseases of the poor—malaria, HIV and tuberculosis. These "neglected diseases" represent a central challenge to the continued security of all of humanity.

Thanks to the efforts of concerned governments like Canada, and NGOs such as the Rockefeller and Bill and Melinda Gates Foundations, the past decade has brought heightened attention to the need to provide vaccines and other advanced therapeutics for treatment of neglected diseases. These efforts have focused primarily upon block purchases of existing products, the prediction of future needs, and on innovative strategies to invest in future R&D. However, in the main, the role of the private sector, recognized as a critical player in transitioning promising vaccine candidates from the lab to large-scale production, has not been successfully integrated into global health and development strategies.

[1] US National Research Council, *Biological Science and Biotechnology in Russia: Controlling Diseases and Enhancing Security* (Washington: NRC, 2005).

Long-term structural impediments deter pharmaceutical companies from expending significant capital at the front end for modest financial return at the back end. The high costs associated with Western R&D and production has led to a flight from vaccine development for Western markets, let alone for developing countries. Left to market control, *affordability, capacity,* and *availability* will remain as significant barriers to effective global vaccination strategies.

Leveraging Resources

Throughout the Cold War, the Soviet Union developed a massive biological weapons infrastructure. Today, as a direct result of those investments, Russia and other states of the former Soviet Union (FSU) host some of the most accomplished labs in the world in critical areas of biology. If harnessed appropriately, their knowledge and added capacity could be used for the benefit of global public health. Unfortunately, this potential is not currently being realized.

Obstacles to more effective engagement are twofold: (1) First, there is a continued inability and unwillingness both in Moscow and in Washington to transform their contentious relationship of the past into mutually beneficial cooperation in the present. And (2) second, existing G8 redirection programming is limited by design and by the strictures of standing bilateral agreements, politics, lethargy, and resistance to change. American BW redirect efforts at the US Department of Defence for example, have been dramatically scaled back in Russia due, in large measure, to the difficult history those countries share. American efforts through the Departments of Energy and State are encumbered by a series of Congressional restrictions that prevent innovative efforts to engage scientists in the FSU productively and sustainably.

Programs operated by the Global Partnership Bureau (IGX) at the Department of Foreign Affairs and International Trade operate under no such restrictions. As such, Canada is uniquely positioned to overcome these obstacles and to provide leadership in regaining momentum for sustainable scientific redirection across the G8. Moreover, Canada's laudable commitment to nonproliferation, international public health, and foreign assistance, if leveraged appropriately, could produce significant advances to the multiple challenges of biological weapons proliferation, neglected diseases, and economic development.

With increasing budgetary pressure upon government agencies in Canada and elsewhere, federal departments must look to maximize their social return on investment (ROI). If configured appropriately, the post-Soviet scientist redirect programs can produce a value beyond the nonproliferation of expertise. Canada's global economic development, international public health, and other domestic and foreign policy objectives could be better served through a coordinated model of engagement supported by IGX. Furthermore, by introducing innovative new models, Ottawa has the opportunity to emerge as a leader within the scientist redirect portfolio of the G8 Global Partnership. If done well, these models can, in turn, be embraced by the other G8 countries in meeting their own commitments to the Partnership.

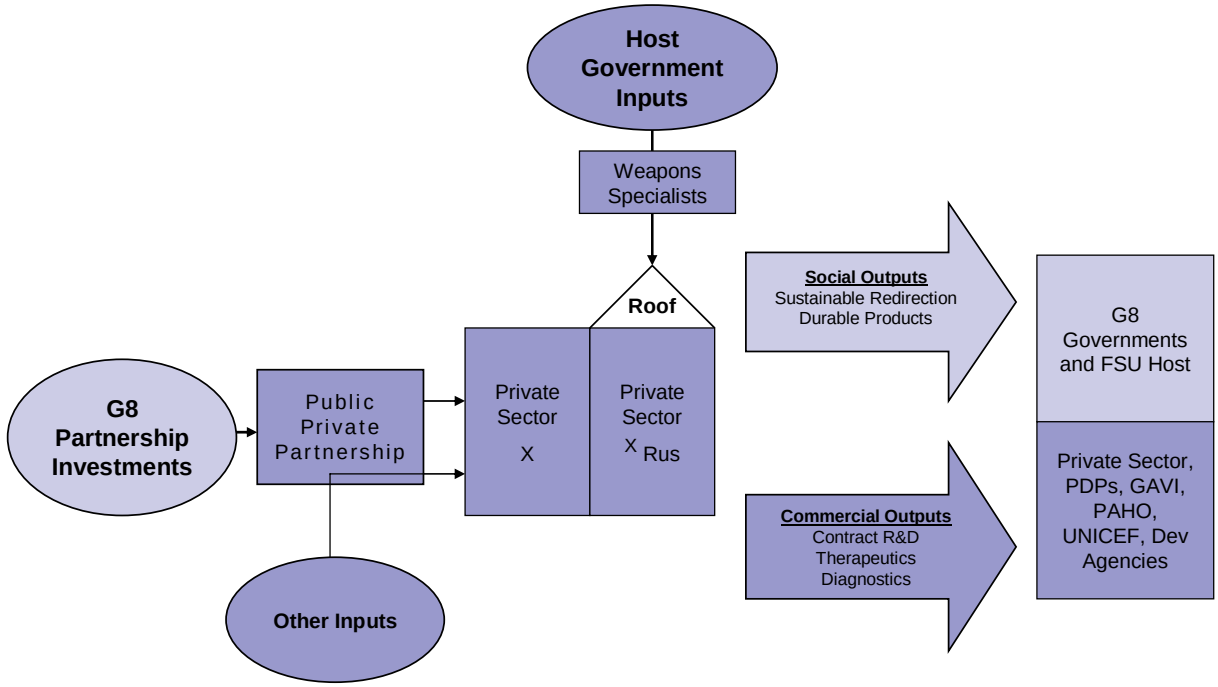
The Pathogens for Peace Initiative (P4P) for Sustainable Scientific Redirection

In December 2005, under a contribution agreement with the Department of Foreign Affairs and International Trade, the Henry L. Stimson Center launched a scoping study—dubbed the Pathogens for Peace (P4P) Initiative—designed to leverage existing investments in the redirection of former Soviet

biological weapons specialists with international public health markets and global economic development resources. Our goal was to develop a model designed to provide sustainable employment to former bio-weapons specialists through short-term incentives to engage private sector companies as employers. Additional involvement of other Canadian government agencies would be leveraged in support of mutual public health, development, and other domestic and foreign policy goals.

This approach differs from existing redirect models by focusing on employment as the core objective rather than scientific collaboration (ISTC and STCU) or technology development (US Department of Energy/IPP). Under existing mechanisms, employment is an indirect and relatively infrequent consequence of the core R&D objective. While these approaches do successfully engage target constituencies in the near term, they are ultimately short-sighted because long term redirect and nonproliferation goals are not being met. When scientist redirect funds sunset in 2012, the brain drain threat will likely re-emerge.

PROPOSED MODEL OF SUSTAINABLE ENGAGEMENT



Surveying capacity throughout the FSU, the Henry L. Stimson Center concludes that only the private sector has the managerial capability and organizational capacity to make productive use of the target community. Apart from open-ended government patronage, no other approach can provide sustainable employment. Such employment, of course, requires employers—yet "employers" are not part of current programming. While many projects involve private sector participants, their role is to serve as clients for research and development services provided by the scientists from within their erstwhile weapons institutes. It is rare that the scientists have an ongoing role to play once proof of concept is achieved, and even rarer that they become employees of the private sector "partner." Shifting the focus to facilitating employment by the private sector may continue to involve collaborative research and technology development, but rather than being the central objective (as with existing programs), it will be a means to the end of creating sustainable employment. Furthermore, it will engage the very community that forms

the critical link between R&D and production of vaccines and therapeutics for neglected diseases and promote regional economic development by seeding private industry into the states of the former Soviet Union. Involving economic development and public health agencies (both public and private) increases the resource base available for job creation, and ensures that there are stakeholders involved who value the output the company creates by employing the scientific capacity. This increases the odds of success and reduces risks to both government and private sector employers.

Conclusion

The Department of Foreign Affairs and International Trade has committed substantial resources to redirection efforts in the states of the former Soviet Union. Moreover, the Government of Canada more broadly has emerged as a global leader in the fight against emerging and re-emerging infectious diseases, poverty alleviation, and global economic development. Ensuring the long-term viability of these efforts, along with the highest possible return on these social investments, however, remains an elusive goal. This study outlines a pragmatic new initiative designed to leverage existing resources, achieve *sustainable* security, add public health *capacity*, and promote *economic development*.

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INTRODUCTION

Throughout the Cold War, the Soviet Union developed a massive state-owned bioresearch and weapons production capacity. In the early 1990s when the government in Moscow cut funding to that complex, the United States launched a series of programs designed to ensure that the intellectual resources within that research and production complex did not proliferate to rogue states and terrorist organizations. While that community continues to represent a proliferation challenge for security experts, it also presents a tremendous—though poorly understood—opportunity for both public health officials and the global development community. Today, Russia retains world class capabilities in, for instance, tissue culture, and is a global leader in the identification and utilization of bacteriophages and in novel drug design and testing. These skills, if properly harnessed, could dramatically enhance global capacity to combat infectious diseases while providing the necessary conditions for economic expansion in developing countries. To date, the failure to channel these talents for the benefit of humankind has been a direct result of the inability of both Moscow and Washington to transform their contentious relationship of the past into a mutually beneficial cooperation in the present.

In January 2005, The Henry L. Stimson Center, a private, non-profit public policy think tank launched an initiative designed to identify, analyze, and promote remedies to the legislative, regulatory, and attitudinal obstacles to successful implementation of G8 nonproliferation programs. That effort was underwritten by a variety of major private philanthropic foundations including the John D. and Catherine T. MacArthur Foundation and the Ford Foundation. The study concluded, *inter alia*, that existing nonproliferation investments across the G8—particularly in the area of scientist redirection and bio-threat reduction—are underperforming and are at risk of premature elimination in the United States due to:

1. A widening strategic disagreement between Russia and Western donors over program-related priorities and non-program related complications;
2. A burgeoning political frustration in the West over the perception of redirection efforts as “welfare science”; and
3. A programmatic failure to successfully introduce innovative models of sustainability.

The Stimson project directors conclude that unless new and inventive models are introduced presently, redirection efforts will face continuing budgetary pressures and premature abolition. Elimination of the scientist redirect efforts will have a significant deleterious impact upon global security from two standpoints:

- Not only could a significant subset of former weapons experts be lured abroad by nefarious opportunities, the next generation of biological scientists could continue to develop dual-use capabilities that would not be absorbed into the peaceful global research networks. Elimination of engagement efforts with states of the former Soviet Union (FSU) would therefore pose significant **proliferation threats**.

- The scientific community in the FSU represents an expanded *capacity*, and in some cases possesses unique *capabilities* in the bio-sciences. Leveraging the FSU, with its vast ecological diversity and large, well-trained scientific workforce, could make these countries important contributors to global efforts to prevent, detect, and respond to the emergence of infectious diseases at home and abroad. Failure to engage poses significant **opportunity costs** based upon the failure to leverage the significant scientific legacy resident within the FSU.

Under a contribution agreement with the Department of Foreign Affairs and International Trade (DFAIT), in December 2005 the Stimson Center launched a scoping study—dubbed the Pathogens for Peace (P4P) Initiative—designed to leverage existing investments in the redirection of former Soviet biological weapons specialists with international public health markets and global economic development resources. The project was led by Stimson Senior Associates Brian Finlay and Elizabeth Turpen and supported by Visiting Fellow, Frederick Kellett (See Appendix B for full biographies of project leadership). What follows is a report on findings along with a proposed model for sustainable redirection designed to expand the Government of Canada's social return on investment (ROI) in the areas of proliferation, public health, defence, and economic development.

Central to this proposed new model is the involvement of the private sector as an enduring employer of the target community within the states of the former Soviet Union. Stimson's approach goes beyond existing—and we believe limited—redirection efforts which focus on maintaining personnel within existing and often times decrepit institutes and facilities. Moreover, while the International Science and Technology Centre (ISTC), Science and Technology Centre in Ukraine (STCU), US Initiatives for Proliferation Prevention (IPP), and the Pentagon's Defence Threat Reduction Agency have made important contributions to reducing the likelihood that critical biological weapons know-how will proliferate from the FSU, the vast majority of these efforts have achieved temporary redirection by providing short term basic research grants to the region's weapons scientists and technicians operating within their former weapons facilities. These programs have been stymied in their attempts to help these people make the transition to sustainable, long-term employment outside the WMD complex.

It is critical to note that this new model is not designed to replace current investments in scientist redirection through the ISTC/STCU, nor critical infrastructure, biosafety, and biosecurity upgrades in the states of the former Soviet Union. Rather, this effort would provide a novel complement to existing efforts by sustainably engaging a subset of the target community of specialists. A diverse community, it is assumed that some will not possess skills readily translatable to the commercial sector. Still others will not be prepared or permitted to leave their erstwhile weapons institutes. It is this subset of specialists that should be continually engaged through collaborative grants such as those offered by the STCs. It is the remaining community of experts that would be subject to more sustainable and cost-effective redirection through this complementary new program of engagement with the private sector.

The "Pathogens for Peace Initiative" seeks to work around existing models by introducing a new paradigm by which nonproliferation funds are used to "incentivize" the *private sector* to develop marketable products. A survey of previous efforts suggests that this approach is not only novel, it clears the most significant impediment to each and every previous effort to redirect scientists into activities serving the public international good. In short, our concept builds upon the successes of existing conversion and redirection efforts while correcting for shortcomings of these programs.

This report proposes a tailored pilot program designed to transition a subset of former-BW specialists within the states of the FSU from long-term Western government support by identifying viable companies and other stable employers. The report is the culmination of a nine-month study that surveyed dozens of private companies and more than one hundred experts in the fields of nonproliferation, business, international public health, and global economic development. Pertinent agencies across the Government of Canada were polled systematically including, *inter alia*, the Canadian International Development Agency (CIDA), the Public Health Agency of Canada (PHAC), Defence Research and Development Canada (DRDC), Agriculture Canada, Industry Canada, the Canadian Food Inspection Agency (CFIA), the International Development Research Centre (IDRC), the National Research Council (NRC), and the Department of Foreign Affairs and International Trade (DFAIT). In addition, dozens of outside specialists from Canada, the United States, and Russia have contributed their thoughts to this cross-sectoral approach to the sustainable redirection of the post-Soviet biological weapons community (See Appendix A for a selective roster of organizations and individuals surveyed by the Stimson team).

This final report is divided into three sub-sections:

1. A background on current threats and a summary of existing efforts to redirect former weapons expertise along with our key findings and conclusions;
2. An outline of a new model of engagement, and three targeted case studies that operationalize that model; and
3. A proposal for phased implementation of the model including: (i) an assessment of the private sector's capacity to absorb former BW specialists in Russia, (ii) development of a pipeline of Canadian biotech and/or pharmaceutical companies that have a strategic reason for entering Russia and that are interested in employing the target community, and (iii) comprehensive engagement of other Canadian government agencies with mutual interests in the areas of public health, security, and global development.

AUTHORS' NOTE:

COPING WITH THE THREAT OF BIO-PROLIFERATION AND THE SPREAD OF INFECTIOUS DISEASES: A VACCINE PRODUCTION PLAN

When the Stimson Center launched the Pathogens for Peace Initiative in 2005, the study was designed to identify opportunities to leverage existing investments made under the G8 Global Partnership to "incentivize" a private pharmaceutical firm operating in the former Soviet Union to bring a vaccine production facility up to global manufacturing and laboratory standards and begin producing reduced price product for use against neglected diseases of the developing world.

The Stimson Center concluded that while this goal remains achievable, implementation of such an ambitious plan is ultimately long term. Based upon discussions with national and international public health agencies and with several multinational pharmaceutical firms who have invested corporate R&D into neglected diseases, incentives designed to bring "Big Pharma" into neglected disease research and production, particularly within the states of the former Soviet Union, would need to be excessively large. Given that such resources are neither possible nor prudent for IGX to expend, the Stimson team began exploring, in conjunction with economic development and public health experts, the possibility of staged contributions to public health needs through limited incentives to small- and medium-sized biotech and pharmaceutical companies. This report thus modifies the timeline to achieve the lofty goals set out in the original proposal to the Government of Canada. By working to develop biotech clusters within the states of the former Soviet Union, it is our goal to achieve not only sustainable redirection, but ultimately move toward an expanded capacity to address the scourge of neglected diseases in a *sensible* and *cost effective* manner.

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BACKGROUND

The Legacy of Post-Soviet Redirect Programming

The ***stated objective*** of all current programs focused on the nonproliferation of expertise is to ***permanently and sustainably redirect*** former WMD specialists. Unfortunately, as currently configured, none of the existing programs is systematically designed to create the new jobs necessary to sustainably engage weapons experts and thus achieve this objective.

The scientist redirection efforts launched by the United States Government—and subsequently adopted and expanded across the G8 partners—were born in an era of extreme uncertainty for the states of the former Soviet Union. Critical to programmatic success was the rapid engagement of a massive scientific community whose expertise, if proliferated, could have significant negative implications for terrorist and rogue state access to weapons of mass destruction. Put crudely, the programs were designed to keep sensitive scientific capacity in place and provide some degree of accounting for the individuals and their activities. Parallel programs were launched to shut down or eventually "graduate" legacy facilities. Under this emergency program, little thought was given to long-term sustainability. Provided experts were not using their talents to inform weapons programs abroad, objectives of government program managers were being met.

A decade later, the environment in Russia and other states of the former Soviet Union has changed dramatically. With increased host-state resources and ever restrictive budgets within the donor community, it is increasingly difficult for the existing programs to justify continuing support. Inventive new models are overdue and must be developed. At a minimum, account should be taken of the lessons learned through more than ten (10) years of redirect programming. Such an analysis reveals that current and previous redirect efforts were designed to produce one of two outputs:

1. Collaborative research and technology development, or
2. Restructuring of state-owned weapons institutes and production facilities.

To understand why these approaches do not lead to sustainable employment and what lessons can be drawn from these programs for future approaches, we offer below a systematic accounting of previous and existing redirect efforts along with an assessment of their shortcomings.

Collaborative Research and Technology Development Approaches

KEY FINDINGS:

- ISTC, STCU, BCR and IPP were designed to produce research, not jobs.
- Research does not inevitably lead to sustainable redirection.
- ISTC and STCU fund research which is seldom valued by others.
- The Bio-Chem Redirect program (BCR) at the US Department of States has engaged US Government researchers as collaborators to ensure that the research is valued and to circumvent structural limitations at the Department of State, but has failed to systematically produce sustainable employment.
- The Initiatives for Proliferation Prevention program (IPP) at the US Department of Energy has engaged the private sector as customers but not employers.
- Moving new technologies from proof-of-concept to commercially viable product is extremely difficult to achieve.
- Commercialization rarely involves more than a token number of the scientists and even more rarely leads to sustainable employment.

LESSONS LEARNED FROM THE RESEARCH AND TECHNOLOGY DEVELOPMENT APPROACHES

Employment requires employers: Existing programs are experiencing difficulty creating jobs for the target community because they have *failed to identify and engage employers rather than customers*. The Science-to-Science programs (ISTC, STCU and BCR) are necessary because the host government is unable to provide adequate employment. Under these programs the moribund weapons institutes effectively "house" the scientists for employment by the donor governments. However, neither these governments nor the STCs are employers—nor do they want to be.

Under the IPP program, the US Department of Energy has tried to address this shortcoming by involving private sector companies as partners in technology development. Being a company is not the same thing as being an employer. In short, industry "partners" and government research collaborators are customers, not employers.

International Science and Technology Centre (ISTC) and Science and Technology Centre of Ukraine (STCU)

The STCs have been limited in their ability to provide sustainable redirection because their structural focus remains scientific engagement, not employment. While STC-funded technologies have been commercialized, few have resulted in permanent new employment for the scientists involved. As such, it is unlikely that they will continue to secure future contract research work (per the current model) absent continued international support through additional STC grants.

The International Science and Technology Centre (ISTC) and the Science and Technology Centre of Ukraine (STCU) are intergovernmental organizations that channel research grants to former weapons scientists still resident in their erstwhile weapons institutes. The lion's share of global redirection funds are passed through these entities at an annual rate of roughly US$100 million. The monies are used to pay salaries, overheads to the institutes, and purchase equipment and materials required for the research. While there is nonproliferation value placed upon the act of scientific collaboration, there is often limited value realized from the results of the research itself. More importantly, even the most interesting research results do not, in and of themselves, lead to new jobs. As collaborative projects wrap up, the scientists involved must again look for state-funding to initiate new research.

ISTC and STCU have recognized this inherent flaw as well; support from their donors will not last forever (signals from the US Congress and White House have been clear on this point and indeed, an American exit strategy from the STCs may come sooner than the G8 Partnership funding horizon). Recognition of the structural flaws within the STCs is due in large part to the leadership of Canada in the early days of STCU. At that time, Ottawa insisted upon building sustainability into programming efforts, but structural challenges and disagreements within the donor community prevented adoption of more sensible approaches.

Both ISTC and STCU are attempting to develop new tactics that will lead to the institutional sustainability of the centres as well as to more long-term sustainable employment for the target community. Unfortunately, as currently configured, neither organization is capable of accomplishing these goals because to do so requires a customer-oriented, efficiently-managed operation that neither the STCs nor the institutes that ostensibly employ the scientists were designed to provide. Engagement of the private sector will be critical for any new model of sustainable redirection.

ISTC AND THE US GOVERNMENT ACCOUNTABILITY OFFICE

Over the course of the past five years, the ISTC has come under intense scrutiny within the United States Congress. In a recent report by the US Government Accountability Office (GAO), the Congress learned that:

- the State Department does not directly monitor the activities or results of the work of scientists participating in U.S.-funded science centre projects;
- that the Department relies on the mostly Russian and Ukrainian specialists at the science centres, overseen by managers from the United States, the European Union, Japan, and Canada, to conduct routine monitoring of the senior scientists' progress;
- that the terms of the project agreements do not allow auditors to track what the scientists are doing while they are not working on the projects;
- that in 2000, for example, 75 percent of the senior scientists worked 4 ½ months or less on US-funded projects and that some senior scientists worked as little as a few days on US-funded

projects over the course of the entire year; and that as a result

- the Department of State knows little about the scientists' activities outside the program which has failed to sustainably redirect the target community.

The conclusions of the GAO have led to dwindling support for the STCs in the Congress and increased budgetary pressures on the State Department's contributions to both ISTC and STCU.

Bio-Chem Redirect Program (BCR)

BCR has wisely sought to leverage the unique talents of the target community in support of other US government activities. However, existing models of engagement fail to turn government agencies into paying clients. Instead, government entities are relied upon as pass-through funding agencies for the continuation of engagement with the former institutes in scientific collaboration and technology development. Funding limitations within the US government agencies will ultimately end even the most fruitful collaborations.

The State Department's Bio-Chem Redirect (BCR) program sponsors peaceful collaborative research between former biological and chemical weapons scientists from the FSU and American scientists at the US departments of Health and Human Services (HHS) and Agriculture (USDA) and the Environmental Protection Agency (EPA). The program was designed to circumvent the institutional limitations within the Department of State emanating from that agency's inability to contract directly with outside entities. Under BCR, funds are passed through to, for example, the Biotechnology Engagement Program (BTEP) at HHS. BTEP then works to encourage collaboration between HHS and the former biological and chemical defence institutes and Ministry of Health institutes. In the US, BTEP support is available only to HHS scientists at the CDC, FDA and NIH. At this time, non-HHS scientists—including the private sector—are not eligible for grant awards. Similar efforts are operated out of USDA and EPA.

For FY2007, BCR is expected to receive $17 million, which is slightly more than the planned allocations for 2006. Examples of 2007 projects include: allowing health-related biological research to continue at Vector and Obolensk, two major Soviet biological research institutes housing large repositories of bacterial and viral diseases; continuing the USDA program to develop research opportunities in civilian agricultural disease detection, monitoring, and prevention; and providing support for EPA-led projects with former Soviet chemical weapons scientists in environmental contamination and remediation.[2]

It is unclear how this collaborative research ultimately leads to sustainable employment for the former weapons scientists. In the current model the US Government is creating demand by paying for the research. Once these subsidies are ended, it is unlikely the other US Government agencies involved will continue to commission research in the FSU as these efforts fall far outside of their departmental missions.

VECTOR AND BCR

Under a partnership between DHHS and the Department of State, a novel vaccine platform technology was identified at Vector, the Soviet Union's premier bio-weapons lab, and is currently being validated

[2] Ibid.

through a BTEP-sponsored project. The State Department organized an independent technical validation of the HIV-1 vaccine in collaboration with Massachusetts General Hospital/CIMIT, Duke University Medical Centre's Human Vaccine Institute and Johns Hopkins University. According to State, initial results support Vector's data, indicating broad reactivity to HIV-1. In addition to these initial findings, State has organized contact between the inventor and Wyeth Vaccines as well as Aventis Pasteur. Based upon positive technical and market feedback, BCR has now supported a strategic patent filing to extend Vector's proprietary approach beyond applications for HIV to include infectious diseases such as Hepatitis C and Influenza.

While the potential value of this research is evident, it remains unclear how this ultimately leads to sustainable employment for the researchers. By definition, Vector is not the long-term employer (this is the foundational reason for the existence of these programs) and it is unlikely that either Wyeth or Aventis will hire more than a couple of the scientists once they achieve effective control of the intellectual property. Furthermore, if the patented approach is commercially successful, it seems counter productive to have provided a new revenue stream to a former bio-weapons lab that remains closed to the program funders.

Initiatives for Proliferation Prevention

While IPP has led the way in engaging the private sector, its involvement is to commission research that will provide "proof of concept" for commercializing new technologies developed at the institutes. Few of the researchers have secured permanent employment with the companies who have tended to take the technology to market without involvement of their Russian counterparts.

The Initiatives for Proliferation Prevention (IPP) program is run by the US Department of Energy (DoE) and works closely with the ISTC and the STCU. IPP, however, was designed to ensure that someone does value the results of the research it underwrites by systematically involving private sector companies as "sponsors" of technology development. These companies do not actually pay for the FSU researchers' work themselves—that is done by the DOE—but they do match the government's investments, act as collaborators with, and ultimately *clients* for, the former weapons scientists.

The program is essentially managed by the US National Laboratories. Personnel within the labs often retain long ongoing relationships with individual institutes within the FSU, and are able to recruit the corporate participants, manage the application process, and then oversee the work undertaken by the scientists at the institutes. In most cases, the private company retains no control over the activities of the individual scientists involved. The value of the labs' contribution varies widely and depends largely upon the competence and interest of the primary investigator, who manages the daily interactions with the DOE bureaucracy and the FSU researchers.

A successful IPP project will produce "proof of concept" for a technology or in some cases a prototype with commercial potential. The next step is proving this potential by engineering a commercially viable product, at which point it is often the case that few if any members of the original research team are needed. Therefore, the incidence of projects leading to new, sustainable jobs is low. Once a new technology is produced, the technology (and potentially a target scientist or two) is brought to the United States, where the product can be manufactured and sold with no need for an ongoing relationship with the host institute.

WIND-SAIL

Wind-Sail is an almost textbook example of a successful IPP project. It began in 2000 with the invitation from a senior scientist at the Lawrence Berkley National Lab (LBNL) to a private sector company, Empire Magnetics Inc, to consider doing an IPP project. Empire Magnetics designs and manufactures specialized motors and alternators, has an ongoing collaborative research relationship with LBNL, and during the late 1990s established a small Russian engineering firm to support its product development. After surveying the field of Russian institutes and proposed technologies, Empire and LBNL settled on the Makayev Design Bureau at the Russian State Rocket Centre to develop a commercially viable vertical axis windmill that would be able to utilize Empire's alternators.

A project proposal for US$2 million to be spent over three (3) years was put together by Empire, LBNL and the Rocket Centre, and submitted to the Department of Energy under the IPP program. After a typically lengthy (2+ years) application process, the project was launched. Thirty percent of the US government funds were allocated to LBNL with the remaining 70% going to support the Russian team. The funds were channeled through the ISTC, which also handles procurement of equipment and consumables. In principle, this ensures transparency and accountability, but according to those familiar with the effort, ISTC involvement proved extremely inefficient.

Five years later, Empire Magnetics is nearing completion of its project. Two prototype windmills have been shipped to the United States for testing and possible commercialization. The central problem is the lack of investors willing to offer both the start-up capital necessary to refine the windmills for commercial launch, and to build a production facility in Russia or elsewhere to manufacture them.

According to those familiar with the program, investors quickly conclude that Russia is high risk, low return. The more knowledgeable among them have added that if they did build the factory in Russia, it would be only a matter of time before the Russian's would force them out. Barriers to entry in the Russian market must be overcome before private enterprise is likely to invest their own resources in such a potentially challenging region.

QED TECHNOLOGIES

QED Technologies is a more complete example of technology transfer leading to successful commercialization and the permanent and sustainable redirection of scientists. From basic research in magnetically controllable fluids, a commercially viable optics finishing technology was developed. It was not, however, a result of the IPP program, but an entirely commercial undertaking. Ultimately, QED did benefit from defence technology programs in the United States, but only after the strategic decision was made to launch this effort.

Byelocorp Scientific, Inc., a privately held American company established to develop business opportunities in the former Soviet Union, identified MRF as a promising new technology at a state-owned lab in Belarus. The company then surveyed the US for potential markets, which lead to a collaborative relationship with the University of Rochester's Centre for Optics Manufacturing (COM). COM had previously received substantial funding from the federal government to develop new optics manufacturing technologies that would ensure that the United States did not fall behind or become dependent upon foreign countries for specialized optics in defence applications.

Initial collaboration with COM ultimately produced a patented application of the technology. BSI then set up a new enterprise, QED Technologies, to develop a commercially viable machine utilizing the technology that could be sold to commercial optics manufacturing companies worldwide. Additional government support was then secured through the US Department of Defence Small Business Innovation Research (SBIR) program, which funds staged defence technology development at small businesses throughout the United States. The Civilian Research and Development Foundation (CRDF), an NGO established by Congress to facilitate a variety of basic science, nonproliferation and threat reduction activities in the former Soviet Union, also provided funding for travel grants and exploratory research to assess former weapons scientists' ability to contribute to new innovations in QED's optics manufacturing technology.

BSI, COM and the Belarusian lab took two years to develop a patented application of the magnetically controllable fluid for optics finishing. It took an additional two years for QED to develop a commercially viable machine for optics manufacturers. The Belarusian lab was involved throughout this period but made steadily fewer contributions as both the science and technology being pursued at QED moved beyond the lab's capabilities. In the end, only two of the former weapons scientists were permanently redirected through employment at QED, where the lead scientist continues to drive the development of new applications of magnetically controllable fluids for both defence and commercial markets.

While this case was successful from a business perspective and resulted in the transfer and commercialization of technology valued by the US Government, it lead to the permanent redirection of only two scientists. Thus even the most successful technology development projects offer relatively modest long-term gains for the nonproliferation of expertise efforts.

Restructuring of State-Owned Enterprises

FINDINGS

- Restructuring can produce commercially sustainable employment.
- State enterprises are not capable of restructuring themselves into commercially viable businesses.
- Commercial restructuring provides the greatest total return on investment for governments because the benefits far exceed the core nonproliferation goals.
- BII has yet to demonstrate how it will create sustainable employment.

LESSONS LEARNED FROM THE RESTRUCTURING APPROACH

- Ownership is critical. When it is not clear and sufficient to ensure full commercial control of the enterprises activities, restructuring projects will very quickly fail.
- There must be sufficient managerial expertise and organizational capacity to ensure that the facility's human and material resources are efficiently engaged in producing value for paying customers
- There must be strategic reasons for Western companies to establish operations in the FSU, if they are to employ former WMD scientists locally.
- Companies entering the FSU should have existing products for existing customers in order to reduce the challenges associated with restructuring state-owned enterprises.

Defence Conversion

The Defence Conversion effort in the mid-1990s produced a wealth of lessons learned for future sustainable engagement efforts. Regrettably, few of these lessons were absorbed by governments working to develop the redirect programs. Without complete commercial control of the venture, American partners could not operate the ventures competitively, and therefore create sustainable jobs.

Defence Conversion was the very first attempt at restructuring former weapons facilities in the FSU. The program exemplified the mixed results of this approach, simultaneously achieving spectacular success and failure.

The program was administered by the US Department of Defence and focused on weapons production facilities rather than scientific institutes. Approximately sixteen (16) joint ventures between US companies and the "former" weapons plants were funded through grants of up to US$5 million each. Of these, only a handful succeeded. (See the case study boxes below). The lessons from the defence conversion experience were extensive, but neither well understood nor widely disseminated.

In addition to the primary objective of eliminating a specific weapons production line, one of the few successful projects created commercially sustainable jobs, and introduced new technology and industrial capability to the region. It also provided extensive training in business management, quality assurance and quality control. While ever every nonproliferation program has undertaken to engage in similar skills transfer, in this case there was immediate and productive application of the training for commercial purposes. As the converted factory grew, it created demand for goods and services that supported other companies in the local economy, thus broadening the economic development impact of the program. Because of the hostile nature of the local business environment, management was constantly advocating for changes in both the laws that affected their operations, as well as how those laws were enforced. Finally, in an unplanned but remarkable twist, the plant fabricated virtually all the equipment needed to shut down a local plutonium-producing reactor in a subsequent nonproliferation project undertaken by the US Department of Energy. Ideally, this sort of synergistic activity would be designed into future nonproliferation programs. The return on investment from this modest US$3 million has been extraordinary.

To replicate the success of this model while avoiding its shortcomings, one must take account of a number of key issues. Above all, successful conversion requires a business structure with clear ownership and the managerial expertise and organizational capacity to ensure that the facility's human and material recourses are efficiently engaged in producing value for a reliable stream of paying customers.

As a practical matter, this means recruiting companies with a strategic reason for entering the former Soviet Union and *existing* products or services that can be competitively produced for an *existing* customer base. They must also be ensured sufficient ownership of the restructured facility to manage it on a commercial basis. Joint ventures and partnerships with state-owned enterprises or institutes have consistently failed for this reason.

Ownership has proven to be critical on a number of levels. Without complete commercial control of the venture, it is not possible to operate competitively and therefore have some assurance that the jobs

created will be sustainable. Ownership is also important in that the foreign company has something to gain or loose. Ultimately, the greatest value realized by establishing a business is not through its operation but its sale. A company that is building equity is likely to be much more committed to overcoming myriad obstacles to ensure success.

A major challenge for the US Department of Defence team was distinguishing between companies with the requisite capabilities and commitment from those seeking short term financial gain. When the companies met the criteria above, not only did DoD succeed in taking a weapons plant out of the global arms market, it created strategic value for meeting other foreign policy objectives in nonproliferation and economic development.

BYELKAMIT

Byelkamit is one of the US Government's most successful redirection efforts and is a case study rich in lessons for ongoing and future programs. Conceptually it followed a very simple approach as compared to previous efforts. The US Department of Defence issued an open request for proposal (RFP) to industry for proposals of up to US$5 million to establish new business operations in a defined list of former Soviet weapons plants.

Byelocorp Sceintific, Inc. (BSI) was awarded a US$3 million contract in 1995 to convert a Kazakh weapons factory that produced nuclear-armed torpedoes into a factory that would make cryogenic storage vessels for the European industrial gas industry. Unique among all of the Defence Conversion projects, BSI negotiated a 75% ownership stake in the joint venture that was formed between it, its Italian subsidiary Supco Sr. and the Kazakh State Property Committee. Over the next two years, BSI and Supco Sr., which had a long history of fabricating equipment for and erecting refineries in challenging environments such as Iraq and Libya, completely restructured the factory both physically and culturally to produce Western code certified products for existing European customers.

Because of the chaotic nature of a region in steep economic decline following the collapse of the Soviet Union, and the lack of western code certified materials on the local market, everything that Byelkamit used to fabricate its products had to be imported from Western Europe. To do this BSI and Supco established their own trucking companies to ensure that materials actually made it to the factory and finished vessels made it back to Italy.

However, BSI did not choose to establish a new factory in remote Kazakhstan in order to export heavy industrial products to Europe. Although labor costs were significantly lower than in Italy, they were not lower than in Belarus, where Supco had another workshop. More importantly, transportation costs (even with its own fleet of trucks) and the endless problems and inefficiencies of establishing a factory in such a hostile business environment made the savings much less than would justify a high risk venture of this sort. The strategic reason for BSI/Sucpo to take over the Kazakh factory was the promise of significant growth in Kazakhstan's oil and gas sector due to massive inward investment by the multinational oil companies. Restructuring the plant to produce the existing cryogenic product line for European customers prepared the plant to manufacture the more complex and varied vessels for oil and gas processing and made it possible to survive long enough to develop this new market, which Byelkamit has done very successfully over the ensuing decade.

These hard-earned commercial accomplishments were only the beginning of Byelkamit's success. From the US Government's perspective, the return on investment achieved went far beyond redirecting the former weapons plant. In an unexpected development, Byelkamit became the primary supplier of equipment for a US Department of Energy nonproliferation project in Kazakhstan in which a breeder reactor that produced large amounts of plutonium was permanently shut down, while significant volumes of plutonium bearing fuel assemblies were secured in canisters fabricated at the new factory.

In terms of local development, Byelkamit broke new ground in Kazakhstan. As a large consumer of goods and services, it created demand for local companies that gradually replaced Byelkamit's European suppliers. To ensure quality and efficient production, the company invested heavily in training, creating a cadre of westernized business managers and skilled workers. To mitigate the negative effects of a government in transition, Byelkamit managers organized industry associations and lobbied for legal reforms as well as proper enforcement of existing laws and regulations. In the end, the company became a model of industrial reform and development for the whole region.

BIOMEDPREPARAT AND ALLEN & ASSOCIATES

In stark contrast to Byelkamit is the $2.7 million Defence Conversion contract awarded to Allen & Associates International (AAI) to form a joint venture with and convert a small part of the Soviet Union's largest bio-weapons production facility, Biomedpreparat located in Stepnogorsk, Kazakhstan. The plan was to manufacture and distribute vitamins, pharmaceuticals, antibiotics, and pharmaceutical supplies. A few months *after* the contract was awarded, AAI representatives made their first visit to the facility and concluded that neither the existing buildings nor the associated infrastructure were suitable for pharmaceutical production due to previous BW contamination.

Given the inherent difficulty in renovating the facility to meet international pharmaceutical production standards, AAI decided that there would be no on-site pharmaceutical production. Instead, the converted facility would import and package pharmaceutical products produced elsewhere. More than a year after undertaking the project, AAI brought in a third party, ICN Pharmaceuticals, Inc. to provide the technical expertise necessary to actually carry out the conversion.

ICN's role was to prepare a full technical design, provide training in pharmaceutical methods and standards for the Biomedpreparat employees and procure pharmaceutical products for packaging. Once this plan was outlined, AAI shipped US$1 million dollars worth of pharmaceutical manufacturing equipment, such as pill presses and packaging lines, to Stepnogorsk. Funds were drawn from the original DoD conversion grant.

However, disagreements between AAI and Biomedpreparat caused continuing problems which made it virtually impossible for AAI to meet its contractual obligations to the US government. By the spring of 1997 (at which point Byelkamit was fully converted and operating on a commercial basis), the US government decided to terminate the AAI-Biomedpreparat contract.

Nuclear Cities Initiative[3]

Due to structural challenges and political difficulties with the NCI program, it is likely to remain a subsidy program for Russia rather than a stimulus for economic development.

The Nuclear Cities Initiative (NCI) was established by the United States and Russia in 1998. Its mandate is to help Russia downsize its nuclear weapons complex by introducing commercial enterprises and redirecting employment in Russia's ten closed nuclear cities. NCI is jointly implemented by NNSA and Russia's Federal Atomic Energy Agency (Rosatom).

Working with the US National Laboratories, NCI has attempted to convert large defence production facilities to civilian applications. Developing private industry in these remote regions where access is never assured has proven to be extremely challenging. That aside, the goals of NCI are laudable: Both the Russian and US governments want to consolidate weapons-related institutes while avoiding social dislocation and unrest. Unless the underlying financial and employment problems are addressed jointly, the proliferation threat will remain. As noted above, other programs have attempted to freeze nuclear scientists in place by funding them to perform basic science tasks, many of which have no applicability to real-world needs or demands. By contrast, the Nuclear Cities Initiative seeks to bring together a variety of commercial activities with other pursuits more familiar to Russia's nuclear sector, including increasing the amount of analytical and development work related to nonproliferation and the environment. Unfortunately, these efforts have been doomed to failure as they continue to engage the target community within their erstwhile weapons laboratories where they cannot benefit from global business leadership. Teaching scientists to be businessmen has never proven to be a viable strategy and is unlikely to bear fruit in future.

In 2002, the Bush Administration sought to dramatically reduce funding for NCI, limiting the program to only three of the closed nuclear cities, and ultimately merging its functions with IPP. With the expectation of US$32 million for both NCI and IPP in FY2007, US$11.5 million will go to NCI. The Administration's objective is to re-focus NCI funding on helping to redirect engineers and technicians associated with the shut-down of Russia's two plutonium production reactors. With a refocusing of funding and the broader scope for IPP activities in general, the original NCI goals of redirecting a broad set of Russia's nuclear scientists and "downsizing" its nuclear weapons complex will evaporate unless new, innovative measures are introduced and implemented.[4]

FRESENIUS-AVANGARD TECHNOPARK

In 2001, German-based Fresenius Medical Care, the world's largest provider of dialysis products and services, signed a joint venture agreement with the Avangard Technopark. Under this agreement, a dialysis equipment plant was to be located within the walls of the declassified Technopark. According to the company, Fresenius required intensive access to the facility during the construction phase, and short-term access for maintenance personnel. The company also agreed to provide equipment while Avangard would provide the workforce and the building. The Nuclear Cities program at the US Department of Energy agreed to provide funding for infrastructure conversion and upgrades.

[3] Author's Note: The NCI program was subsequently cancelled in September 2006 after the agreement authorizing the program expired.
[4] Amy Woolf, "Nonproliferation and Threat Reduction Assistance: US Programs in the Former Soviet Union," Congressional Research Service Report for Congress (Washington: CRS, April 19, 2005): 35.

The project ultimately failed to launch for three reasons: (1) The Russian government could not fulfill its access promises to Fresenius, as regular, intensive access could not be arranged and short notice (24 hour) access was untenable for the Russians; (2) Unbeknownst to Fresenius at the time of the agreement, Russian law prohibits foreign ownership or foreign leasing of property and companies in the nuclear cities. Thus, the joint venture agreed to by all parties ultimately required a special exemption from the Russian prime minister; (3) Finally, Fresenius lost confidence in Russia's ability to meet its commitments and terminated the arrangement.

In retrospect, Fresenius managers believed that working outside of the fence within commuting distance of the nuclear city of Avangard may have proven a workable alternative. Regrettably, Avangard Directors lacked the necessary stature and contacts within the Russian Government to push the project forward.

ALTERNATIVE PRODUCTION LINES

Unfortunately, from its inception, NCI has not taken account of the lessons learned from the Defence Conversion program. Five years after Defence Conversion was implemented, NCI invited one of the authors of this report to review a number of proposals to fabricate commercial products they had never made before for customers that did not yet exist. The business plans for these projects were developed by US National Laboratory employees who know as little about running an industrial products company as their Russian counterparts who were supposedly going to be redirected through these ventures.

The BioIndustry Initiative (BII)

BII has taken positive steps toward private sector engagement and sustainability. However, it continues to focus on collaborative research and restructuring former institutes to become commercially sustainable enterprises. Previous efforts have shown, and major pharmaceutical manufacturers agree, that both political and technical hurdles to conversion are far more substantial than "green fields" efforts.

The BII was created by Congress after September 11, 2001 in an attempt to engage the private sector and provide effective new models of sustainability. Its mandate is focused solely on biological threats, and works to transition large-scale FSU biological weapons production facilities, their technology and associated expertise to commercial uses. It also seeks to partner US researchers and former Soviet biological and chemical weapons scientists to develop and accelerate the production of vaccines for infectious diseases that affect the FSU and the world. The central priority of BII is the long-term transformation of *existing* facilities into viable research and production institutions. BII purports to engage specific institutes, assesses their core capabilities as well as the appropriate domestic and international market, and then pairs Russian laboratories with American researchers in both academic and industrial sectors. It is anticipated that in 2007 major commercial reconfiguration projects such as the dismantlement of BW production buildings and the development of an animal feed mill at a former production facility in Georgia will come to fruition, thus testing the viability of the BII model.

It is not at all clear how engaging in joint research or marketing former BW scientists and institutes to western companies produce sustainable jobs.

JOINT STOCK COMPANY VOSTOK AND THE THE BIOINDUSTRY INITIATIVE

Since the establishment of BII, the initiative has met with some success. Joint Stock Company (JSC) Vostok was first established as a biologics manufacturing facility utilizing large-scale fermentation under the auspices of Biopreparat. Currently, Vostok's major activities include production and sale of medical infusions, pharmaceuticals and industrial enzymes, although the facility suffers from the underutilization of its fermentation manufacturing capacity. To achieve long-term sustainability of this facility, BII and Vostok began a joint effort to analyze the marketing environment to determine how to best utilize its manufacturing capabilities and resources. Vostok is currently working towards a production line upgrade to address the results of the market study. BII continues to support Vostok's redirection to commercial, transparent and ultimately profitable activities. The early successes at Vostok indicate the benefits of *private sector market analyses* at the front end of collaborative scientific efforts. Still, the expense of upgrading existing facilities to redirection efforts—particularly for pharmaceutical production—can prove exorbitant and can result in the ultimate undoing of the project.

Lessons Learned — The Legacy of Post-Soviet Expert Redirect Programming

Each of the programs and participants surveyed agreed that the universal failing of prior and existing redirect efforts is the indelible connection of redirect funding to existing government institutes. The goals of redirection at government operated institutes and the development of commercially sustainable efforts are mutually exclusive. Russian law and institute structures provide no effective legal mechanism to spin these efforts off into viable, sustainable enterprises.

The principle impediment to successful conversion of former BW facilities in Russia remains structural. The Russian Federation inherited from the Soviet Union the world's most militarized economy, which for almost half a century planned and prepared itself for a protracted world war. War plans demanded massive materiel resources, including a well planned colossal mobilization capacity for biological weapons. This led to a network of highly specialized and vastly oversized facilities that faced no expectation of meeting pharmaceutical production standards. Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP) govern all aspects of production and, therefore, far exceed the kind of standards used in former BW facilities. Throughout each prior effort to convert *existing* facilities in Russia, critical elements of the above mentioned system have continued to dominate state and institutional thinking in Russia. Mobilization requirements engrained within existing institutes have prevented the conversion of existing premises. Privatization efforts based upon conversion of existing machinery and equipment, labor force, and facilities more generally have been prevented from using military technology for civilian purposes. In addition, the leadership at Russian institutes is not accustomed to solving problems of distribution of products and marketing. Building upon existing facilities not only requires investments that generally far outstrip that required for "green fields" efforts, it further requires a sea change in attitudes at the leadership level within the Russian institutes. In addition, commercialization would eliminate the overhead garnered by leadership at these institutes from existing programs. While defence conversion in most Western countries meant that land, premises, machinery, labor force etc. was sold or moved, this is not the case in Russia. Indeed, before privatization of state resources can occur, a Biopreparat facility must face bankruptcy under Russian law. Each effort to set up an off-shore company within an existing institute has therefore been doomed from the outset. Finally, a further problem faced by previous efforts is the inability to guarantee that there was no residual

contamination of agents from previous BW production. In more than one case, this proved a significant enough hurdle so as to jeopardize the entire initiative.[5]

Our model builds upon the concepts developed by these previous efforts and avoids the obstacles that ultimately prevented their realization. A summary of the six lessons necessary to shape sustainable redirect programming are as follows:

LESSON ONE	Avoid excess legal hurdles within the host state by avoiding engagement through traditional employers in the region (former weapons institutes and facilities);
LESSON TWO	Develop a new mechanism within the sponsoring governments by which resources can be used to "incentivize" local commercial initiatives more directly, thereby encouraging matching investments from the private sector both in the region and in the West;
LESSON THREE	Tap existing private sector markets to ensure prompt access to capital, rather than expending government resources to create new markets and products;
LESSON FOUR	Recognize that emerging markets mean high risks and low returns and that, therefore, new markets must be guaranteed through long-term government contracts (or other market guarantees) with the goal of evolving into other commercial products;
LESSON FIVE	Transfer management of the emergent venture as quickly as possible from states parties to commercial players, allowing for appropriate but not restrictive levels of government oversight;
LESSON SIX	Work to develop distinctly Canadian engagement efforts that utilize the lessons of previous attempts within the United States but avoid complications involved in the US-Russian relationship over BW conversion/redirect.

[5] Sonia Ben Ouagrham and Kathleen M. Vogel, "Conversion at Stepnogorsk: What the Future Holds for Former Bioweapons Facilities," Cornell University Peace Studies Program, Occasional Paper #28 (February 2003).

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FINDINGS

The lessons learned from previous and existing redirect efforts are critical yet ultimately insufficient benchmarks from which to design new programs to correct for programmatic shortcomings. Truly *sustainable* redirect must ultimately leverage new constituencies and develop new avenues via which the private sector can produce commercially viable goods or services. This, in turn, makes the target specialists valuable assets for industry and ultimately transitions them from government grantees to corporate employees.

To that end, and as part of the DFAIT-funded Pathogens for Peace Initiative, the Stimson Center has systematically consulted with a wide cross-section of government, industry, and non-governmental experts in the areas of security, public health, and development. The purpose of these discussions was to map the landscape upon which new models of sustainable engagement could be built. An illustrative list of individuals and organizations surveyed can be found in Appendix A. Below is a summary of the findings generated as a result of these consultations:

There is a continuing risk of brain drain proliferation from the former Soviet Union which does not appear to be diminishing.

> The abysmal conditions that stoked "brain drain" concerns from the FSU through the 1990s have largely improved. Today, the number of Russian scientists who represent a WMD proliferation threat is relatively small, but remains large enough to warrant continuing concern. Anecdotal evidence collected from scientists and private companies operating in the states of the former Soviet Union suggest that some portion of the region's former WMD talent is being siphoned off and recirculated by so-called "rogue" states. Moreover, solid empirical evidence collected by a recent US Department of Energy study—though questionable in and of itself—points out that while majority of Russian scientists are unlikely to migrate to rogue countries or sell their WMD expertise to hostile governments, sizable minorities continue to pose a threat: 21 percent would consider taking a job that would require moving to one (or more) of four rogue states; 13 percent deem WMD work for an authoritarian government acceptable under some circumstances; and 59 percent view dual-use work for a foreign firm as acceptable under certain circumstances.[6]

Former BW scientists are not the only threat. Young FSU scientists with modern laboratory skills, direct access to biological materials, and strong financial ambitions could present an equally challenging risk.

> Proliferation threats can emanate from sources far beyond the existing target list of institutes and individuals once part of the massive Soviet biological weapons complex. According to a study by the US National Academy of Sciences, much of the research conducted in facilities that were never associated with defence programs is inherently

[6] Deborah Yarsike Ball and Theodore P. Gerber, "Russian Scientists and Rogue States: Does Western Assistance Reduce the Proliferation Threat?" *International Security*, Vol. 29, No. 4 (Spring 2005): 50–77.

dual use. The study further found that a sharp bifurcation of between former defence and non-defence scientists is inhibiting the exchange of information within Russia. More importantly, this has led to a lack of adequate attention to the proliferation potential of the historically civilian biological research sector. As a result, young FSU scientists with modern laboratory skills, direct access to biological materials, and strong financial ambitions—whether inside the target institutes or beyond their walls—could present a proliferation threat.[7] While this subset of scientific talent is far beyond the mandate of existing nonproliferation programming, *unless models of engagement can ultimately capture and integrate the scientific community of the FSU writ large, it is unlikely that the brain-drain threat will ever be systematically addressed.*

Providing underemployed WMD specialists with sustainable jobs reduces the brain drain threat.

Empirical analyses complement anecdotal evidence suggesting that the lion's share of former WMD researchers in the states of the former Soviet Union are not predisposed to employment in so-called "rogue states." It is therefore logical to assume that if viable employment alternatives can be found in their home country, the target population will not become a brain drain threat. To date, the preponderance of unclassified evidence supports this conclusion.

Sustainable jobs reduce the need for long-term government expenditures on existing redirect programs.

While existing redirect efforts have generally succeeded in the near term, they have ultimately failed to eliminate the threat in the long term. Even those programs that have sought to build in the private sector as "clients" of government-funded research at the former weapons institutes have not succeeded at introducing industry as sustainable employers of the target community. As a general rule, when government funding has evaporated, weapons researchers are again underemployed or even unemployed, and again pose a global proliferation threat.

The science retained within Russia and other states of the former Soviet Union remains valuable.

Throughout the Cold War, the Soviet Union developed a massive state-owned bioresearch and production capacity. While the Western world funneled its most gifted medical researchers and scientists into solving the most vexing public health challenges of the day, Moscow pushed its talent into a then-65,000 employee strong biological weapons complex. Over the course of decades, *the Soviet Union developed unmatched capabilities in the biological sciences* and, in turn, weaponized thousands of tons of viruses, toxins, and bacteria, including anthrax, smallpox, botulinum toxin, and the plague.

Russia hosts some of the most accomplished labs in the world in critical areas of biology. Their activities can be translated directly to the benefit of global public health.

Today, as a direct result of that legacy, Russia hosts some of the most accomplished labs in the world in critical areas of biology. Their activities can be translated directly to the

[7] US National Research Council, *Biological Science and Biotechnology in Russia: Controlling Diseases and Enhancing Security* (Washington: NRC, 2005): 72.

benefit of global public health. The Russian BW complex successfully weaponized a broad range of highly infectious pathogens such as the filovirus Ebola. Today, these skill sets could be equally useful in devising new strategies for influenza virus culture, strain generation, and banking. If applied to influenza vaccine development, this knowledge base and additional capacity could revolutionize scientific practices in even the most developed countries of the world. The Russians, Georgians and Ukrainians remain world leaders in the identification and utilization of bacteriophages in human medicine. Additionally, legacy capacity in the states of the former Soviet Union could also be turned quickly to bioremediation as well as novel drug design and testing.

Redirection can and should produce value beyond the nonproliferation of expertise, thus maximizing the government's return on investment.

Governments can maximize return on their hard security investments. Bio-scientist redirect funds can leverage—and be further leveraged by—other government interests including: a] global economic development, b] international public health, c] basic science research, and d] nation building. For instance, encouraging development of the biotechnology industry in the states of the former Soviet Union can become a *significant income generating sector for the local economies*. Such an effort would support the Government of Canada's global economic development efforts in the states of the former Soviet Union.

While effective partnerships have been developed in the affluent world between governments, private foundations, and industry, the absence of adequate markets have prevented similarly successful joint ventures in the developing world. As a result, more than 3 million people die every year of preventable diseases. An additional 2 million die each year of diseases whose vaccines may be on the horizon.

Scientific advances in vaccine development and other therapeutics have dramatically altered the course of human history. Current and imminent scientific knowledge has been used to conquer diseases that kill millions of people each year. But while scientific breakthroughs have all but eliminated the threat of life-threatening infectious disease among children in the developed world, we have yet to develop vaccines and other advanced therapeutics against diseases of the poor—malaria, HIV and tuberculosis. According to the most recent figures available, of the $106 billion expended globally in 2001 on health R&D, national governments provided approximately 44 percent of the total with the pharmaceutical industry investing about 48 percent. The remaining 8 percent was derived from non-profit and philanthropic sources. The importance of private investment becomes startlingly clear when these figures are compared with total R&D tailored to address health issues in the developing world. Of that $6 billion in 2001, 83 percent was derived from the public sector while 17% was donated through philanthropic sources. Here, private investment was almost negligible. The result has been a two-tiered system of R&D and production—one for diseases of the developed world, and another for neglected diseases of the developing world.[8]

[8] Ruth Levine, Michael Kremer, and Alice Albright, *Making Markets for Vaccines: Ideas to Action* (Washington: Centre for Global Development, 2005): 18-19.

While vaccine production is rapidly evolving into a state-funded mandate due to an en masse migration of private companies out of the industry, the role of the private sector in moving promising drug candidates from the lab to scaled up production remains critical.

Thanks to the efforts of concerned governments and NGOs, the past decade has brought heightened attention to the need to provide vaccines and other advanced therapeutics for treatment of neglected diseases of the developing world. These efforts have focused primarily upon block purchases of existing products, the prediction of future needs, and on innovative strategies to invest in future R&D. However, in the main, the role of the private sector, recognized as a critical player in the transition of promising vaccine candidates from the lab through to scaled-up production, has not been successfully integrated into global health and development strategies. Only more recently have innovative concepts designed to promote market-based incentives and industry involvement been systematically explored. *Without targeted initiatives designed to "incentivize" private sector involvement, international aid and development efforts will never achieve their goal.*

The indispensable role of private industry in scientist redirection and vaccine/therapeutic drug development and production creates a natural symbiosis between national security programs to ensure nonproliferation of expertise, and public health efforts to address neglected diseases.

Both existing efforts to promote private sector development of vaccines and advanced therapeutics for neglected diseases are laudable, there is a logical and unexploited nexus between the parallel goals of foreign aid, vaccine/therapeutic drug development, the development of a scientific services industry, and the redirection of former biological weapons scientists in the FSU. *Exploiting that nexus could provide an entirely new and untapped avenue of support for low-cost R&D and production of vaccines and other therapeutics for the developing world.* As currently constituted, national and global efforts in both areas face formidable obstacles to success. The mass production of therapeutic drugs to combat new and reemerging infectious diseases in the developing world cannot be adequately addressed without a reduction or circumvention of market barriers including the identification of low cost R&D and production alternatives. Similarly, former weapons scientists will not be sustainably redirected to peaceful pursuits until long term employment opportunities utilizing their expertise are presented. Industry involvement in both fields comes at a critical time in the global debate over vaccine/drug development and scientist redirection as experts come to realize that, *inter alia*, investments in R&D over the past decade will ultimately face significant production capacity bottlenecks as new products move to production, and as macro industry trends continue to pressure the pharmaceutical sector to consider the outsourcing of manufacturing as a core strategy to remain competitive.

Existing engagement programs have largely succeeded in their immediate goal of nonproliferation, but have failed in their attempts to restructure state-controlled institutes to provide for sustainable employment.

Existing programs to address the threat of bio-proliferation were developed in an era of national crises across the FSU. In order to meet the emerging "brain drain" threat, the international community developed a patchwork of programs whose immediate intent

was to account for the whereabouts and activities of former weapons researchers. All prior *engagement efforts have focused on facility conversion, scientific engagement, or technology development, and were designed to keep specialists at their lab benches within their former weapons institutes, not to create sustainable jobs in the private sector.* Nor have these programs addressed the systemic problems within the host states that ultimately drive the proliferation threat. Questions of sustainability were not—and could not—be systematically addressed in the face of this immediate threat. Building sustainability into existing programs has proven challenging due to structural inflexibilities within ISTC, STCU, and the bilateral programs of the US government (IPP, NCI and BII). While these programs continue to serve legitimate nonproliferation goals, they are no longer able to fully address evolving challenges or take advantage of opportunities. Nor are they ultimately sustainable beyond their current funding horizons.

New models must therefore be developed that identifies "employers" rather than customers.

Sustainable employment cannot be achieved until the private sector is led to see continuous value in the talents and skills of the target community. By making this critical link, *governments can ultimately begin to transition the target community from state grants to private sector payrolls.* Existing efforts fail to introduce industry and employers, seeking instead to pair private companies with former weapons scientists in client/researcher relationships.

Sustainable redirection necessitates a transition from government investments in redirect, to private sector investments in business development.

In order to ensure sustainability beyond the funding horizon of existing G8 programs, new models of engagement must build long-term partnerships with the private sector. Ultimately *a transition must occur from government investments in redirect to private sector investments in business development.* This cannot be achieved without short term incentives that motivate private sector interests in the near term, and help secure their financial investments in the long term.

Barriers to business development in Russia are significant. Therefore, industry must be coaxed into participation during early stages.

While studies have shown that the scientific community in Russia possesses skills and capacities of commercial interest to the private sector, *barriers to business development in the FSU are significant*. Furthermore, the perception within private industry of Russian government obstructionism and hostility has further inhibited economic development and foreign investment. In light of recent high-profile cases of government interference in Russia such as the Aerostar Hotel affair, motivating private sector involvement will become increasingly challenging. In order to gain the collaboration of the private sector, risk to entrepreneurs must be mitigated to a sufficient level.

In light of political sensitivities, employment cannot be provided outside of the host country.

Some of the most successful and sustainable redirect efforts have occurred when scientists from the former weapons institutes were drawn out of these state-run facilities and absorbed into Western private sector companies (see QED case study above). Due to

personal and political sensitivities, as well as global economic development needs, programs that promote peaceful brain drain to the West are infeasible.

Capacity of local employers is limited by the nascent state of the private sector in the host countries; therefore we must bring foreign employers into the country in the near term.

Introduction of private sector companies based in the region is the next most cost effective model for sustainable redirection outside of the former weapons institutes. But market conditions for domestic industry in the region have yet to develop a robust private sector capable of absorbing sufficient numbers of scientists from within the target community. Nor do many existing companies within the FSU yet possess sufficient markets to provide an existing client base for sustainable redirection. While this remains a long-range strategic goal, the needs of *near-term sustainable redirect cannot be fully met by incentivizing existing private sector companies within the FSU.* As such, foreign companies must be leveraged into the region to ensure viable, sustainable redirection while encouraging incremental improvements in the rule of law and global economic development.

Innovative and sustainable redirection models will only address a portion of the target population.

Research capacities in the states of the former Soviet Union, like the West, span a broad range of skill sets and applications. Similarly, the target community is composed of a wide array of individuals whose interests, both personal and professional, vary greatly. Many of these individuals will not be interested in seeking sustainable employment outside of their home institutes. Others will be valued to such an extent by the host government that they will not be allowed to leave. Still others will not possess talents that are directly marketable by private sector companies. For this subset of individuals, other engagement alternatives such as the STCs should continue.

Innovative models will force the Russian government to make a clear commitment to scientists it intends to keep within state-controlled institutes and reduces the number of scientists for which G7 funds are required.

The process of downselecting individuals from the target community whose skills and talents are readily translatable to commercial application will promote an additional benefit to ongoing redirection programming. Phase one will involve the categorization of skills into “employable” and “non-employable” groupings. *Those that are not readily attractive to the private sector will remain within the existing STC system provided their skills remain of proliferation concern*. Those that are considered “employable” will, in turn, have the option of exiting their institutes to seek work within the private sector. If, as is anticipated, some individuals are not permitted to leave their home institutes by their host government, G7 contributors can then offload these individuals from the target list and concentrate their resources on those that remain a proliferation threat.

Ottawa has the opportunity to emerge as a leader within the scientist redirect portfolio of the G8 Global Partnership.

Existing G8 redirection programming is limited by the strictures of existing bilateral agreements, politics, lethargy, and resistance to change. American BW redirect efforts have been scaled back dramatically in Russia due in large measure to the difficult history

those countries share. IGX programs in Ottawa operate under no such restrictions. Moreover, Canada brings to the table a long history and solid international reputation in the fields of nonproliferation, foreign assistance, and public international health that, if leveraged, could produce significant advances to the dual challenges of neglected diseases, economic development, and biological weapons proliferation. In short, Ottawa has the opportunity to emerge as a leader within the scientist redirect portfolio of the G8 Global Partnership by building new effective models of sustainable engagement and redirection.

— 4 —
A NEW APPROACH: SUSTAINABLE REDIRECTION AND BIOTECHNOLOGY DEVELOPMENT: THE PATHOGENS FOR PEACE INITIATIVE

Given the inability of existing engagement efforts to sustainably redirect the target community, Canada should leverage its resources to develop and prove a new model that deterministically creates employment in the states of the former Soviet Union. Ideally, this effort could ultimately become a conduit for redirecting and more productively utilizing G8 nonproliferation funds while furthering Canada's nonproliferation, public health, global economic development, and other domestic and foreign policy goals.

Defining "Employers"

Recognizing the absence of the necessary managerial capability and capacity in the existing programs, the first step must be to recruit industry as employers rather than customers. For purposes of program implementation, there are essentially two categories of employers:

1. companies currently operating in the states of the former Soviet Union, and
2. foreign companies (in this case Canadian) that will have to be brought into the region.

The first group is small due to the nascent state of private sector development throughout the post-Soviet economies. Because they are already operating locally, however, those that do exist and that are capable of effective management should be relatively easily and inexpensively engaged as employers. A survey of companies that could make productive use of former weapons scientists could be accomplished quickly and would provide a clear sense of the potential for, and costs associated with, turning them into employers.

The second group is much larger and generally speaking will have greater organizational capacity to make efficient and productive use of the target community. This group will have extensive networks of customers and suppliers in developed markets, which is important to both the viability and sustainability of the program as a whole. However, it will be more expensive to engage these companies as employers because of the need to help them establish new operations in the region. Nevertheless, there is little or no opportunity cost to utilizing limited resources to this end as compared with continuing to disperse funds through the existing programs because the latter are only infrequently producing sustainable employment opportunities for the target community.

Canadian companies that would have an interest in former bioweapons scientists are most likely biotech companies, which will be fairly easy to identify and engage. Determining their level of interest and what incentives they will require to establish subsidiaries in the FSU will be somewhat more time consuming. The biggest challenges will be in ensuring that they have a strategic reason (apart from incentives) for doing so, and mitigating the risks of failure.

Mitigating Risks

Ultimately, risk for the private employer *as well as to IGX* must be mitigated to the greatest extent possible. To this end, bringing additional stakeholders into IGX programming—such as CIHR, DRDC, CIDA, PHAC, CFIA, Agriculture Canada, NRC—will not only provide a wider menu of incentives for private sector participants at the front end, it will also reinforce IGX programming by building in potential clients for goods and services at the back end. For example, DRDC, CIHR, CFIA, and Agriculture Canada all have an interest in tapping into FSU phage research. DRDC is sponsoring an airborne pathogens sensor that requires strains of anthrax-responsive phage, while CIHR, CFIA, and Agriculture Canada are interested in developing alternatives to antibiotics for treating infections in both humans and in livestock. All have grant making and contract research programs that involve Canadian biotech companies in an effort to meet these goals.

As noted, involvement of other government agencies has two values from a program management perspective:

1. Wider participation increases the financial resources available to the company/employer; and
2. More importantly, wider participation helps validate industry participation by demonstrating a real market for the scientific expertise the company is acquiring. It further increases the motivation/commitment of the company to ensure success of its new FSU operation.

Over time, as the field of candidate companies is broadened beyond Canada, the opportunities and overall benefits to the program would increase significantly. Though it would require more time and effort on the part of project managers, the benefits could be significant. For instance, the US government spends far more on scientific research and technology development through grants to the private sector than Canada. The US also spends heavily on direct assistance to the FSU for the elimination and securing of weapons and weapons grade materials. Accessing these markets and engaging the companies who supply them as employers can dramatically increase the base of prospective employers. Once the P4P model has proven to be effective, its extension across G8 redirect programming is possible. The model of private sector engagement could be further translated beyond global nonproliferation objectives in direct support of economic development needs in other regions.

Stimson has begun the process of engaging other stakeholders both north and south of the border—and not only from within government. A significant potential market for former BW scientists in the FSU, for example, would be the series of nonprofit drug development organizations started by the Rockefeller Foundation and funded on an ongoing basis by the Bill and Melinda Gates Foundation. These virtual drug development ventures outsource all of their research and development work to contract research organizations (CROs) globally. Some of these CROs could become employers of key BW specialists, but there is also potential to engage their sponsors in surveying the broader FSU innovation systems and public health sectors in order to identify untapped resources that could make critical contributions to their drug and diagnostics development goals. If Gates and Rockefeller can be persuaded to invest in enabling increased Russian participation in addressing developing world health needs, this would create additional demand for the services of former bioweapons specialists.

Recruiting, Selecting, and Enabling Employers

Prospective employers should be identified though an ongoing process of outreach through existing nonproliferation programs, industry associations in both the FSU and North America, the nonprofit drug development ventures funded by Rockefeller and Gates, and potentially in a less targeted way through the issuance of requests for proposals (RFPs).

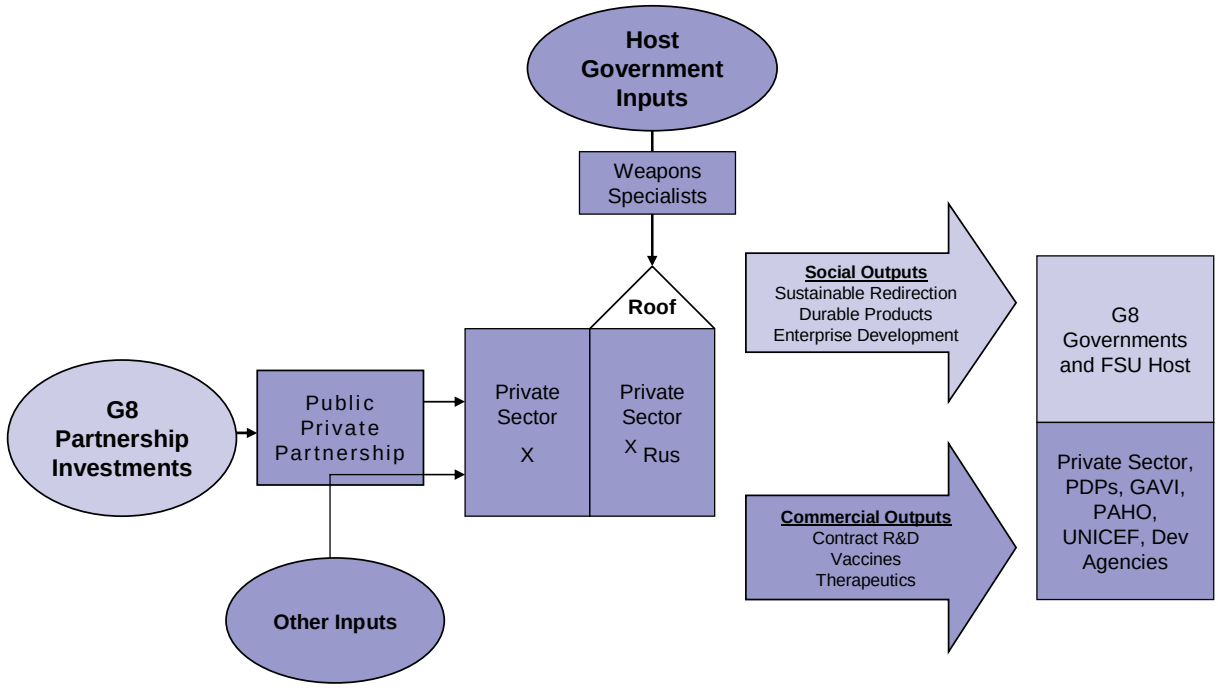
Once identified, companies should be carefully screened for the attributes that have proven to be critical for success in previous and existing programs. At a minimum, these include having a strategic reason for establishing an operation in the target country, sufficient managerial expertise and capacity to manage such an operation, existing products or services to be produced there for existing customers who can reasonably be expected to pay for them, and the financial resources to be in business without participating in this program. It is also important to ensure that the companies have sufficient ownership of the new ventures to exercise effective commercial control.

To mitigate the risks of failure a number of steps can be taken to reduce the challenges the companies will face. Cash incentives will be the core mechanism for recruiting and enabling the employers. These can take a wide variety of forms, from grants to subsidized or forgivable loans. They should not, however, be the sole focus of the program. To the degree that bilateral inter-governmental agreements are put in place, they should ensure that the Canadian companies have the right to sufficient ownership of the new ventures, that they will be protected from governmental manipulation and criminal activities, and to the degree possible, will enjoy the most advantageous trade and tax regimes possible.

Finally, in the case of small biotech ventures, it would be sensible and probably economically beneficial to establish some sort of core R&D facility, which would allow the companies to share resources, particularly in the early stages as they set up their ventures and learn how to do business in the former Soviet Union. Such a facility could provide lab and office space, the legal and administrative resources needed to establish a new company in the host country, recruitment of staff other than the redirected scientists, local procurement, customs and logistics support as well as expert advise on tax and legal issues.

A core facility would also afford the overall program greater flexibility in negotiating terms with the prospective employers. As an alternative to offering capital grants that would pay for equipment and start up costs, the program could agree to provide operational funding in decreasing amounts over a period of, for instance, three to four years. Instead of building its own facility, the company would lease space and assume an increasing percentage of the operational costs over time. A variety of approaches will be necessary, and the more flexibility the program has regarding terms and mechanisms by which it can reduce risks to the companies, the better.

Below is a graphic depiction of the basic "Sustainable Redirect" model that we propose:



G8 Global Partnership Investments

The model is driven by the nonproliferation goals of the G8 Global Partnership. While under pressure, annual G8 redirect appropriations are substantial. A portion of these resources should be carved off and funneled through a discrete funding mechanism designed to temporarily subsidize employment of former weapons specialists in the private sector.

Public Private Partnership

A new Public Private Partnership capacity should be established to manage government nonproliferation investments. This PPP would provide broad-based portfolio management by "investing" resources in private companies willing to sustainably employ the target population. The PPP would be responsible for conducting due diligence on behalf of all government client(s) (DFAIT, CIHR, CIDA, DRDC etc) in order to ensure the long term integrity and viability of private sector participants. The partnership would also be responsible for interfacing with and coordinating the participation of industry, academic partners, and other contractors.

Other Inputs

While nonproliferation investments are critical, they are ultimately short-term as the Global Partnership will sunset in 2012. As such, the nonproliferation agencies must work to develop additional "clients" over the course of the next seven years in order to ensure sustainability once nonproliferation funding evaporates. For bio-scientist redirect, that target community can range from other national governmental

agencies (CIDA, DFID, USAID, PHAC, CDC[9]) to other international public health and development agencies (the World Bank Group, UNICEF, WHO, PAHO[10]), to Public Private Partnerships dedicated to mitigating the threats of neglected diseases (IAVI, TB Alliance, MVI, PATH[11]). Additional private investment (venture capital) would be sought in the medium- to long-term to support ongoing growth of a biotech cluster seeded through this program.

Host Government Inputs

Unlike existing programs, the burden placed upon the Host Government is minimal. Coordination and match-making with domestic scientific talent would become the responsibility of the private sector, under the supervision of the PPP, which is ultimately answerable to the contributing government authorities. The responsibility of the Host Government therefore becomes: A] the release of targeted scientists from state-run institutes; and B] the provision of a "roof"— a clear and sustained signal to lower levels of government and to potentially corrupt local regulatory officials not to manipulate or harm the companies established under this program.

Private Sector X

Interested private sector firms would make a single application to the Public Private Partnership. The PPP would coordinate funding from across the range of participating grantors to develop a targeted incentives package for each successful down-selected applicant. In exchange for defined incentives, the private sector company would be obligated to employ specific individuals who qualify for redirect support because of their WMD expertise. Due to the embryonic state of the private biotech sector within the states of concern, in most cases, we anticipate that industry within contributing states—Canada for instance—will form the lion's share of ventures. This does not, however, preclude local firms within the host state from successfully bidding on redirect funding from the PPP.

Private Sector X_{Rus}

Recognizing that only a limited subset of the target population can be drawn out of the host country, and recognizing that various permutations of business models can be applied successfully, we anticipate that the majority of cases will involve establishing FSU subsidiaries of the Canadian biotech companies hiring the redirected specialists.

Outputs

- *Social*: Social outputs are the "goods" directly and indirectly produced by government incentives. The primary social output of nonproliferation of expertise programs should be the permanent redirection of former WMD specialists into commercially sustainable jobs. Because this requires the introduction of new biotech companies into the FSU, other "goods" naturally arise as a by-product of the effort: broader economic recovery and development, professional training, adoption of international quality regimes and management techniques, advocacy for further

[9] Canadian International Development Agency (CIDA), UK Department for International Development (DFID), United States Agency for International Development (USAID), the Public Health Agency of Canada (PHAC), and the US Centres for Disease Control and Prevention (CDC).

[10] The United Nations Children's Fund (UNICEF), the World Health Organization, and Pan-American Health Organization (PAHO).

[11] The International AIDS Vaccine Initiative (IAVI), the Malaria Vaccine Initiative (MVI), and the Program for Appropriate Technology in Health (PATH).

economic reform, increased demand for local goods and services, new business creation due to this increase in demand and to spin-off activities, and new technology development.

- *Commercial*: Commercial outputs are the real goods and services that ultimately justify and finance the long-term employment of redirected specialists. These outputs are critical to the success of this model. Without the provision of viable products to a paying client base, sustainable redirect will never be achieved. These products can ultimately be marketed to a broad array of national and international health agencies providing not only potentially discounted new sources (over time) but also expanded capacity for neglected disease research.

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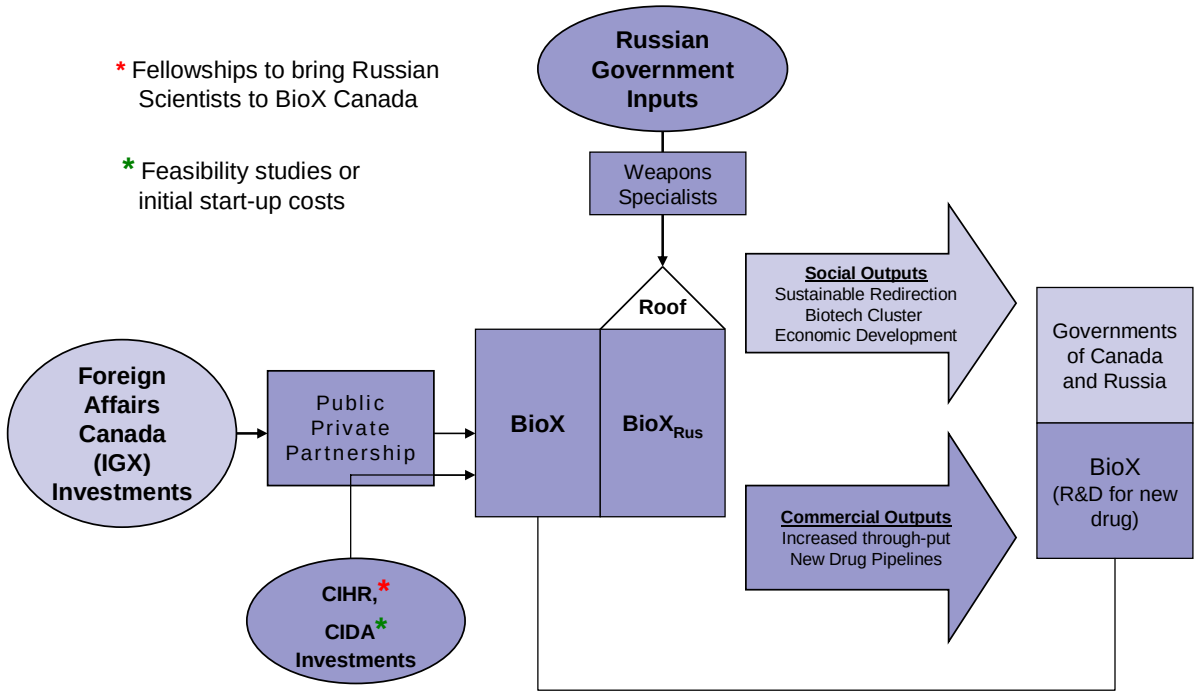
CASE STUDIES: OPERATIONALIZING THE SUSTAINABLE REDIRECTION MODEL

As part of the contribution agreement between the Government of Canada and The Henry L. Stimson Center, the Centre began exploratory discussions with various Canadian government agencies and private sector companies to define illustrative pilot efforts operationalizing the model defined above. Below is offered three case studies of efforts that leverage the private sector as well as cross-sectoral government interests. Due to sensitivities within the private sector, and the need for balance from a Government of Canada perspective, the Centre has redacted the names of private sector companies described below.

Canadian Subsidiary Development in Russia: Case One—"BioX"



The company we refer to as BioX is a small Canadian biotech firm that has a significant pipeline of drug targets identified and at various stages of development. Its most advanced target is nearing Phase 3 clinical trials. The company is well capitalized, having recently completed a third round of venture funding, giving it sufficient capital stock to see multiple drug targets through Phase 3 trials over the next five year period. At present, all operations are focused within Canada, although, the management team is currently considering a modest expansion of capacity into the United States.

In many ways BioX is not a company that would likely engage in a high-risk venture employing former BW specialists in the FSU. Yet because BioX is well capitalized, and has an extensive pipeline of target drugs to work on, its most sensible path forward at the moment is to concentrate all of its human resources on bringing the most promising targets in this pipeline to market as quickly as possible. Its biggest risk under the current situation is a distracted management team.

Although its tolerance for risk is necessarily very low, BioX is interested in the suite of government funded efforts designed to engage capacity in the states of the former Soviet Union. Moreover, it is interested for the best possible of reasons: the quality of science available. The lead scientist at BioX is among Canada's foremost experts in the field and recognizes comparable talent in a Russian colleague who still works within the walls of one of that country's former weapons institutes.

In principle, BioX could hire the Russian scientist away from the institute and resettle him in Canada. However, BioX management believes that he can potentially be even more productive by remaining in Russia where he can maintain his own team at a fraction of the cost necessary to have them all resettle in Canada.

BioX perceives three benefits to be achieved by establishing a subsidiary in Russia:

1) Increase the through-put of drug target assessment thus accelerating the potential to bring a drug to market;
2) Potentially add a new pipeline based upon the Russian scientist's knowledge; and
3) Potentially acquire a lower cost production facility that could reduce current costs and therefore give them more time to achieve perhaps a greater number of hits.

Benefits

The primary nonproliferation benefit of engaging BioX to establish a Russian subsidiary is that they will hire a top Russian scientist and his team of roughly a dozen former BW specialists out of their erstwhile weapons institute. If the Russian team's value is established in the first few years, their continuing value to BioX will be considerable, and as long as BioX achieves some measure of financial success within the timeframe provided by the existing private capital stock, it will have both the means and the motivation to continue to employ the Russian team indefinitely.

If the venture matures as planned, it has the potential to provide additional employment and training in both technical fields as well as in business management, create new markets for other local companies in the provision of a variety of goods and services utilized in its operations, and it will inevitably advocate for improvements in governance as it impacts business operations and value.

Risk and Challenges

- *Cost*: The cost of engaging BioX will be relatively high for two reasons. First, the risk to BioX of dispersing management attention by undertaking a Russian venture is very high, so it will have to be at least cost neutral to BioX. This means that government subsidies will have to fund essentially the entire venture in the early years. Second, although the labor costs are modest, the capital equipment costs will be significant.

- *Sustainability*: BioX's business model offers pros and cons in terms of sustainability. On one hand, its capital base means that the risk of going out of business over the next 5 years is extremely low. Provided its Russian subsidiary remains cost neutral, or demonstrates sufficient value to justify raising additional capital, the redirected scientists will enjoy secure employment for this period while learning how to manage and function in an internationally viable biotech company. On the other hand, the long-term viability of this employment depends on BioX succeeding in bringing a drug to market and securing the revenues commensurate with that or at least in raising additional capital in five years through another round of private equity financing or an initial public offering.

Risk Mitigation

A core biotech facility established for use by a number of nonproliferation funded enterprises could reduce BioX's capital and operational expenses by sharing both infrastructure and administrative services. By clustering enterprises like BioX, it would also provide redirected scientists an opportunity to market themselves to other tenants or to angel investors in the event that BioX does not survive.

Project Implementation

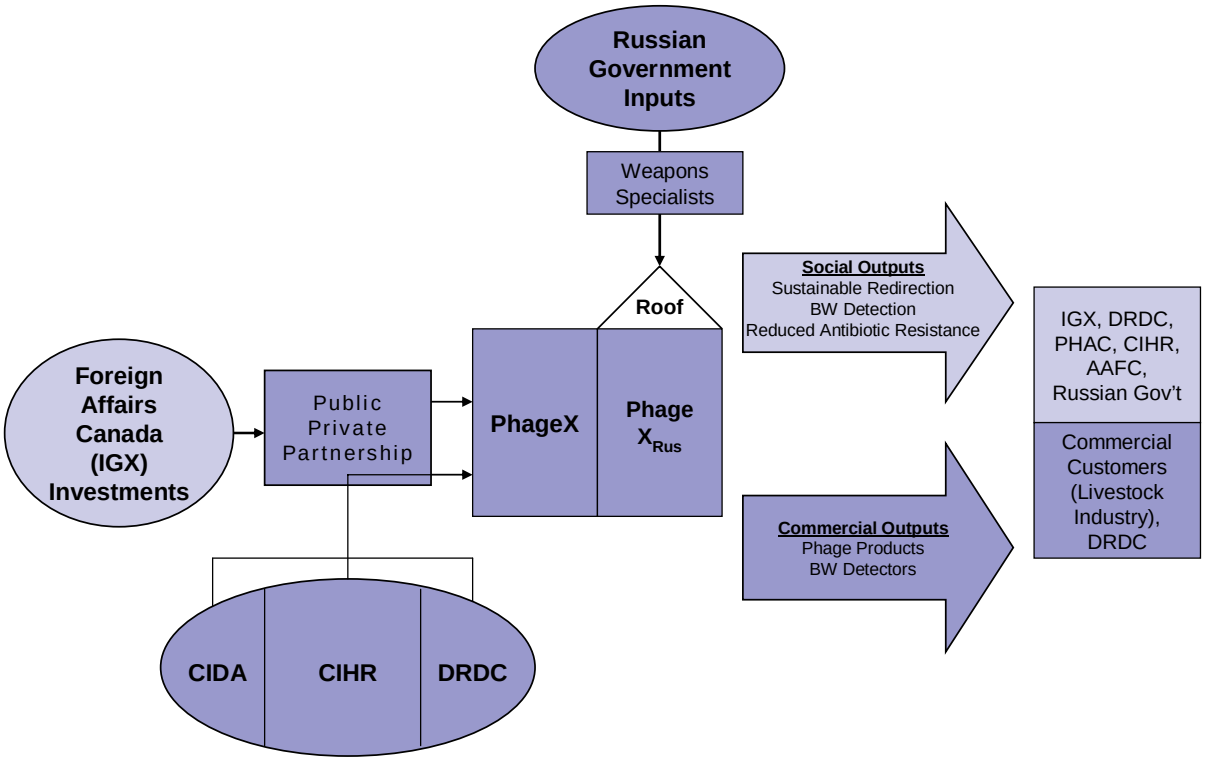
Following the model below, IGX would contract the Public Private Partnership to work with BioX and other Canadian government agencies to develop a business plan and funding profile for a BioX subsidiary in Russia.

The steps taken during project implementation would depend in large part on the degree of confidence and speed with which BioX wants to proceed. One possible scenario might begin with a fact-finding trip to Russia by company managers. However, in the BioX case, a specific Russian scientist has already been identified and there is a high level of confidence that he or she is capable of directing new BioX research in Russia. Therefore, as a logical first step, the PPP would negotiate a research fellowship from CIHR or other interested agency for the Russian scientist(s) to spend a year at BioX in Canada.

Having the scientist work at the Canadian parent facility has the merit of determining the value, capabilities, and compatibility of him/her to be an employee of BioX and a key manager of a Russian subsidiary. It also allows BioX to provide targeted training in management practices specific to their business, thus laying a more firm foundation for starting up a new venture in Russia.

Sometime during the course of year one, or immediately afterwards, BioX together with the Russian scientist(s) would prepare a business plan and funding proposal for submission to the PPP. If the PPP accepts the proposal, BioX would then be contracted to execute the business plan bringing in the full Russian team and starting up the new venture.

Canadian Subsidiary Development in Russia: Case Two—"PhageX"



In this scenario, the role of other government agencies is more pronounced. The Canadian Institutes for Health Research (CIHR) have identified phage as a potential alternative to antibiotics and is providing more than $3 million in funding to encourage more research in this area. Simultaneously, Defence Research and Development Canada (DRDC) has sponsored research into the use of anthrax-sensitive phages in sensors to monitor airborne pathogens. DRDC leverages approximately $150 million each year for private sector research to meet the scientific and technological needs of the Canadian Forces.

Unlike the research underway at BioX, which is based on the insights and expertise of Canadian scientists, knowledge of phage is very limited in Canada. The former Soviet Union holds the lion's share of global expertise in phage. There are, nevertheless, a number of Canadian companies engaged in developing a fairly wide range of applications of phage. One of these has already been working with DRDC to develop the anthrax sensor.

This hypothetical Canadian company, which we will call PhageX, is interested in the expertise of the Russian scientists but is also looking for additional strains of phage that will be useful in developing a sensor capable of detecting anthrax and other airborne pathogens. Again, because the FSU is the world's best source of expertise and well documented strains of phage, both CIHR and DRDC have a direct and active interest in supporting activities that increase the flow of expertise and materials from the FSU to Canada. CIHR can fund fellowships for Russian phage specialists to conduct research at PhageX as part of a wider collaboration between the company and a Canadian university laboratory. DRDC can provide direct funding to support PhageX's efforts to develop an airborne pathogens sensor utilizing Russian expertise and phage strains—all at subsidized rates based upon the nonproliferation investments made by DFAIT.

Benefits

Not only do these other government programs increase the resource base available to develop the case for and establish a PhageX subsidiary in Russia, they provide ongoing demand for the company to make productive use of competent scientists in the FSU. Success on the CIHR funded research may lead to novel treatments for antibiotic-resistant infections or an ability to reduce the use of antibiotics in order to postpone the development of resistance. For DRDC, success would provide Canada, and in principle the entire world, a way of more quickly or accurately recognizing and responding to a bioweapons attack.

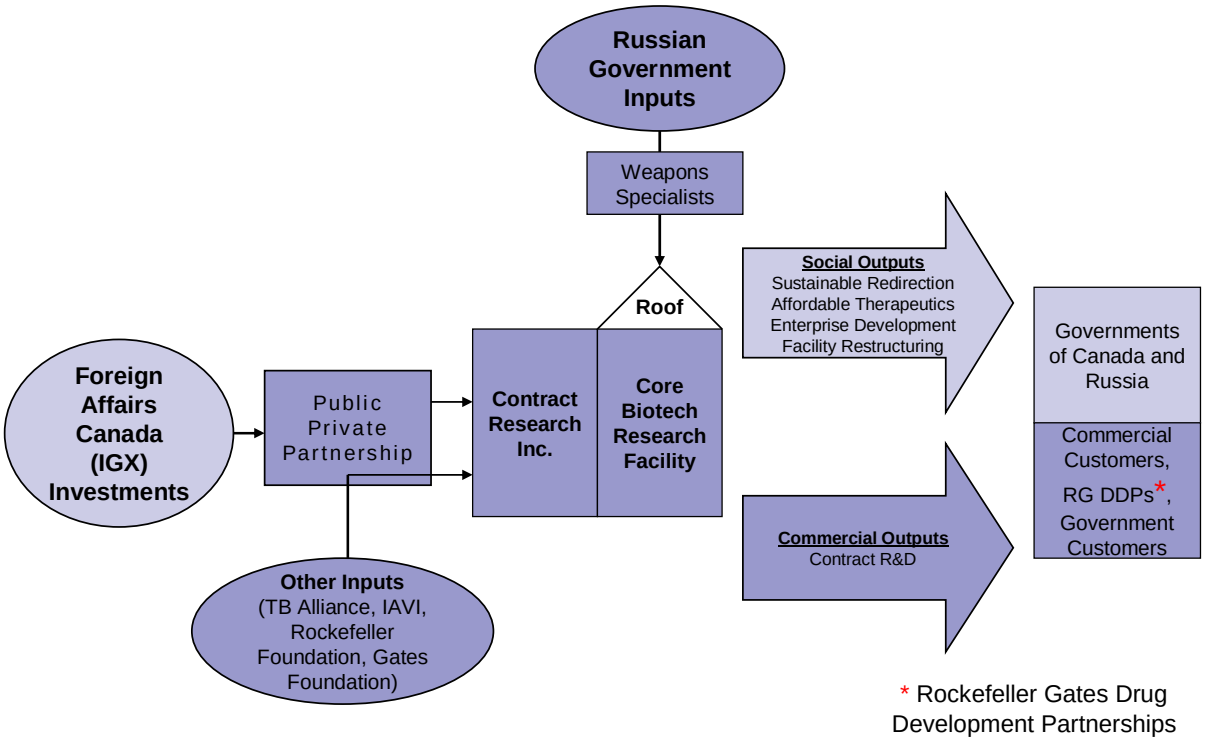
Having a Canadian company establish a subsidiary in Russia that can capture some part of this knowledge and materials base would be a very effective way of building a bridge to support this flow.

Implementation

In this case, the company will need to start with a fact finding trip to Russia to determine if the relevant expertise and phage strains it requires are available within the former BW complex. If that proves to be the case, the next step would be to bring the key scientist(s) to Canada on a CIHR-funded fellowship. Then, as with BioX, a proper assessment of the scientist's compatibility and competence can be made, he or she can be trained to manage a PhageX subsidiary in Russia, and a proposal can be submitted.

PhageX differs somewhat from BioX in its business model. Although the company was similarly created to develop a novel drug, it is not as well capitalized and has therefore had to engage in provision of goods and services, which produce an immediate source of revenue. A Russian facility could potentially augment the company's production and increase the revenue base, increasing the resources available to support its novel drug development. Moreover, the expertise and well-documented strains of phage available in the FSU may further augment the potential value of both its service and research activities.

Canadian Contract Research Organization (CRO) Development in Russia: Case Three—"Contract Research Inc."



Contract Research Inc. is a fictional Canadian firm. Although this company is constantly involved in research and development, most of it is done for clients rather than in development/pursuit of its own product line. Contract Research Inc. is therefore a service provider. The company makes money filling gaps at and adding value to other businesses—such as BioX and PhageX.

This company ideally already provides services to existing product development partnerships sponsored by the Rockefeller and Gates Foundations, BioX, and PhageX. A key issue is to what degree it can produce its services in Russia for customers in North American.

Core Facility

This should only be done in support of self-sufficient biotech companies entering Russia and agreeing in advance to utilize the facility.

Benefits

The core facility is something of a cross between an incubator and a contract research facility. It is conceived in response to a number of observations:

1) The challenges and risks faced by a Canadian company with no experience of the former Soviet Union in establishing a subsidiary there are extensive. With more than one biotech company entering the country under the program, there will be significant benefits to sharing an established facility rather than setting up a new one for each company;

2) In surveying the biotech sector, The Stimson Center realized that there are many companies engaged in providing contract research services to the rest of the industry. Such companies appear to be ideally suited to the task of absorbing excess biotechnological expertise in the states of the former Soviet Union. More needs to be done to assess this potential;

3) An emerging theme among companies already operating in the region suggests that there is insufficient skills-specific training of prospective employees. The reported attrition rates of new hires and costs of on-the-job training are high. A core facility could therefore build in a modest training component funded by other government programs that would both train and help screen potential candidates for jobs in the companies operating at the core facility;

4) This facility, with its training component, has the potential to form the kernel of a Russian biotech cluster. As the number of companies entering the facility increases, so too does the demand for additional goods and services which they consume. With time, this facility could become a self-sustaining magnet for former BW specialists.

Implementation

Critical to success of the contract research company is the acceptance and support of the Russian or other host government. As has been well established, trust is a commodity in short supply in Russia. This is true at both the political and commercial levels. To mitigate these risks, projects should be decidedly modest in their initial ambitions, but should actively build the basis for trust and with it growth in both capability and capacity.

The ultimate goal is a Biotech cluster built around an international life sciences research institute.

Step 1: Establish a small, easily expandable biotech facility that houses a contract research enterprise and 2 to 3 small biotech tenants. Participants in this venture would include: the real estate management company, the contract research company, and 2 to 3 biotech companies leasing space from the former.

Step 2: Expand the core facility to accommodate tenant growth and additional tenants.

Step 3: Establish a small internationally funded research institute that enjoys synergies with tenants and with international public health initiatives. The purpose of such a facility would be to connect the skills of target community and hard investments in their redirection with global health challenges in the field of neglected diseases.

Step 4: Develop a small scale cost-effective GMP-consistent production facility.

Step 5: Expand the institute.

Initial output of the CRO and its tenants is likely for export only; however, domestic companies could also be solicited from the host state. The intent of the facility would be to move to meet needs of the local market as quickly as possible. Growth of the cluster must be responsive to interests of governmental, intergovernmental, non-governmental, but above all, private sector clients. For instance, Russia or the host state may seek to increase quality production of a particular vaccine. In service of its mandate,

UNICEF wants to support an increase in Russian immunization capacity. TB Alliance, a Rockefeller-created and Gates Foundation-funded Product Development Partnership, wants to undertake drug trials or research on a promising compound. Draper, Fisher, Jurvetson, a private venture capital fund in Silicon Valley, wants to co-locate and share administrative resources among new start-ups it is funding or have ready access to contract research or production facilities for its maturing companies.

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PHASE TWO: IMPLEMENTING THE P4P MODEL

Under the contribution agreement with the Department of Foreign Affairs and International Trade Canada, the Henry L. Stimson Center concludes:

1) That the Government of Canada has an opportunity to provide leadership in the development of nonproliferation programs focused on the redirection of WMD scientists in the states of the former Soviet Union;
2) That US Department of Defence bio-redirect programming in Russia has been dramatically scaled back, and that other US-led scientific engagement efforts elsewhere in the states of the former Soviet Union have stagnated due to a series of impediments both self-inflicted and externally imposed;
3) That while evidence indicates that the threat of bio-proliferation may be increasing, topline funding is decreasing due to rising dissatisfaction within the United States (which provides the lion's share of program funds) on the viability and sustainability of current programming;
4) That high commodity prices mean that host governments no longer need emergency funding to support activities within the existing state-run institutes beyond the sharing of best practices in the areas of biosafety and biosecurity; and
5) That Canadian and other G7 programs can therefore shift their "brain drain" focus to enabling employment outside the state sector in areas of strategic interest to other parts of the Canadian government.

The Henry L. Stimson Center's initial findings clearly point to the need for a more deterministic approach to job creation that, if done well, produces value well beyond immediate nonproliferation objectives. This ultimately makes it possible to attract other government and nongovernmental stakeholders that significantly increases the sustainability of both employment for redirected scientists as well as the program itself. The redefined goals of the scientist redirect program within DFAIT should:

1. Meet the immediate nonproliferation needs of the Global Partnership;
2. Build sustainability into existing programming to ensure continuation beyond the sunset of G8 funding in 2012; and
3. Leverage current appropriations in cross-sectoral support of Canadian government priorities.

To achieve this outcome, the Department of Foreign Affairs and International Trade should:

1. Develop interdepartmental buy-in to leverage mutual resources in support of nonproliferation, economic development, and public health objectives.
2. Build capacity to identify and enable the private sector to employ the target population by:
    a. Validating the science available by cataloguing available skills and competencies;
    b. Engaging prospective employers through a systematic survey in Russia and North America with particular focus on viable Canadian biotech firms;

3. Pilot this initiative and ultimately market its utility to other G7 partners as well as to other "clients" in the global health and economic development communities.

This approach is substantively different from those currently in use as it focuses on nonproliferation through employment as the core objective rather than research (ISTC and STCU) or technology development (IPP). At present, employment is an indirect and relatively infrequent consequence of the core R&D objective—it is a byproduct rather than direct result of the programs and therefore, does not achieve *sustainable* nonproliferation objectives.

Nor do existing approaches effectively leverage cross-sectoral/interdepartmental interests. While the Stimson Center finds that Canadian government agencies can make common cause to pursue an agenda, due to a variety of challenges largely related to staffing shortfalls, collaboration to date has occurred on an infrequent and *ad hoc* basis.

The Henry L. Stimson Center proposes to fully develop this new initiative in support of the Government of Canada over the course of the next year. The proposed action plan moves beyond a paper study and begins the process of matchmaking and relationship building that will ultimately lead to implementation of a series of pilot initiatives that sustainably redirect members of the target community. Execution of this plan would unfold in three distinct yet interrelated phases. The culmination of each stage would provide for built-in oversight opportunities and periodic reviews by IGX/DFAIT program managers. Provided that progress is acceptable, and the strategic directions of the initiative continue to fit with the priorities of the Department, it is assumed that each subsequent stage of funding would be made available. The review process would include an opportunity for both IGX and the Henry L. Stimson Center to modify tactics to ensure that we are meeting the appropriate benchmarks for success.

Stage One (6 Months)

Building the Pipeline

In order to build a large number of candidate companies, the Stimson Center will begin to systematically engage the full spectrum of Canadian biotech and life science businesses. At this stage, the central objective will be to comprehensively document the community's interest in and potential for employing FSU scientists and technicians in the states of the former Soviet Union. Existing relationships between these companies and other Canadian government agencies will also be identified in order to more quickly and effectively identify opportunities to integrate the agencies with parallel (or synergistic) objectives into the redirect programming.

Early in this stage, the Stimson team will also travel to Russia and other key FSU states to undertake a landscape study of the countries' respective potential to support a pilot of the new model. This study will entail:

- identifying prospective employers operating locally,
- determining their motivation for participating, as well as
- isolating the incentives they would likely require to hire former bio-weapons scientists, and
- characterizing the existing business environment in order to prepare an appropriate strategy for bringing Canadian companies into the countries.

It would be sensible to include on this trip a knowledgeable member of the IGX team or a third party with the requisite bioscience expertise to independently document the science available within the target community and assess future needs for, and obstacles to, validating it.

Identifying Valuable Science

Validating the science in former bio-weapons institutes in the FSU is an inherently long-term undertaking that requires building trust between the scientific communities in Canada and the host state. Fortunately, the process has already been initiated under the auspices of IGX programming.

Stimson will recruit an advisory working group from this community of specialists to provide the expertise necessary to adequately assess the quality of science available in the target community. Members of this group will be drawn from government, academia and the private sector. This approach will have the additional value of facilitating buy-in from the constituent communities as programming moves into Stage Two. It will also build a self-reinforcing network in support of IGX programming.

In order to quickly compile a baseline of data on the skills and competencies of the scientists and technicians in the target institutes, IGX, as a member of the ISTC and STCU, should commission these organizations to provide what information they have collected and request similar data from the US State Department's Bio-Industry Initiative and Bio-Chem Redirect programs.

The working group will then be convened to sift through the data assembled through the IGX commissions and Stimson field study to identify labs or scientists whose work and competencies warrant more in-depth study. A team of the working group members will then travel to the labs to validate or dismiss the value of these groups to the private sector and government collaborators. Upon return they will support Stimson in marketing the labs and scientists whose capabilities have been validated to prospective employers and government agencies.

Constituency Building

As noted above, the Stimson Center finds that the Department of Foreign Affairs and International Trade should make the inclusion of other government or non-government programs that focus on research and technology development a central component of its national approach to nonproliferation. Involvement of additional government agencies increases the resource base available for job creation, and ensures that there are stakeholders involved who value the output the company creates. This simultaneously reduces risks and increases the odds of success.

This is an ongoing dialogue that will lead project implementers to prospective employers while at once increasing the resources available and strategic reasons for establishing (or expanding) permanent operations in the FSU. The Stimson Center has gone far to develop relationships across a broad array of government departments in Ottawa. In conjunction with the offshore activities outlined above, the next step is to define areas of mutual collaboration and begin to develop programmatic ties between the objectives and capabilities of IGX and the other agencies. The Stimson Center will undertake this bridge building exercise with other federal government departments, and with relevant provincial agencies.

At the end of Stage One, the Stimson Center will present a detailed report on its findings in each activity area. As noted, based upon our findings, that report may include a modified plan for Stage 2 implementation.

Stage Two (5 Months)

Following the assessment undertaken in Stage One, and with the support of the working group, the Stimson team will begin actively marketing the validated science to private companies and collaborating government agencies identified in Stage One. This effort would also begin to translate the IGX's ongoing, in-house commercial "partners" program from constituency building to effective implementation of new pilot efforts. This process will produce a pipeline of prescreened Canadian and local FSU companies interested in employing former BW specialists in the FSU. Criteria for qualifying companies for participation in future programming would include, but not necessarily be limited to:

1. A strategic interest in establishing or expanding operations in the region
    - Serving local commercial markets
    - Utilizing unique intellectual or material resources
    - Supplying goods or services to donor county governments and international organizations for use in the region
2. Sufficient managerial competence and organizational capacity to start up and operate the intended business
3. Existing products or services for an established customer base (commercial, governmental and/or nongovernmental)
    - With the added caveat that these can be cost effectively supplied from the FSU
    - Ability to secure support from other government or non-governmental stakeholders such as CIDA, DRDC, CIHR, NIH, USAID, TB Alliance, IAVI, PATH, etc.

In conjunction with IGX, and in response to the business models of the pipeline companies, Stimson will propose a new funding mechanism to operationalize the new redirect model. Again, a final report detailing our activities will be presented to IGX program managers.

* * *

Two additional stages will be undertaken following the successful completion of Stages One and Two. These steps will be subject to considerable revision as a result of findings and developments in Stages One and Two. Nevertheless, we include an outline sketch below in order to conceptualize the basic steps required to transition to a fully operational program:

Stage Three

1. Begin engagement of prospective employers with potential employees:
    a. Exploratory trips to Russia or Ukraine;
    b. Fellowships at Canadian companies;
2. Transition to permanent management structure;
3. Develop pipeline of potential US employers.

Stage Four

1. Launch first round of programming;
2. Continue developing pipelines;
3. Turn US and other G8 Government agencies and international organizations into clients.

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CONCLUSION

The Department of Foreign Affairs and International Trade has committed substantial resources to redirection efforts in the states of the former Soviet Union. Moreover, the Government of Canada more broadly has emerged as a global leader in the fight against emerging and re-emerging infectious diseases, poverty alleviation, and global economic development. Ensuring the long-term viability of these efforts, along with the highest possible return on these social investments, however, remains an elusive goal. Our scoping study has outlined a pragmatic new initiative designed to achieve this goal.

APPENDIX A -INTERVIEW LIST

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APPENDIX B – ABOUT THE AUTHORS

Brian D. Finlay is a Senior Associate at the Henry L. Stimson Center, where he works on issues of weapons proliferation, global health and development, scientist redirection, and private sector engagement in the former Soviet Union. Brian currently serves as co-director of the Cooperative Nonproliferation Program, a multifaceted program designed to accelerate existing efforts and design innovative initiatives aimed at more rapidly and sustainably securing dangerous nuclear and biological weapons, materials, and expertise while leveraging resources to address other issues of global concern such as international public health and global economic development. Prior to joining the Stimson Center in January 2005, Brian served as Director of the Nuclear Threat Reduction Initiative and as a Senior Researcher at the Brookings Institution. Before emigrating from Canada, he was a Project Manager for the Laboratory Centre for Disease Control, Health Canada, in Ottawa. He has also served as a consultant to the Department of Foreign Affairs, where he worked on the Ottawa Treaty on Landmines and the Comprehensive Nuclear Test Ban Treaty. He holds an MA from the Norman Paterson School of International Affairs at Carleton University, a Graduate Diploma from the School of Advanced International Studies, Johns Hopkins University, and an Honors BA from the University of Western Ontario.

Dr. Elizabeth "Libby" Turpen joined the Centre in 2001 to establish the Senate component of the Security for a New Century (SNC) program at Stimson. SNC is a bipartisan study group series designed to educate Congressional staff about the complex security challenges now facing US policymakers. Prior to joining the Centre, she served as Legislative Assistant for Senator Pete Domenici, responsible for defence, nonproliferation, and foreign affairs. Previously, she was a consultant on nonproliferation policy, US-Russian programs and the national security implications of technology advances for Aquila Technologies Group. Dr. Turpen also has extensive teaching and lecturing experience. She holds a PhD from the Fletcher School of Law and Diplomacy at Tufts University and a BA from the University of New Mexico. Today Libby co-directs the Cooperative Nonproliferation Program, which encourages action by Congress to secure nuclear materials, dismantle existing weapons, and provide new employment for former weapons scientists. Building on a program of research, analysis, and public education, this project also leverages existing networks of private-sector actors to raise awareness of the value of threat reduction and nonproliferation initiatives. Dr. Turpen also continues to direct the Security for a New Century program.

About The Henry L. Stimson Center

Located in Washington, DC, The Henry L. Stimson Center is a nonprofit, nonpartisan institution devoted to offering practical solutions to problems of national and international security. From the beginning, the Stimson Center has been committed to meaningful impact, a thorough integration of analysis and outreach, and a creative and innovative approach to solving problems. The Center has three basic program areas, including: Reducing the Threat of Weapons of Mass Destruction; Building Regional Security; and Strengthening Institutions of International Peace and Security. These three program areas encompass work on a wide range of security issues, from creative approaches to nonproliferation to regional security in Asia to peace operations and domestic preparedness.