James Martin Center for Nonproliferation Studies
Monterey Institute of International Studies
An Affiliate of Middlebury College

SECOND-TIER SUPPLIERS OF BIOLOGICAL WARFARE TECHNOLOGY, EQUIPMENT, AND MATERIALS: THE POTENTIAL ROLES OF CHINA, INDIA, AND CUBA

Raymond A. Zilinskas, Ph.D., Principal Investigator
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CNS MAIN OFFICE
460 Pierce Street
Monterey, CA, 93940
Tel: 831-647-4154 | Fax: 831-647-3519
CNS Washington, DC, Office
1400 K Street, NW | Suite 450 | Washington, DC 20005
Tel: 202.842-3100 | Fax: 202.842.0556
http://www.cns.miis.edu

EXECUTIVE SUMMARY

"Second-tier" suppliers of biological warfare (BW) technology, equipment, and materials are industrializing states with current or past BW programs and/or growing biotechnology sectors, whose commitment to halting the spread of BW capabilities is uncertain. This combination has generated international fears that such suppliers, a group that includes China, Cuba, and India, among others, might be prepared to assist states of proliferation concern to acquire BW programs or enhance the capabilities and scope of existing programs.

This study identifies capabilities and propensities that might lead a second-tier supplier state to assist a state of proliferation concern. A state with a past or suspected current BW program, a BW defense program, or a reasonably advanced civilian bio-technology sectors was found to have the capability to assist others to acquire or enhance a BW program. It was judged that significant political and/or security links between a supplier state and a state of proliferation concern, such as a military alliance, shared strategic threats, and close diplomatic ties and scientific cooperation, make it more likely that the former might be prepared to support the latter's BW ambitions. A state's propensity to proliferate can also be intensified by its need for hard currency. A history of BW-relevant exports, weak export controls, and poor export control enforcement were found to be additional indicators of a second-tier supplier state's propensity to share BW-relevant dual-use commodities with others.

After reviewing the great difficulties confronting efforts to control the proliferation of biological weapons, especially the challenge posed by the inherently dual-use nature of most BW-relevant equipment, materials, and technology, the study assesses the potential of three second-tier supplier states, China, Cuba, and India to assist foreign BW programs, organizing its inquiry around the following questions:

- Does the second-tier supplier have access to previously developed technology for BW?
- What BW-relevant dual-use capabilities and commodities might be available for export from the respective second-tier countries' civilian biotechnology and pharmaceutical sectors?
- What evidence is there, from the status of bilateral relations or from past behavior, to indicate that a particular second-tier supplier might be prepared to share BW-relevant technology or commodities with one or more state of proliferation concern?
- If evidence is found that BW-sensitive items are being exported by a second-tier supplier state, is the export a matter of state policy or of illicit activity by entities not under state control?

When the Center for Nonproliferation Studies began this project, which uses exclusively open sources, its staff expected to be able to access data suggestive or indicative of illicit international trade in dual-use biotechnology equipment and materials. However, despite the use of various search strategies in several languages, no such information was uncovered. Thus, the project did not generate information that allowed its staff to reach a definitive conclusion on the question of whether the Chinese, Cuban, and Indian governments, or companies that operate in these countries, have sold biotechnology dual-use items of BW concern to proliferant nations. Nonetheless, considerable data was collected on the biotechnology capabilities of the three case-

study countries, as well as on international collaboration and trade among research institutions and companies in China, Cuba, India, with Iran.

The three case studies show a pattern of collaboration on apparently non-military, dual-use biotechnology projects between each of the second-tier supplier states and states of proliferation concern. There was no evidence to suggest, however, that the two supplier states with the greatest access to know-how and commodities with strictly military BW applications (China and India) have shared any of this with proliferant states. Moreover, given that underlying relationships between these two suppliers and the proliferant states do not include close military or strategic ties, such transfers would seem inherently unlikely.

The Cuban and Indian governments appear to have approved dual-use biotechnology projects with Iran, and India may also have at least one with Syria. Entities in all three second-tier supplier states considered here have been sanctioned by the United States for providing Iran with Australia Group-listed commodities that could "materially" contribute to a BW capability, but it is not clear whether such exports were licensed and thus were approved by the supplier-state government or were made in violation of the relevant nation's export controls. The supplier-proliferant relationship that appears to be the strongest is between Cuba and Iran, reflected in a number of projects and in the two states' shared hostility to the United States. If the Pasteur Institute vaccine production project in Karaj city (approximately 160 km northwest of Tehran) has been cancelled, this could reflect a diminution of this relationship, however. The following table (also reproduced later in the text, as Table 3) summarizes these findings.

Capabilities and Propensities of China, Cuba, India to Provide BW-Relevant Know-How and Commodities to States of Proliferation Concern

Country	Current BW Program	Past BW Program	Biodefense Program	Dual-Use BW-Relevant Know-How	Manufacture of Dual-Use BW-Relevant Equipment	Gov't Approved Dual-Use Projects with, Transfers to Proliferant States	Private Dual-Use Projects with, Transfers to Proliferant States	Alliance, Strategic Ties to Proliferant State	Close Diplomatic Ties to Proliferant State	Important Economic Relations With Proliferant State	Export Controls
China	Possible	Probable	Yes, significant capability	Yes, significant capability	Yes, significant capability	No major gov't-to-gov't projects w/ Syria, Iran, DPRK. Some with Cuba.	10+ cases since 2000; approval of PRC gov't not clear	No.	Yes. Historically ally of DPRK. Relations now more cautious. (Also, opposes new UN sanctions on Iran)	Yes. Iran (oil)	Yes, Australia Group (AG) list. Enforcement capabilities uncertain. (See p. 7 for a discussion of the AG.)
Cuba	Has relevant capabilities	Some allegations	None apparent	Yes, significant capability	No. Relies on imported equipment	Yes. On-going BW-relevant trade, projects with Iran	Yes. Scale not clear; "private" entities in Cuba extension of government	No	Yes. Shares common hostility with Iran to the U.S.	Yes. Extensive direct investment, financing provided by Iran	Yes. Scope, effectiveness uncertain
India	None alleged	None alleged	Yes, significant capability	Yes, significant capability	Yes, significant capability	Yes. Iran, Syria	Yes. Syria, Iran, Cuba. May be tapering off.	No. Some joint military exercises w/ Iran.	No.	Moderate with Iran (e.g., IPI pipeline)	Yes. AG list. Enforcement capabilities uncertain

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INTRODUCTION AND METHODOLOGICAL CONSIDERATIONS

"Second-tier" suppliers of biological warfare (BW) technology, equipment, and materials are industrializing states with current or past BW programs and/or growing biotechnology sectors, whose commitment to halting the spread of BW capabilities is uncertain. This combination has generated international fears that such suppliers, a group that includes China, India, and Cuba, among others, might be prepared to assist states of proliferation concern to advance their BW programs.

Assessing the potential contribution of such suppliers of BW-relevant technology, equipment, and materials to the proliferation of biological weapons is a subject of considerable complexity, which requires a carefully constructed analytical framework. Although this study focuses on the role of the three states named above as second-tier BW suppliers, it also presents a universally applicable methodology for assessing the potential of other second-tier supplier states to facilitate the BW programs of governments and terrorist groups.

Because the subject is fundamentally a question of supply and demand, a preliminary step in the analysis is to understand the potential customers for of BW-relevant technology, i.e., which are the states of BW proliferation concern and what are their potential needs. A second step is to determine the readiness and capabilities of the second-tier suppliers to meet these needs.

A. The Demand Side: Identifying "States of BW Proliferation Concern" and Their Potential BW Program Needs

In considering of BW proliferation facilitated by second-tier suppliers, it is important to identify which states might be seeking to acquire BW capabilities. In early 2008, three states – Iran, Syria, and North Korea – are of particular concern to the United States and its allies. According to the U.S. Intelligence Community, each of these states is engaged in activities relevant to the production of biological weapons and may have an active BW program.[2]

Identifying the states of current proliferation concern is important, among other reasons, for understanding the particular type of BW program each might seek to develop. Historically, for example, it has been assumed that BW pathogens or toxins, to be of use for weapons purposes, would need to be delivered against enemy population centers or troop concentrations by means of specialized delivery systems, such as ballistic or cruise missiles or aircraft carrying specially designed cluster bomb systems or equipped with spray equipment. To be sure, Iran, Syria, and North Korea have sought to develop potent missile capabilities that can strike all potential adversaries in their respective regions, conceivably including missiles with biological warheads. But they also have sought to pursue regional politico-military objectives by other means, such as terrorist-style activities within adversary states or military operations short of war through the actions of proxies, including state-supported terrorist groups.

Thus, for these states, a BW program that relied on unconventional means of delivery might be as effective in achieving strategic goals as biological attacks using missiles or other military delivery systems. Specifically, while classic national BW programs would need to develop BW agents that could survive during the flight of a missile warhead and while being dispersed in a pattern that covers the area occupied by the target population, the use of unconventional delivery means – such as the use of mail systems, person-to-person transmission of pathogens, or trucks carrying spraying equipment – might be no less effective in the theaters of interest to Iran, Syria, and North Korea and might even be better suited to these nations' strategic goals by leaving less or no evidence as to the originator of the attack.

Also important to understanding the potential demand for BW-relevant technology is the current status of the BW programs in the states of proliferation concern. We posit the existence of two types of programs. The first is comprised of programs that are already advanced; in this case, the demand for matériel from outside suppliers might be minimal. The second type is comprised of limited or undeveloped programs; in this case, the demand for outside assistance could be substantial. As discussed below, the political relationships between specific states of proliferation concern and specific second-tier suppliers of BW-related technology, equipment, and materials are also important.

With this in mind, what external support might the three states under consideration need to advance a military BW program or to supply dependent terrorist groups with biological weapons capabilities? As a starting point, Table 1 (see next page) contains lists identifying capabilities of importance to both types of BW programs and key commodities and know-how that would be required to enhance or advance such programs, including matériel that proliferant states might seek from second-tier supplier countries.

In principle, it should be possible to determine the actual needs of specific states of proliferation concern and match them with the supply capabilities of the three second-tier supplier states. Given the secrecy surrounding the possible BW programs in proliferant states, however, in this study it has not been possible to pursue this analysis further.

B. The Supply Side: Second-Tier Suppliers – Uncertain Commitment to Nonproliferation Plus Extensive BW or Dual-Use BW-Relevant Capabilities

States of proliferation concern are likely to look to second-tier suppliers to advance their BW programs because the first-tier suppliers, i.e., advanced industrialized states with highly developed biotechnology sectors – principally the OECD countries – are less likely to be willing to provide such assistance. With the possible exception of Russia, all of the first-tier supplier states have demonstrated their commitment to the nonproliferation of biological weapons through their adherence to and compliance with the Biological and Toxin Weapons Convention (BWC), which prohibits State Parties from providing BW-related items to other countries or sub-national groups, and (again excepting Russia) through their membership in the Australia Group (AG), an informal coalition of supplier states that have voluntarily established strict controls over exports of dual-use chemical and biological production technologies, equipment, and materials.[3]

Although the second-tier supplier states considered here are BWC state parties, none has been invited to join the AG, in part because of uncertainty on the part of the group's membership regarding these states' compliance with the BWC and/or their commitment to the

Table 1: Proliferant State BW Program Requirements Provided by Second-Tier Suppliers

Military BW Capability	Terrorist BW Capability	Essential Commodities Potentially Needed from Second-Tier Suppliers
Highly lethal BW pathogen strains or toxins	Same	Virulent BW bacterial or viral strain or quantities of toxins
Weaponized agents (i.e., agents formulated and sized for aerosol delivery)	Same	Specialized processing knowledge; specialized formulation knowledge, BSL-3 or BSL-4 containment laboratories, personal protective clothing and equipment; aerosol inhalation chambers; separation equipment, drying equipment, milling equipment, filling equipment.
Aerosolization technology to ensure effective dispersion	Useful	Specialized knowledge pertaining to explosive and spray dispersal of BW agents; specialized knowledge related to meteorology; sprayers or nebulizers emitting particles of less than 10 micron size, personal protective clothing and equipment.
Industrial-size production of BW agent	Laboratory-size production of BW agents	Specialized processing knowledge; bench-top fermenters and down-stream processing equipment for terrorists including separation and drying equipment, industrial-size fermenters and down-stream processing equipment for military programs, including separation and drying equipment.
Weaponized agent suitable for military delivery	Not required	All of above focused to ensure compatibility of agent with delivery system (e.g., survivability during flight and after release into the environment).
Specialized bombs, bomblets, or missile warheads for delivering BW agents	Not required	Specialized know-how related to weapons engineering and energetics; specialized alloys for manufacturing delivery components; guidance systems for missiles; manufacturing equipment all the above.

nonproliferation of BW. Assessing the readiness of the second-tier suppliers to lend support to BW programs elsewhere is, undoubtedly, not an easy task; such an assessment must take two key factors into account, namely whether the supplier state possesses *capabilities* that might assist a proliferant state and whether its leadership has a *propensity* for doing so.

1. Capabilities

To determine the capabilities of a second-tier supplier to support a foreign BW program, it is necessary to examine the scope of the former's own offensive BW program, if any; the scope of its biodefense program, if any; and the scope and capabilities of its civilian biotechnology sector.

- Offensive BW program. If the second-tier supplier has, or previously had an offensive BW program, then it presumably would have the ability to transfer a wide-spectrum of BW-relevant knowledge and equipment to others. Two of the three second-tier suppliers that are the focus of this study (China and Cuba) have been accused of pursuing offensive BW programs, either currently or in the past.
- BW defense program. Even if the second-tier supplier has pursued only a BW defense program, however, in doing so, it may have mastered skills useful for an offensive BW effort that it could share with states of proliferation concern. The second-tier supplier, for example, might have learned to enhance the lethality of various pathogens in order to develop counter-measures. As will be seen, China and India have extensive biodefense programs.
- Significant biotechnology industry. Because of the dual-use nature of materials, equipment, and technology used in the civilian biotechnology industry, the more advanced and extensive a second-tier supplier's biotechnology sector, the greater the state's ability to support BW programs elsewhere. Each of the three second-tier suppliers discussed here has a substantial civilian biotechnology industry, although some are more advanced than others in certain areas.

2. Propensity

The readiness of a second-tier supplier state to provide BW-related assistance to a state of proliferation concern also depends on the *propensity* of the supplier to do so. Relevant factors are whether the supplier and potential recipient are allies, share a common strategic outlook, or have close diplomatic ties; whether the supplier is in dire need of hard currency; and whether the supplier has a history of WMD-relevant exports to states of concern. In contrast to these factors that may stimulate dubious dual-use trade, the commitment of a state to effective export controls may be an indicator that it is less likely to share sensitive technology with would-be proliferants.

- Military alliance. The political and military relationship of a second-tier supplier state with a particular state seeking assistance is an important element in this calculation. If a second-tier supplier country is a close ally of a proliferant state, for example under a mutual defense treaty, it is more likely that the former might wish to assist the latter to achieve a WMD capability. None of the states examined in this study has a military alliance with current states of proliferation concern.
- Shared strategic threats. Conceivably one or more of the second-tier suppliers that are the subject of this study might seek to enhance the BW capabilities of one or more states of proliferation concern in order to create a counterweight to the United States. Both Cuba and Iran, for example, have hostile relations with Washington and might seek to collaborate in developing a BW capability to threaten the United States.
- Close diplomatic ties; scientific cooperation. Even without a strategic relationship, a second-tier supplier might adopt a relaxed attitude toward dual-use biological exports to a state that it sought to influence or with which it wished to show solidarity. Cordial relations could also facilitate the pursuit of joint projects, such as vaccine production facilities or collaborative scientific research, through which BW-relevant technology and commodities might be transferred to the state of proliferation concern and then diverted to military purposes. In this regard, Cuba's ties to Iran are the most salient.

- Financial need. A second-tier supplier state's need for hard currency could also make it more ready to sell BW-relevant dual-use goods to states of proliferation concern. This could, for example, be a possible motivating factor for Cuban biotechnology sales to Iran. The drive for profits can also be a motivation for entities within second-tier supplier states to make such sales, including, in some cases, readiness to bypass relevant export controls. Entities in China and India appear to have made BW-relevant transfers for this reason.
- History of WMD exports. The history of a second-tier supplier state's WMD-related exports may also provide evidence of a propensity to support foreign BW programs. The export of specialized know-how and equipment required for the weaponization and delivery of BW agents; exports of dual-use items in quantities or with characteristics inconsistent with civilian uses; or a pattern of extensive civilian dual-use exports to states accused of developing BW would all be indicative of a propensity to assist such programs. Cuba's exports to Iran may fall into the last category; Chinese and Indian entities have made some BW-relevant exports to Iran in recent years, but on a more limited scale and in circumstances making it difficult to determine whether the exports were authorized by the national government involved.
- Export controls and enforcement. The adoption of strict regulations on the export of dual-use BW-relevant technology and goods and the effectiveness of their enforcement can also provide insight into a second-tier supplier state's propensity to support foreign BW developments. China, India, and Cuba have been accused of improper BW-related exports in the past, but the frequency of such episodes has decreased in some cases. The three states have also adopted tightened regulations on the export of dual-use biological equipment and materials, but their enforcement of these regulations appears to be weak.

C. Issues for Consideration

In sum, many issues need to be examined regarding both supply and demand of BW-relevant commodities before a judgment can be offered on the potential role of the second-tier supplier states, the chief four of them being:

- Does a second-tier supplier have access to previously developed technology for BW?
- What BW-relevant dual-use capabilities might be available for export from the respective second-tier countries' civilian biotechnology and pharmaceutical sectors?
- What evidence is there, from the status of bilateral relations or from past behavior, to indicate that a particular second-tier supplier might be prepared to share BW-relevant technology or commodities with one or more state of proliferation concern?
- If evidence is found that BW-sensitive items are being exported by a second-tier supplier state, is the export a matter of state policy or of illicit activity by entities not under state control?

In the study that follows, these issues are examined as they relate to China, Cuba, and India. The study is divided into four sections. The first section, a background section, briefly describes special characteristics of biological weapons, examines the international regime that seeks to prevent the use and proliferation of biological weapons, including the AG and the BWC, and discusses the dual-use dilemma presented by biotechnology. The second section is

comprised of case studies of the three main second-tier suppliers that pose a BW proliferation risk. As is explained in the introductory paragraph to that section, each case is organized similarly. The third section uses the information from the case studies for the purpose of analyzing the four issues presented above in terms of each country. The fourth section contains the study's conclusions. Endnotes provide references and added informational material.

The information in this study was all derived from open sources, including declassified government documents from the Defense Technical Information Center, news outlets (e.g., Cuba's *Granma Internacional* and *Cubavision*, and the *Tehran Mehr News Agency*), government websites (e.g., The Presidency of the Islamic Republic of Iran), research institutes (e.g., the Nuclear Threat Initiative), and scientific and other periodicals. The researchers also used many web-based databases, including the Open Source Center (*OpenSource.gov*) and search engines. The completeness of this study was ultimately limited, however, by the extent of information that is available from open sources.

I. Background to Biological Weapons and Arms Control

A. Uniqueness of Biological Weapons

Biological weapons pose a unique and substantial set of challenges for those seeking to prevent their proliferation and use. First, biological weapons can be used in a variety of attack scenarios, including large-scale aerosol attacks against human populations to cause mass casualties or against livestock or crops to harm national economies.

Second, virtually all of the equipment, supplies, and knowledge required for biological weapons are dual-use: they are primarily used in peaceful and productive pursuits, including industrial microbiology, pharmaceutical production, fermentation, and agriculture, but they may be adapted fairly easily for BW purposes. Although some of the items used in nuclear and chemical weapons programs are also dual-use, the difference is that essentially all BW-related items are dual-use.

Third, the availability of even sophisticated dual-use items and BW-related knowledge has increased dramatically over the past 25 years because of four factors:

- The biotechnology revolution, which has fueled the development of dual-use equipment, is now a global phenomenon;
- The population of competent biomedical scientists and technicians has grown tremendously, and its members are now dispersed throughout the world;
- The disruption of state-level BW programs in the Soviet Union, South Africa, and Iraq has led to the unemployment of former bio-weapons developers, who are potentially available for hire by proliferant countries and terrorist groups; and
- The dissolution of the Soviet Union and the fragmentation of Iraq have resulted in many insecure facilities containing biological agents, increasing the risk that pathogenic microorganisms and dual-use equipment and materials could be stolen or otherwise diverted to biological weapons development.

In addition to these developments, the international biological arms control regime is weak, lacking verification or inspection provisions to ensure compliance by the participating states.

B. Biological Arms Control

The main instrument of international law that seeks to stem the proliferation of BW is the BWC. For the purpose of this study, Article III is of greatest relevance. It provides:

> Each State Party to this Convention undertakes not to transfer to any recipient whatsoever, directly or indirectly, and not in any way to assist, encourage, or induce any State, group of States or international organizations to manufacture or otherwise acquire any of the agents, toxins, weapons, equipment or means of delivery specified in Article I of this Convention. [The commodities specified in Article I are "(1) Microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes and (2) Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict."]

Although some BW-related proliferation has taken place since the BWC came into force in 1975, Iraq's BW program and the acquisition of biological weapons by the Japanese sect Aum Shinrikyo being the important examples, no BWC State Party has asserted that Article III has been violated. One reason for this inaction probably has to do with the difficulty of detecting illicit transfers by other nations. Moreover, if a suspect transfer is detected, it is difficult for member states to reveal this information without compromising intelligence sources and methods. In view of the apparent ineffectiveness of Article III of the BWC in stopping the international proliferation of BW-related equipment and materials, Western democracies have instituted alternative means, such as national export controls and the AG. In addition, in 2004 the United Nations Security Council adopted Resolution 1540, which requires all states to pass domestic legislation to regulate the transfer of all WMD-relevant technologies to prevent proliferation of WMD and WMD-capable missile systems.[4]

The AG is an informal international export control arrangement that was established in 1985 in response to the use of chemical weapons during the Iran-Iraq War.[5] The AG, whose "participants" currently number 40 nations and the European Commission,[6] is "informal" because it is not established under an international treaty or other formal legal document. The group's membership is limited, with new members accepted only by a consensus of the current members. The group meets semi-annually in Paris.[7]

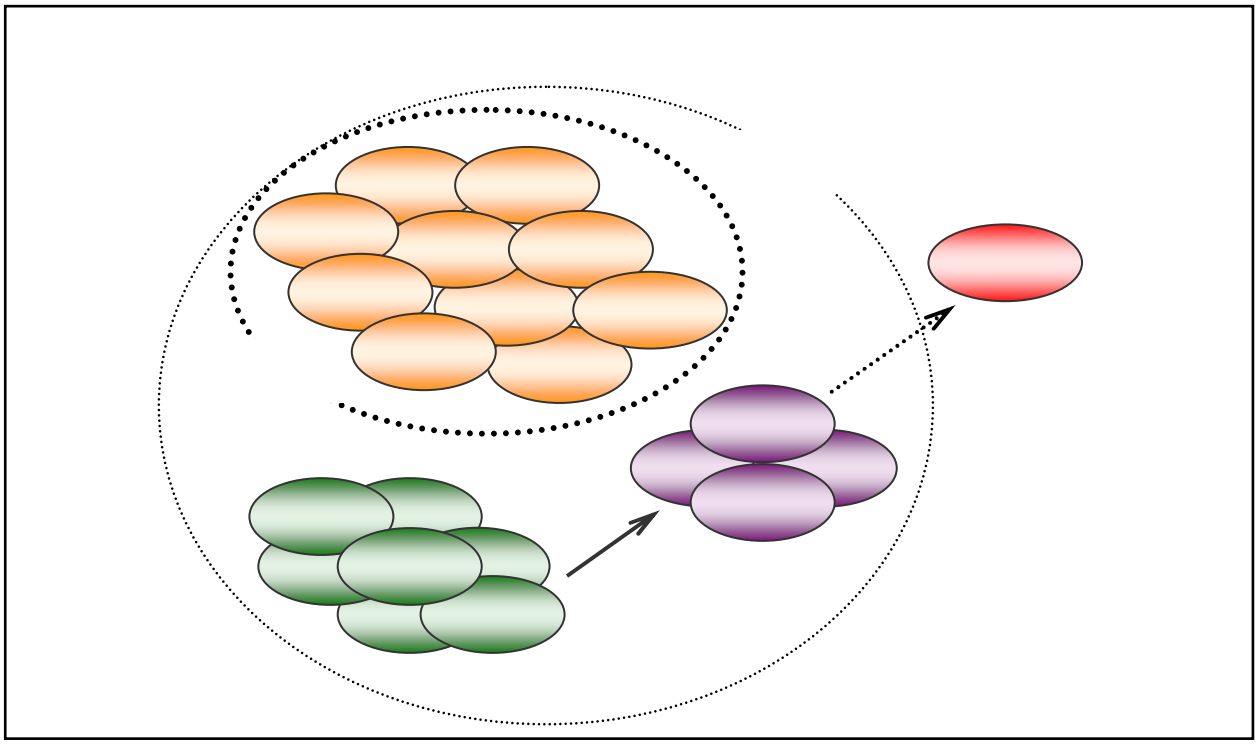
AG participants engage in two main types of activities. First, they seek to harmonize their national export controls to impede states of concern or terrorists from acquiring dual-use equipment or materials produced in participating countries. Second, AG participants informally share information derived from national intelligence gathering efforts to help inform their respective export licensing decisions.

Altogether, the individual AG participants are said to consider a total of 2-3 million requests annually for transfers of items on the AG control list.[8] Only about 0.3 percent of these requests are actually denied. Historically, nearly all of the denials have involved proposed exports to only four countries: Iran, Iraq, North Korea, and Syria.[9]

A number of countries, especially members of the Non-Aligned Movement (NAM), believe that the AG should be abolished in favor of the import/export restrictions and related commitments contained in multilateral agreements, such as BWC, Article III discussed above.[10]

The BWC also contains a provision guaranteeing the right of all parties to exploit biological technology for peaceful purposes and calling on the more advanced states to help less developed nations to exploit the technology for this end.[11] Many developing countries object to the AG as restricting this right of access to biotechnology and have demanded that export controls be limited to those implicit in the BWC's prohibition on the transfer of biological weapons and related BW-specific equipment. Under UN Security Council Resolution 1540, however, all states are required to implement effective export controls on WMD and missile related commodities, which presumably means adopting control lists comparable to those of the Australia Group.[12] Figure 1 illustrates these relationships.

Figure 1: Dual-Use Trade and its Regulatory Environment



In Figure 1, the small individual ovals surrounding individual state names represent national export controls, which limit BW- relevant exports beyond states' respective borders. For all states, such controls have been required under UN Security Council Resolution 1540 since 2004. For parties to the BWC, such controls are also implicitly required by the convention's ban on providing biological weapons to other states. The dashed circle around the AG represents the guidelines of the AG through which AG members voluntarily coordinate exports to other states, including exports to potential second-tier supplier states and states of proliferation concern. Individual second-tier supplier states and even states of proliferation concern also have their individual export control systems, of varying comprehensiveness and effectiveness, but do not coordinate exports among themselves. They are shown within the Resolution 1540/BWC circle.[13] Second-tier supplier state export controls are not known to have restricted BW-relevant exports to the states of proliferation concern, and because of links between members of each group described later in this study, an arrow indicates the possibility of transfers of this kind.

Non-state actors fall outside the UN Security Council Resolution 1540/BWC circle (that is, their behavior is not regulated by these instruments). Because the United States has designated Iran, Syria, and North Korea as state sponsors of terrorism the possibility of transfers from these states to terrorist organizations is indicated by the arrow between them.

C. The Dual-Use Dilemma and Transfers from Second-Tier Supplier States

BW specialists Ronald Atlas and Malcolm Dando have succinctly described the dual-use dilemma presented by biotechnology:

> The life sciences embody an inevitable "dual-use dilemma" – the need to balance the quest for advancing biomedical research and biotechnology with the need to prevent the development of biological weapons for biocrimes, bioterrorism, and biowarfare.[14]

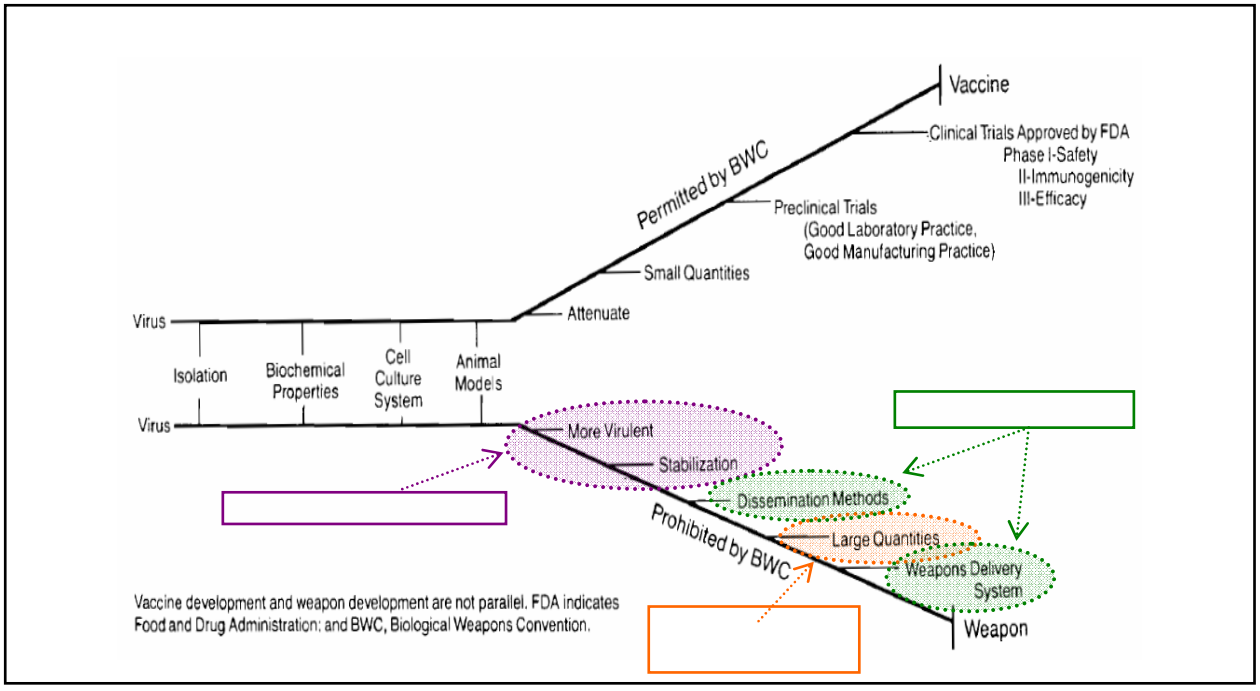


Figure 2: The Dual-Use Dilemma Illustrated – Vaccine vs. Weapons Development.[15]

Figure 2 illustrates several aspects of this dilemma, including problems pertaining to distinguishing between licit and illicit research and development (R&D).[16] At the research stage, it is impossible for an outsider to determine whether the intent of particular work being pursued by a state is peaceful or is being carried out for hostile purposes. In both cases, for example, it would be necessary to measure the growth characteristics of the pathogen of interest, characterize the relationship between the pathogen and the host, identify the infectiveness and virulence characteristics of the pathogen, and so forth. Because the research would be similar regardless of the intent behind it, the BWC does not attempt to control research. It is not until the development stage that an outsider might have a chance of determining the goal of the activities taking place.

As indicated in Figure 2, a bifurcation occurs at the development stage. To develop a vaccine, the developer needs to attenuate the virus of interest, whereas to weaponize the virus, the developer needs to enhance such properties as infectivity, virulence, and hardiness. Weaponization is, of course, a violation of the BWC.

The dual-use nature of BW-relevant technology and commodities means that second-tier supplier states can contribute to BW programs in states of proliferation concern in a number of ways. Most obviously, the supplier can offer direct assistance to the military aspects of the program in areas prohibited by the BWC, such as the weaponization of pathogens or information on delivery systems. But it can also give a boost to a BW program by providing more generalized research support, equipment, and training, which is subsequently applied by the recipient in advancing the development of its BW program. AG members avoid transfers of both types to states of proliferation concern, but second-tier suppliers appear to be less cautious. Some, for example, have openly engaged in transactions and joint projects with apparently peaceful purposes, but which by their inherent nature inevitably build capacity in the recipient state potentially useful for BW. Although research reported in the open literature has not disclosed examples of second-tier supplier state support for the military side of a foreign BW program, it is possible that such transfers have taken place or could occur in the future.

When analysts consider what types of dual-use items a second-tier supplier might be capable of developing, manufacturing, and exporting, they typically refer to the AG lists of biotechnology equipment and biological pathogens and toxins as a basis for analysis. The biological control list developed by the AG provides a good starting point for discussion because the participating states have agreed by consensus that these items should be subject to export controls. The list is somewhat outdated, however, and lacks some important categories of items, such as milling devices, peptide synthesizers, and Class III biosafety cabinets.

In addition to the AG list, an analyst assessing the capabilities of a second-tier supplier state must also examine so-called “knowledge indicators.” There are two types of knowledge indicators: (1) expertise associated with operating specific equipment and processes; and (2) knowledge of specialized biomedical and bioscientific fields, such as molecular biology, genetic engineering, and bioprocessing. In terms of specific equipment and processes, knowledge indicators include the ability to enhance the desired characteristics of a microorganism through the use of genetic engineering, to process and formulate microorganisms for aerosol dispersal, and so forth. Industry knowledge indicators include the number and size of state- and privately funded research facilities possessed by a country, the annual number of advanced degrees it confers in the biological sciences, and the extent of scientific achievement of its scientists (such as the number of patents or unique pharmaceutical brought to market). As will be clear to the reader from Section III of this study, all three second-tier supplier states investigated here possess both types of knowledge, underscoring their potential to contribute to foreign BW programs.

The dual-use dilemma also increases the difficulty of discovering illicit BW programs or, for the proliferator, facilitates hiding them. In the cases of the Soviet Union and Iraq, illicit BW activities were concealed in the guise of R&D for peaceful or defensive purposes. These programs also avoided detection by (a) hiding facilities, sometimes in plain sight; (b) developing elaborate cover stories for illicit programs, usually that they are peacefully directed or for defense only; and (c) using covert purchasing networks to bypass export controls.

Given the international revulsion to biological weapons and the fact that all current states of proliferation concern are BWC parties or signatories, it may be assumed that these states are

hiding their BW activities from all observers, including one or more of the second-tier suppliers. Nonetheless, in view of the allegations repeatedly publicized by the United States to the affect that Iran, Syria, and North Korea have or are pursuing BW capabilities, second-tier supplier states are on notice that their biotechnology exports to these three countries may ultimately contribute to military programs. Indeed, if for this reason the second-tier suppliers are limiting the biotechnology exports to states of proliferation concern, it is possible that the states of proliferation concern have turned to using covert purchasing networks to by-pass the export controls not only of AG members, but also of one or more second-tier supplier.

II. COUNTRY CASE STUDIES: CHINA, CUBA, INDIA

The three case studies of second-tier suppliers are organized so that sufficient high-quality information is presented to allow a robust analysis of these cases in Section III of this study. As noted above, four major issues are covered in depth.

Thus, to address the issue, "Does a second-tier supplier have access to previously developed technology for BW," it is necessary to determine whether the country in question may have, or previously had, a BW program and/or whether it possesses a program to defend against BW and, if so, the extent and quality of that program. The second is important because in order to be able to effectively defend against BW, a state must be knowledgeable about how offensive BW programs operate. Therefore, the first of the four sub-sections that constitute each case study consists of a description of the country's possible involvement with BW.

To address the question of, "What BW-relevant dual-use capabilities might be available for export from the respective second-tier countries' civilian biotechnology and pharmaceutical sectors," the second subsection of each case study contains a characterization of the respective country's biotechnology capabilities.

To address the issue, "What evidence is there, from past behavior or from the status of bilateral relations, to indicate that particular second-tier suppliers is prepared to share BW relevant technology or commodities with one or more state of proliferation concern," the third subsection of each case study is dedicated to a consideration of the nature and extent of the second-tier supplier country's trade relationships pertaining to dual-use biotechnology items, as well as other relevant bilateral links. This review includes an examination of the sanctions imposed by the U.S. government on entities headquartered in the three case study countries for making exports to countries of proliferation concern of items on international control lists, including the AG list. The U.S. government currently has in place eight legal instruments for imposing sanctions against foreign individuals, private entities, and governments that engage in such activities.[17] Unfortunately, the U.S. government rarely explains in the open literature why a particular sanction has been imposed, leaving some ambiguity as to the particular nature of the offense at issue.

Finally, for the very difficult issue, "If evidence is found that BW-sensitive items are being exported by a second-tier supplier state, is the export a matter of state policy or of illicit activity by entities not under state control," the fourth subsection of each case study considers the country's export rules and regulations and information that cast light on government-industry relations.

A. The People's Republic of China

1. China's possible involvement with offensive biological warfare

According to a 2001 report by the U.S. Department of Defense, China operated an offensive BW program prior to joining the BWC in 1984 and was believed as late as 2001 to be operating a clandestine BW program based on technology acquired before that time.[18] The pre-1984 program allegedly was never completely dismantled after China ratified the BWC; rather, the report states, it was scaled back and hidden in government-owned biotechnology research facilities. This line of thinking appears to persist; in 2003, Paula DeSutter, U.S. Assistant Secretary of State for Verification and Compliance, alleged that China was not in compliance with the BWC, stating that there were "strong indications" that China probably maintained an offensive BW program, including the development, production, and stockpiling of agents.[19] A subsequent statement by DeSutter was more cautious. It was made in 2006, when DeSutter testified that the U.S. government had "reservations about China's current research activities and dual-use capabilities, which raise the possibility that sophisticated CBW work could be underway" at military and civilian institutions in China.[20] However, in January 2007, Lieutenant General Michael D. Maples, director of the U.S. Defense Intelligence Agency (DIA), stated "DIA believes China continues to maintain some elements of an offensive biological weapons program. China possesses a sufficiently advanced biotechnology infrastructure to allow it to develop and produce biological agents."[21] No specific evidence has been published to support these U.S. government allegations, however.

Although China is a party to the BWC and the CWC, it is not a participant in the AG. Until late 2004, China argued that the AG trade restrictions were unfairly discriminatory and violated the CWC.[22] To illustrate, in 2000, the Chinese Minister of Foreign Affairs published an official statement that read: "China holds that the Chemical Weapons Convention which has entered into force should constitute the sole legal basis for governing the international chemical trade. Those export control regimes incompatible with the convention should be transformed or abolished. China strongly opposes the actions by the member states of the Australia Group in obstructing the normal chemical trade between States Parties to the Convention under the pretext of non-proliferation."[23]

For unknown reasons, China appeared to have changed its mind about the AG and began discussing membership with it in 2004.[24] In June 2006, Chinese government officials held further talks in Beijing with the AG Chairman.[25] Also in 2006, the Chinese government added 14 new items to its biological control list, reflecting updates that had been made to the AG list. It seems that although China either has made the decision to stay out of the AG for the time being, or is being kept out by one or more AG participants, it is expecting membership in the future and therefore is using the AG as a model for its CW and BW export control system.

The Chinese government has endorsed UN Security Council Resolution 1540, which requires domestic controls to prevent the proliferation of weapons of mass destruction, including biological weapons, to non-state actors and proliferant states. In this regard, the official Chinese statement reads as follows:

> China attaches great importance to the UN Security Council Resolution 1540 and is among the first to submit national report on the implementation of the Resolution. We will continue our active participation in the work of the UNSCR 1540 Committee and work with all parties to ensure the effective implementation of the Resolution. China is

positively considering hosting a regional seminar on issues related to UNSCR 1540 and is discussing this matter with relevant body of the UN.[26]

China did, in fact, host the promised seminar, on July 12, 2006.[27] Although it achieved no concrete results, it did demonstrate that the Chinese followed through on their promise to host the event in support of the resolution.

As for Chinese institutions and facilities that have been alleged to be involved in BW-related activities, some appear phantom-like while others have concrete form. Examples of the first type include two unnamed "ostensibly civilian research institutes" that U.S. intelligence officials are supposedly concerned about.[28] (U.S. specialist Milton Leitenberg believes that the facilities in question may be the Institute of Epidemiology and Microbiology in Beijing and the School of Medicine in Shanghai.[29]) On April 5, 1999, Soviet defector Kanatjan Alibekov (Ken Alibek), the former deputy director of the Soviet Biopreparat BW program, asserted that China had suffered a serious accident at a BW laboratory in the late 1980s. Alibekov stated that Soviet reconnaissance satellites had identified the BW laboratory near the Chinese nuclear weapons test site at Lop Nor. He also claimed that after two epidemics of unidentified hemorrhagic fever swept the region in the late 1980s, Soviet analysts "concluded that they were caused by an accident in a lab where Chinese scientists were weaponizing viral diseases."[30] No corroborating information is available to support the foregoing two allegations.

2. China's biodefense program

China has a large biodefense program on which it reports annually to the UN Department of Disarmament Affairs as part of the BWC confidence-building measures (CBMs).[31] This declaration suggests that China has conducted a substantial amount of research on potential BW agents, ostensibly for defensive purposes. Agents researched include the causative agents of tularemia, Q fever, plague, anthrax, eastern equine encephalitis, psittacosis, and others.[32] China also possesses the capability to mass-produce most of the traditional BW agents, including those that cause anthrax, tularemia, and botulism. It has expertise in aerobiology, reportedly having conducted laboratory-scale aerosolization experiments with various microorganisms.[33]

China's 1992 CBM declaration identifies three organizations within the Ministry of Defense as being involved in its national biodefense R&D program: the Medical Department of the General Logistics Department, the Academy of Military Medical Sciences, and the Institute of Microbiology and Epidemiology.[34] Other sources indicate that an additional organization also has a role in biodefense, the Military Medical Research Institute of the Beijing Military Region. No information is available on the first of these agencies, but brief descriptions of the other three follow.

Academy of Military Medical Sciences (AMMS), Beijing. The AMMS describes itself as follows:

> The Academy of Military Medical Sciences (AMMS), founded in August l951, is the highest medical research institution of the People's Liberation Army (PLA). The Academy is organized into six research institutes: including the Institute of Medical Information, Institute of Radiation Medicine, Institute of Basic Medical Sciences, Institute of Hygiene & Environmental Medicine, Institute of Microbiology & Epidemiology, Institute of Pharmacology & Toxicology, and

> Institute of Medical Equipment and Institute of Bioengineering. In addition, there are subordinate units such as the Affiliated Hospital, Experimental Instrument Plant, and Laboratory Animal Center. Employing a large group of senior scientists and technologists, including four academicians of the Chinese Academy of Sciences (CAS) and four academicians of the Chinese Academy of Engineering (CAE), AMMS is mainly engaged in research on the medical protection against extreme environments and special injuries in peace and war time and sanitary and anti-epidemic technologies and equipment. After more than 40 years of construction and development, AMMS has become a multidisciplinary and comprehensive medical research institution with about 20 cross-disciplinary research centers and key laboratories such as the National Center for Biomedical Analysis, the National Center for New Drug Nonclinical Safety Evaluation (GUP laboratory), the National Base for Clinical Pharmacology, the Army Research Center for Preventive Medicine, and the Army Emergency Medical Aid Center for Nuclear Accidents, The Academy has undertaken and completed a number of important research projects assigned by the Army and the State, and earned about 1500 awards for research achievements.[35]

In 1995, the *ASA Newsletter* published a more complete report on the AMMS Institute of Pharmacology and Toxicology (IPT).[36] It reported that the IPT is the "prime" research facility of the AMMS and the People's Liberation Army (PLA). The IPT was founded in 1958, and in 1995 it consisted of 10 divisions or laboratories and had a staff of 300 researchers, engineers, technicians, and administrative personnel. Most of the divisions concentrate on defenses against chemical weapons. With respect to BW, however, three IPT divisions are of interest: Psychopharmacology (mechanisms of drugs at the receptor, enzymatic, and molecular levels), Immunopharmacology (biological actions of drugs and toxins), and Natural Products Chemistry (toxins).

An article published in 1995 in the Chinese government publication *People's Military Surgeon* also discussed the ITP, but in more general terms. According to author Zheng Baozhen, the ITP is mainly concerned with developing defenses against nerve agents, blistering agents, and "biological-source agents," a probable reference to toxins.[37] The article did not discuss the size of the institute, its personnel, or specific work program. According to another article in the same journal, the AMMS Intelligence Research Institute tracks BW-related activities in other countries.[38] Its work on "neurotoxicants" was lauded in a Chinese newspaper.[39]

In 1998, the AMMS reportedly entered into an agreement with the Shenzhen city government to build a "biological engineering industrial base" there.[40] Reportedly, the AMMS "will provide its latest biological engineering discoveries" to this base.[41]

Institute of Microbiology and Epidemiology. Very little information exists about this institute.[42] The institute is located in Beijing, supposedly has a small BSL-3 laboratory, employs 246 persons (106 of them scientists), and its fields of interest are aerobiology, biochemistry, epidemiology, and microbiology.

Military Medical Research Institute of the Beijing Military Region (MMRI). MMRI's predecessor, the 26th Epidemic Prevention Unit, was set up during the Korean War to improve the "extremely poor" hygienic conditions of the PLA.[43] It is not stated when the 26th Epidemic Prevention Unit became MMRI. Also called the "anti-biological warfare unit," MMRI is reportedly under the authority of the public health division of the PLA's General Department.[44] Wong Mei reports that the facility is staffed by 20 "research personnel" and that during 1984 – 1994 it completed 61 research projects, of which 46 "won awards."[45]

MMRI's major laboratory is the All-Army Laboratory for Medical Prevention and Control of Insects; reportedly, it houses a collection of "tens of thousands of deadly insects." The institute also is reported to have a "virulent bacteria laboratory" and to work with *Brucella*, the causative agent of brucellosis.[46] The facility reportedly develops products for sale on the open market; 16 products were identified by Mei, including "sewage purifying machines, multifunctional ozone disinfectors, and hand disinfectants."[47]

Vaccine Manufacturing Plants. In its CBM report for 1995, China named seven vaccine production facilities: National Vaccine and Serum Institute (Beijing), Shanghai Institute of Biological Products, Lanzhou Institute of Biological Products, Changchun Institute of Biological Products, Wuhan Institute of Biological Products, Chengdu Institute of Biological Products, and Institute of Medical Biology, Chinese Academy of Medical Sciences.[48]

3. Other institutions linked to offensive or defensive Chinese BW activities

Beyond the biodefense institutions identified by the Chinese government in its confidence-building declarations, information is available on two additional institutions of interest, the Xian Jiatong University and the Harbin Veterinary Research Institute (HVRI).

Xian Jiatong University. Chinese universities are continuously expanding educational opportunities in the field of biotechnology so that students do not have to attend a foreign institution to obtain the training needed to become a working professional in the field. Xian Jiatong University is located near Xian and is one of the China's primary universities, operating directly under the State Education Commission. Many Chinese universities with biotechnology programs lack transparency and have the potential to perform clandestine R&D. However, of the 1,075 universities in China, Xian Jiatong University is the only one that has been identified by outsiders as being involved in BW-related activities.[49] Further, Pentagon sources claim that Xian Jiatong University is a center for Chinese Army biological and chemical warfare research.[50]

In December 1997, the U.S. Department of Commerce asked permission to perform a routine inspection at Xian Jiatong University prior to the export of a high-performance computer made by the Digital Equipment Corporation. Inspectors sought to ensure that the Chinese university would not use the computer for illicit purposes related to WMD. Although the Chinese government denied permission for an inspection,[51] the U.S. government approved the sale of the supercomputer anyway.[52] Concerns have since then been expressed that China is using this supercomputer to develop advanced methods for toxin dispersion.[53]

Harbin Veterinary Research Institute (HVRI). In the late 1970s, scientists at HVRI, which is under the Chinese Academy of Agricultural Sciences, developed more than 120 types of diagnostic reagents and vaccines for the prevention and control of infectious animal diseases.[54] HVRI claims to have been the first in the world to develop a vaccine against viral equine anemia, which at the time was killing large numbers of horses in China. The vaccine was used successfully during the 1980s to prevent the spread of the virus.[55] HVRI is the best known of a network of several large-scale Chinese producers of animal vaccines.[56]

4. China's biotechnology capabilities

The Chinese biotechnology industry has undergone remarkable growth in recent years. Primary reasons for this growth include the availability of low-cost, highly skilled technologists and scientists trained in China and abroad, a strong track record in life-sciences research, government policies for supporting biotechnology R&D coupled with low levels of biosafety and biosecurity regulation, increased government and private funding for biotechnology R&D programs, and the creation of "high tech zones" specializing in biotechnology.[57] R&D takes place in government-run laboratories and universities, as well as an ever-increasing number of private enterprises. The Chinese biotechnology industry has generated remarkable developments in many fields, but particularly in pharmaceuticals and agriculture.[58]

The Chinese biotechnology infrastructure is extremely large. To illustrate, China is estimated to have approximately 20,000 biologists with masters or doctoral degrees.[59] It is not possible to estimate the number of Chinese biotech companies and enterprises because most of them are owned by local, provincial, or military governments or agencies, which do not report publicly on their holdings. According to one estimate, however, there are approximately 1,700 Chinese-foreign pharmaceutical joint ventures,[60] suggesting that several thousand more Chinese companies are engaged in biotechnology without such ties. Biotech has a substantial impact on the Chinese economy. According to government statistics, China's market for biological products surpassed $2.5 billion in 2004.[61] According to a Chinese industry source, "China's biomedical industry is growing at more than 20 percent, with more than 30 biomedicines and vaccines on the Chinese market and over 150 biotechnology products undergoing clinical trials."[62]

Funding for basic research in China is very low compared with that in developed countries. Although China's funding for R&D increased from 0.6 percent of GDP in 1995 to 1.34 percent in 2005, 70 percent of this funding is for applied R&D and only 30 percent supports basic research.[63] According to a report by the Organization for Economic Cooperation and Development, "China is far from building the 'innovation-oriented' economy it aims to achieve by 2020."[64]

As for biotechnology dual-use equipment, this study focused on fermenters (including bioreactors) as an exemplar of China's overall dual-use equipment manufacturing capabilities. The manufacture of fermenters of a quality to be marketed internationally requires special engineering expertise. A search for Chinese manufacturers of fermenters found 20 such companies. Shanghai Ritai Medicine Equipment Project Co., Ltd., is an example of a high-end company that claims to meet the internationally recognized Good Manufacturing Practice (GMP) standard and U.S. Food and Drug Administration (FDA) requirements. The company asserts: "Not only are our products sold well in China, but also we have exported our products to Italy,

Holland, Australia, India, Egypt, Indonesia, Saudi Arabia, Malaysia, etc."[65] The advertised product line includes stainless steel fermenters with mechanical agitation.[66]

Despite improvements in China's biotechnology industry, it appears that most of its companies do not meet international standards because they have antiquated equipment and use obsolete technologies. Having recognized these shortcomings, the Chinese government has taken three important steps to address them.

First, in April 2007, China launched the National Medium and Long-term Science & Technology Development Plan (2006-2020), which gives top priority to biotechnology over the next 15 years.[67]

Second, China promotes the establishment of joint ventures between Chinese and foreign companies, as noted below. Because of the low costs of labor, equipment, consumables, and reagents, investors can obtain a greater return on their investment in pharmaceutical manufacture in China than in more industrially advanced states. Foreign investment in China's biotechnology industry has occurred through a number of channels, including outsourcing, biopharmaceutical and laboratory supply manufacturing ventures, and, in some cases, R&D-based ventures.[68]

Third, the Chinese government has decided to spend an estimated $600 million per year on biotechnology R&D. By some estimates, this amount is expected to increase fivefold by the year 2010.[69] In addition, China's local governments invest an unspecified, but sizeable amount of money in private companies in the biotech sector.

Problems related to intellectual property rights and an underdeveloped capital market remain the principal barriers to growth of the biotechnology industry in China. Most venture capitalists are cautious about investing in Chinese biotechnology companies. A lack of experienced managers is also an impediment to foreign participation. Although many managers gain experience abroad before founding companies in China, relatively few have prior executive experience gained through this or other means.[70]

5. *China's trade partnerships in biotechnology, including with states of proliferation concern*

Over the years, China has been accused by the United States of exporting unnamed dual-use items to Iran, Iraq, Syria, and Cuba,[71] but China's relationship with Iran has generated the most concern. Past CIA reports have suggested that Iran maintains stocks of biological agents and possibly weapons,[72] and a November 2006 U.S. pronouncement declared that, "The United States believes that the regime in Iran probably has an offensive biological weapons program in violation of the BWC."[73] There have also been a number of cases in which Iranian entities linked to military agencies have sought to obtain equipment and commodities with potential uses in the production of biological weapons.[74] Under the 2005 Iran and Syria Nonproliferation Act,[75] in December 2005, the U.S. government sanctioned eight Chinese companies and individuals for "the transfer to Iran of equipment and technology that's used for the manufacture of chemical and biological weapons, equipment that's controlled under the Australia Group"[76] The U.S. government has not released specific information on the companies' offenses.

In the past, the U.S. government had concerns that Syria was a destination for Chinese dual-use items. In 1992, then-Director of Central Intelligence Robert Gates testified on proliferation issues before the U.S. Senate and mentioned the possibility that Syria possessed a BW program. He also noted that Syria "apparently is seeking assistance from China and Western firms for an improved capability with biological warheads."[77] However, no other information

about possible trade between China and Syria involving dual-use biological items has been published in recent years.

Exchanges and trade between China and Cuba involve ostensibly civilian researchers and industrialists. According to a Chinese source, the basis for the "first major Sino-Cuban biotechnology joint venture" was established when the Center of International Science (a unit of the Chinese Academy of Science) and the Center for Molecular Immunology in Cuba agreed to jointly invest 120 million yuan to build a plant in Beijing to develop, manufacture, and market monoclonal antibodies for cancer diagnostics and treatment.[78] Construction of the new plant, called Biotech Pharmaceutical, began on September 26, 2002. A Cuban report in May 2006 stated that the joint venture's first product, the human monoclonal antibody h-R3, had yet to be produced.[79] The joint venture will supposedly lead to Cuban-Chinese efforts to develop various vaccines. In a separate initiative, the Cuban pharmaceutical laboratory Labiofam announced a project to develop viral equine anemia vaccine in cooperation with Chinese scientists (presumably from HVRI).[80]

China is one of Cuba's principal trade partners, importing tobacco, seafood, high-tech medical equipment, and vaccines, and exporting electric appliances, machinery, and other products to the island. In the first nine months of 2004, bilateral trade is said to have reached $493 million, surpassing $357 million in trade in 2003.[81] It is not possible from open sources to determine whether Cuba sells dual-use biological items to China. If such trade exists, it is of minor importance because China's capabilities in biotechnology, especially with regard to equipment, exceed those of Cuba.

In addition to bilateral scientific exchanges and trade, China has sought to participate in multilateral arrangements that foster collaboration in the biotechnology sphere. China is a member of the Federation of Asian Biotech Associations (FABA), which was established on February 10, 2005, during the BioAsia conference in Hyderabad, Pakistan. The original members of FABA were India, Malaysia, Pakistan, Philippines, Singapore, Sri Lanka, and Thailand.[82] China, Indonesia, Iran, Israel, Japan, Kazakhstan, Saudi Arabia, and South Korea later joined. FABA's stated purpose is to promote biotechnology as a profession, to enhance the interaction of academics and industry professionals, to facilitate relations between industry and government, to encourage increased investment and inter-state trade in biotechnology, and to sponsor international gatherings of scientists in the field.[83]

Chinese companies also participate in the Developing Country Vaccine Manufacturing Network (DCVMN). The stated purpose of this network is to create "a voluntary public health-driven alliance of vaccine manufacturers from developing countries, aiming to provide a consistent and sustainable supply of quality vaccines at an affordable price to developing countries."[84] The DCVMN is comprised of vaccine manufacturing companies, both state-owned and private, from developing and middle income countries, which are interested in networking and collaborating amongst themselves. Iranian and Cuban vaccine producers are also members of the DCVMN.[85]

While researching for this study, we discovered information that signifies a new development of probable proliferation concern related to commercial botulinum toxin. The use of therapeutic botulinum toxin type A (BoNT) in medical practice has grown rapidly over the past 20 years. Although BoNT was initially approved by the FDA in 1989 for treating neuromuscular conditions such as blepharospasm, the market for botulinum toxin grew at an explosive rate after its cosmetic applications became widely appreciated, especially the ability to temporarily reduce unsightly wrinkles. Botox®, manufactured by Allergan Inc., was approved by

the FDA of this application in 2002. Since then, Botox sales for aesthetic and therapeutic applications far exceed those of any other Allergan product, having surpassed $1 billion in 2006. At the time of this writing, in addition to its use for cosmetic purposes, Botox has been approved by regulators in more than 70 countries for the treatment of 20 medical conditions, including juvenile cerebral palsy, severe underarm sweating, cervical dystonia, and anal fissures. It can be seen that botulinum toxin is no longer a rare compound. However, the quantity of botulinum toxin used for any treatment is exceedingly small as illustrated by the fact that a single gram of botulinum toxin is sufficient for Allergan to make a one year supply of Botox. One hundred units of the purified, dried Botox is vacuum-sealed in clear vials that are shipped to physicians who reconstitute its contents with saline solution. Even were a criminal to possess a large number of these vials, he would not present a sizeable threat since these tiny quantities are insufficient to cause mass casualties.[86] Botox itself therefore is not considered a proliferation threat.[87]

In China, the Lanzhou Institute of Biological Products (LIBP), a state-owned enterprise under the China National Biotec Corporation, sells a formulation of botulinum toxin type A for injection with the trade name Prosigné. This product is, in effect, a Botox "biosimilar."[88] In addition to Prosigné, LIBP produces over 100 types of biological products, including vaccines, antitoxins, toxoids, blood preparations, immunoregulators, and diagnostic reagents. All of the company's manufacturing practices conform to GMP standards established by the Chinese State Food and Drug Administration.[89] (Although LIBP is a legitimate Chinese company, Prosigné may violate Allergan's patent on Botox.)

Allergan management is also aware of numerous counterfeit products that resemble Botox but contain formulations of botulinum toxin of uncertain strengths and mixtures. Allergan has been able to track the countries of origin of some of these counterfeits, including China, the Philippines, Russia, Singapore, and Taiwan.[90] Thus, secret production laboratories in one or more of these countries are producing and supplying botulinum toxin, or a substance alleged to be botulinum toxin, to criminal enterprises, which then sell counterfeits resembling Botox to customers in Asia and elsewhere. Presumably criminals who possess manufacturing facilities that are capable of producing actual botulinum toxin in gram or larger quantities would have no compunction about selling it to anyone willing to pay the asking price, be they suppliers to cosmetic treatment facilities, criminal gangs that black-market the toxin, or terrorist organizations. Accordingly, these clandestine production facilities and their distributors pose a significant and growing BW proliferation threat.

6. China's BW export controls[91]

A careful study of China's export controls was performed by the Center for International Trade and Security at the University of Georgia in 2005.[92] The following summarizes the highlights of the controls noted in the University of Georgia study.

In October 2002, the Chinese government issued Decree No. 365 containing new export controls on dual-use biological agents, equipment, and technology. The regulations list several pathogens and toxins that are subject to control. Domestic control measures include an export licensing system, application process, and criminal prosecution for violators. These measures went into effect on December 1, 2002.[93] The Chinese government subsequently claimed that its export controls were "fully in line" with AG regulations.[94] The Center for International Trade and Security (CITS) researchers went even further, reporting in 2002:

> China closed much of the gap between national export controls and international regulatory standards set by promulgating missile export control regulations and control lists in August, chemical dual-use and biological dual-use export control regulations in October, and amended arms control regulations and an arms control list in November of that year. The new regulations brought Chinese export control regulations into effective compliance with the guidelines and lists of the Australia Group (AG), the Nuclear Support Group (NSG), and the MTCR [Missile Technology Control Regime], and they heralded a new age, in which Chinese export control behavior could be judged by the self-established standards of a *de jure* system of export controls rather than against opaque administrative procedures and the uncertainty of bilateral nonproliferation commitments.[95]

Although some Chinese export controls appear to meet international standards, this does not mean that these controls are effectively enforced. The CITS study makes clear that "Enforcement ranks as the weakest link in the Chinese export control system."[96] Problems identified included the inability to monitor large volumes of exports, the lack of communication among operational level officials, the poor capacity of Chinese intelligence agencies to identify front companies, the limited ability to conduct post-delivery verification of end-use, and many more.[97] Thus, even if the Chinese government appears to have the will and the legal basis for an adequate export-control regime, it will be many years before this regime operates efficiently at the enforcement level. As noted, a number of Chinese entities have been sanctioned by the United States for exports to Iran, including BW-relevant exports. As discussed below, it is not apparent whether the entities involved obtained export licenses from Chinese authorities, an outcome that would indicate that Chinese officials are applying less stringent standards to such exports than their Western counterparts, or whether the exports represented violations of the Chinese export control system, in which case questions would be raised about the effectiveness of the system.

Regulating the biotechnology industry will present a notable challenge for the Chinese government in the coming years. Chinese policy-makers are beginning to see the positive effects of adopting and implementing international standards, both ethical and technical, which are slowly improving in this sector. This development can be attributed in part to China's joining the World Trade Organization in 2001.[98] Furthermore, scientists who study abroad and return to China often bring back the bioethical standards of their host institutions. Nevertheless, no outsider can know the extent to which ethics are taken into consideration by practicing scientists in China.

B. Cuba

1. Cuba's possible offensive biological warfare and biodefense activities[99]

The United States and Cuba have had a contentious relationship since Fidel Castro seized power in 1959. This antagonism was institutionalized in 1961 after the United States imposed a trade embargo on Cuba that remains in force today. Over the years, Cuba and the United States have each accused the other of illicit BW-related activities. Beginning in approximately 1980 and continuing until today, the Cuban government has accused the United States and U.S.-supported groups of "more than a dozen covert releases of infectious-disease agents"[100] and one release of an insect pest. An independent analysis concluded that all of these outbreaks were

"caused by nature or were accidentally brought about by human activity, such as trade and commerce."[101]

The United States has made similar allegations about Cuba. In 2002, then Undersecretary of State for International Security and Arms Control John R. Bolton asserted, "The U.S. believes that Cuba has at least a limited offensive BW research and development effort" and has "provided dual-use biotechnology to other rogue states."[102] These remarks were made on the eve of a trip to Cuba by former President Jimmy Carter. Some suspect that Bolton's allegations were an attempt to undermine Carter's visit and other efforts being undertaken at the time to normalize relations between the United States and Cuba.[103] Bolton's assessment, however, was apparently not an independent judgment, but was said to be taken verbatim from a U.S. Intelligence Community analysis.[104] Nonetheless, after learning of Bolton's assertions, President Carter said that the U.S. officials he met with prior to his departure "never mentioned any concerns about Cuban involvement in developing biological weapons."[105] (Carter also reportedly said, "I asked them myself on more than one occasion if there was any evidence that Cuba has been involved in sharing any information with any country on earth that could be used for terrorist purposes. And the answer from our experts on intelligence was no."[106])

Bolton's allegations were not in accordance with prior or subsequent official U.S. statements. A 1998 intelligence review, for example, "concluded that Cuba does not pose a threat to U.S. national security, which implies that Cuba no longer sponsors terrorism."[107] In 2004, a national intelligence estimate based on "stringent standards" concluded that it is "unclear whether Cuba has an active offensive BW effort now, or even had one in the past."[108] Nonetheless, the estimate asserted that the U.S. Intelligence Community "continues to believe that Cuba has the technical capability to pursue some aspects of an offensive biological weapons program."[109] (It should be noted that the "capability to pursue" metric is highly inclusive, encompassing virtually every industrialized country, as well as developing countries that possess biotechnology industries.)[110]

One aspect of John Bolton's allegation survives, namely that Cuba is supplying "rogue states" with biological dual-use technology. Specifically, Cuba is known to have transferred dual-use items to Iran, primarily in the form of scientific training and production expertise.[111] Relevant Cuba-Iranian trade relations are discussed below.

The most specific allegations of illicit Cuban BW-related activities have been made by Cuban defectors. Thus, Roberto Ortega, a former chief of Cuban military medical services, claimed in early 2007 that Cuba is weaponizing *Yersinia pestis* (plague), botulinum toxin (botulism), and yellow fever virus in an underground laboratory near Havana.[112] According to Ortega, Cuba is stockpiling BW agents "to blackmail the United States in case of an international incident."[113] Other Cuban defectors have made similar allegations, but Ortega's claims are taken more seriously because he once held a senior position in the Cuban military. Nevertheless, none of the claims made by private individuals has been supported by objective evidence, and none has been supported or cited by official U.S. sources.

After Bolton made his accusations, the Castro government denied them and invited a U.S. nongovernmental organization, the Center for Defense Information (CDI), to assemble a group of experts for the purpose of visiting any Cuban biological facilities of their choice. In the end, CDI ended up sponsoring the visits of three groups between 2002 and 2004; in each case, the groups selected the sites they wanted to visit.

Before the visits began, Cuba's ground rule was that "the visits would not resemble the UN weapons inspections in Iraq, which were highly intrusive and became confrontational when

Iraqi officials denied access to sensitive sites."[114] This condition was accepted by the CDI representative, whose trip report makes clear that the visit in "no way constituted 'inspections,' a term that implies a certain degree of confrontation and an element of surprise… our visit would provide neither the 'smoking gun' nor the 'clean bill of health' that might put an end to the controversy."[115] Nevertheless, the CDI concluded that it was worth undertaking such a visit because it would, among other things, gauge the openness and transparency of Cuban biological facilities, help to establish a dialogue between Cuban and U.S. bioscientists, and begin a process of future exchange visits.

None of the experts participating in the visits found anything suspicious about the visited facilities. A former UNSCOM inspector who was a member of the first team, after cautioning that they saw only a small fraction of Cuba's biological facilities clustered in and around Havana, observed:

> Neither I nor any member of the group found any indications that Cuba was involved in other than legitimate biotechnical activities. We did not expect that we would uncover anything to the contrary. The consensus of the group is that while Cuba certainly has the capability to develop and produce chemical and biological weapons, nothing that we saw or heard led us to the conclusion that they are proceeding on this path.[116]

Despite the lack of objective evidence for an offensive Cuban BW program, some reasons for concern remain, according to this expert:

- Given his former position in the Cuban military, the allegations by Robert Ortega of a covert Cuban BW program should not be rejected out of hand.
- Outside observers have found it suspicious that scientists at the Carlos J. Finlay Vaccine and Serum Institute, one of Cuba's advanced scientific centers, have published relatively few papers, either on their own or as a result of a clinical trial partnership with GlaxoSmithKline (discussed further below)..
- Some evidence suggests that the Cubans employed evasion tactics during the CDI visits, which included extensive presentations that left only a limited amount of time for actual observations of laboratory activities.[117] (It bears noting that the Soviets used similar tactics when visitors from the United States and United Kingdom visited Soviet BW facilities as part of a trilateral agreement in the late 1980s.)
- Despite Cuba's claim that the United States has conducted at least 12 separate biological attacks between 1964 and 1997, Cuba has never declared extensive biodefense activities under the BWC confidence-building measure declarations.[118]
- Cuba's only high-containment laboratory is controlled by the National Command for Civil Defense, which is under the Ministry of Armed Forces.[119]
- The Cuban military controls La Fabriquita, a factory that manufactures powdered shark cartilage for medicinal purposes and possesses milling machines capable of producing micron-sized powders.[120]

These open-source items are not proof of illicit activity but do provide the basis for further investigation by an impartial group or agency.

2. Cuba's biotechnology capabilities

Cuba's concerted effort to acquire a major biotechnology industry began in the early 1980s, possibly stimulated by a damaging dengue fever outbreak in 1981 that sickened 344,203 Cubans and killed 158.[121] Another impetus may have been a meningitis outbreak that began in the late 1970s and continued until the mid-1980s, sickening as many as 1,400 Cubans annually.[122] At that time, there were no drugs available internationally to treat victims of either disease beyond supportive treatment, nor were vaccines available to protect the public from infection. In the early 1980s, a cytokine called interferon was believed to have powerful antiviral properties. Castro strongly supported efforts to manufacture interferon in Cuba and sought technical assistance for this purpose from the Soviet Union.

There also is the possibility that the Castro government believed its own allegations that the United States was waging BW against its human, animal, and plant populations.[123] If so, then an indigenous Cuban biotech capability would have been consistent with a strategy of developing medical countermeasures to defend against BW attack. Whatever the reason, the Cuban government began making heavy investments in biotechnology at the expense of other sectors of the economy. One early sign of Cuba's commitment to biotechnology was joining the initiative begun in 1982 by the United Nations Industrial Development Organization (UNIDO) to establish the International Centre for Genetic Engineering and Biotechnology (ICGEB) as a focal point for Third World aspirations in this field.

One of Cuba's first accomplishments in biotechnology was to develop the means to combat the meningitis outbreak noted above. The Cuban government quickly set up a multidisciplinary, multi-institution research group with the goal of developing a meningitis vaccine.[124] A candidate vaccine was introduced in 1985 and by about 1994 its use had led to the near-elimination of meningitis in Cuba (Figure 3).[125] The meningitis vaccine research group eventually became part of the Carlos J. Finlay Vaccine and Serum Institute.[126]

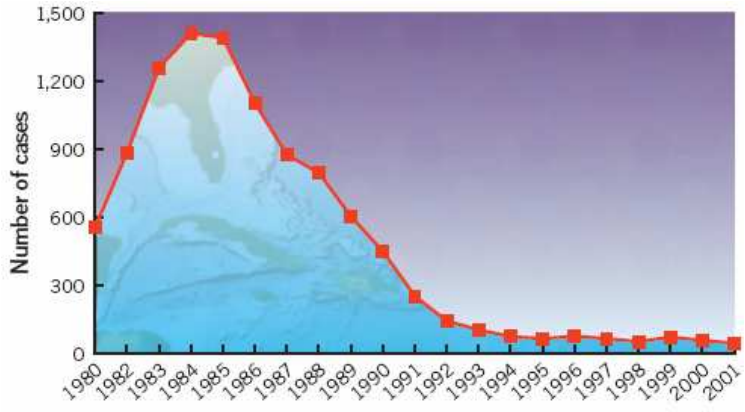


Figure 3: Number of cases of meningitis by year in Cuba.[127]

In addition to developing the world's first recombinant vaccine against meningitis B, Cuba's accomplishments in biotechnology include the world's first human vaccine with a synthetic antigen. At present, Cuban scientists are researching vaccines against AIDS, cholera, some cancers, Alzheimer's disease, and dengue fever.[128,129] Cuba has over 650 biotechnology-related patents and patent applications worldwide,[130] biotechnology exports to more than 50

countries, and a hepatitis B vaccine certified by the World Health Organization (WHO) in 2001 and pre-qualified for purchase by United Nations (UN) agencies.[131] Cuban scientists have genetically engineered yeast cells, transferred foreign genes into tilapia, and performed the "cloning, expression, and clinical testing of proprietary antigens."[132] Figure 4 provides a partial list of Cuban biotechnology accomplishments, along with the facilities in which they were achieved.

Sector	Type	Application	Producer[a]
Vaccines	Purified meningococci	Meningitis B and C	Vacunas Finlay (FI)
	Recombinant hepatitis B surface antigen	Hepatitis B	Heber Biotec (CIGB)
	Synthetic Hib	Pneumonia and meningitis	Heber Biotec (CIGB)
Therapeutics	Recombinant streptokinase	Cardiovascular disease	Heber Biotec (CIGB)
	Recombinant IFN-α	Viral infections and oncological diseases	Heber Biotec (CIGB)
	Recombinant epidermal growth factor	Burns, ulcer healing	Heber Biotec (CIGB)
	Recombinant granulocyte colony-stimulating factor	Leukopenia, neutropenia	Heber Biotec (CIGB) and CIMAB (CIM)
	MAb to CD3	Organ transplant rejection	CIMAB (CIM)
	Recombinant erythropoietin-α	Anemia	CIMAB (CIM)
	Humanized MAb against epidermal growth factor receptor	Head and neck tumors	CIMAB (CIM)
	Ateromixol (PPG)	Anti cholesterol	Laboratorios Dalmer (CNIC)
Diagnostics	Miniaturized enzyme-linked immunosorbent assay kits	AIDS, blood certification, prenatal diagnosis	Tecnosuma Internacional (CIE)
	Radiolabeled mAbs targeting various cancer markers	Cancer imaging	CIMAB (CIM)
	Enzyme-linked immunosorbent assays	Syphilis, celiac disease	Heber Biotec S.A. (CIGB)

[a]Abbreviations of associated research institutions are in parentheses: CIE, Center for Immunoassays; CIGB, Center of Genetic Engineering and Biotechnology; CIM, Center for Molecular Immunology; CNIC, National Center for Scientific Research; FI, Finlay Institute.

Figure 4: Examples of Cuba's Biotechnology Health Products[133]

According to the Department of State, Cuba's biotechnology infrastructure reflects a "very large capital investment [that] includes a full range of modern dual-use facilities for R&D, large-scale production, downstream processing, and product finishing. Its product inventory includes vaccines, research reagents, medical diagnostic supplies, transgenic animals and plants, agricultural materials, and various pharmaceuticals supplying over 40 countries. Many of these products were developed using state-of-the-art recombinant DNA technology and reflect a sophisticated technical capability."[134]

Cuba's biotechnology infrastructure includes 52 institutes in Havana's Western Scientific Pole alone.[135] Institutes of particular importance are:

> Center for Genetic Engineering and Biotechnology (CIGB) is Cuba's premier biotechnology facility. It has been an ICGEB affiliated center since 1986, and its commercial arm Heber Biotec, markets a wide range of biotechnology products developed at the CIGB. Of importance to this report, CIGB was sanctioned for unpublished reasons in 2006 by the U.S. government under Section 3 of the Iran Nonproliferation Act of 2000.[136]
>
> National Center for Biopreparations (BIOCEN) is Cuba's major production facility for biotechnology drugs, including hepatitis B vaccine, recombinant streptokinase, colony-stimulating factor, combined diphtheria-whooping cough-tetanus-hepatitis B vaccine, and

some types of interferon. BIOCEN claimed to have produced a record 17 million doses of hepatitis B vaccine in 2003.

Carlos J. Finlay Vaccine and Serum Institute, which is collaborating with GlaxoSmithKline on meningitis B vaccine trials.

Center of Molecular Immunology (CIM), which has development partnerships with Canada, China, and India.

Biological Pharmaceutical Laboratories (Labiofam), which began a partnership with China in 2000 to research a vaccine against infectious equine anemia.

Pedro Kouri National Institute of Tropical Medicine (IPK), which performs international level research on arboviruses, including dengue fever viruses, and has trained scientists from 72 countries, including the United States.

These institutes and others located in the Western Scientific Pole house a large array of BW-relevant dual-use technology, including production equipment, dangerous pathogens, and advanced scientific and engineering knowledge. Even so, most sophisticated biotech equipment in Cuba is not manufactured indigenously but has been purchased from Western industrialized countries. A search for Cuban manufacturers of fermenters (including bioreactors) found none. Moreover, of the many laudatory articles on Cuban biotechnology that have appeared in the scientific literature, none claims that Cuba can manufacture biotechnology equipment. The tentative conclusion is that Cuba's light industry has little or no capability to manufacture fermenters and other major items of biotechnology equipment for export.

In reality, Cuba's "private" sector is an extension of its public sector. Many of the major Cuban institutes, all of which are owned by the state, have established commercial branches that "carry out activities more commonly associated with private firms in other countries."[137] The tight integration between applied research, production, and health care is credited with fueling innovation by creating a cooperative feedback loop between healthcare providers and consumers that promotes rapid development and delivery.[138] Table 2 lists examples of the private-public biotechnology structure in Cuba. It bears noting that no significant basic research is performed in Cuba.

Table 2: Examples of Public-Private Biotechnology in Cuba

INSTITUTE	COMMERCIAL ARM	COMMENTS
Center for Genetic Engineering and Biotechnology (CIGB)	Heber Biotec (Havana)	Sells a large variety of products to more than 40 or 50 countries
National Centre for Scientific Research	Laboratorios Dalmer (Havana)	Markets natural products and nanotechnology
Finlay Institute	Vacunas Finlay (Havana)	Sells vaccines
Center of Molecular Immunology	CIMAB	Markets monoclonal antibodies and cancer vaccines.

To sum up, Cuba has an extensive and highly advanced biotechnology industry that rivals many industrialized countries in capability and innovation. This is a result of having invested approximately $3 billion in biotechnology since 1982,[139] some of which has been used to purchase foreign equipment. Cuba's biotechnology sector was in a position to develop and market the world's first recombinant meningitis B vaccine and is currently researching vaccines for AIDS, cholera, dengue fever, various cancers, and Alzheimer's disease. These impressive accomplishments demonstrate that Cuban scientists have substantial expertise in genetic engineering and molecular biotechnology. Given Cuba's highly trained and dedicated scientific workforce and access to cell culture collections, including a wide variety of pathogens, the Cuban government certainly has the capacity to pursue an offensive BW program were its leaders to decide to do so. In addition, the Cuban government would be able to supply other nations with relevant know-how.

Cuba's industry does not appear to have manufacturing capabilities for major items of dual-use equipment, such as fermenters. However, it certainly would be possible for a Cuban agency to purchase such equipment from a first-tier supplier that ignores U.S. economic sanctions on Cuba and then transship it to a destination of its choosing.

3. Cuba's trade partnerships in biotechnology

Cuba has established ties in the field of biotechnology with governments and private companies in many parts of the world, including with such industrialized countries as the United States, Canada, and the United Kingdom. For example, a joint venture between Cuba's Center for Molecular Immunology (CIM) and Canada's YMBiosciences known as CIMYM (the name is derived from the acronyms of the two entities) has an agreement with CancerVax (Carlsbad, CA) to jointly develop and license Cuban cancer vaccines.[140] In addition, the Finlay Institute has partnered with GlaxoSmithKline (Brentford, U.K.) on clinical trials of the former's meningitis B vaccine. If the trials are successful, the vaccine will be distributed initially in Europe and Latin America, to be followed by possible marketing in the United States.

Cuba's biotechnology market includes other countries that the U.S. government considers friendly, as well as some that it regards with concern. CIGB, for example, "has negotiated contracts with Algeria, China, India, Iran, Syria, and Russia that involve the transfer of technologies for biopharmaceutical production, formulation, filling, and/or packaging."[141] In 2006, a Cuban source claimed that Heber Biotec, Inc. was marketing 38 different Cuban biotechnology products for human, animal, and plant applications in 40 countries, but did not list them by name.[142] Given that over 50 percent of Cuban biotechnology products are vaccines,[143] it is reasonable to assume that most of its exports are vaccines, as well. Because the Cuban government does not publish statistics, one can only guess the value of Cuba's biotechnology exports. One estimate is that Cuba earned a total of $800 million from biotechnology exports between 1998 and 2003, or about $160 million annually;[144] another estimate is that Cuban biotechnology exports earn between $45 and $290 million annually.[145] Still, there seems to be a general sense among international traders and business people that Cuba's income from biotechnology products is likely to decline in the future for three reasons: (1) increasing international competition, especially from Indian and Chinese suppliers of inexpensive biologicals; (2) decreasing investment by the Cuban government in the biotechnology sector; and (3) some cases in which Cuban products have not met international Good Manufacturing Practice standards, leading buyers to avoid Cuban products.

Of all markets, Iran appears to be of highest importance to Cuba. Diplomatic relations between Cuba and Iran date back to 1975, during the rule of Shah Reza Pahlevi.[146] After the Shah was deposed, diplomatic relations between Cuba and the new revolutionary Iranian government were established in August 1979, although Castro was believed to have reservations about radical Islamism. However, relations between the two countries improved significantly when Cuba provided substantial aid to Iran after it suffered a devastating earthquake in 1990.[147]

The first concrete indication of a budding collaboration in biotechnology between Cuba and Iran occurred in 1993 when the two signed a biotechnology transfer agreement under which Cuba agreed to provide recombinant DNA hepatitis B vaccine production capability to the Pasteur Institute of Iran.[148] According to that agreement, the Pasteur Institute was to build and operate a production unit that would be able to manufacture 10 million hepatitis B vaccine doses per year. At that time, it was claimed that this production unit would be the only one of its kind in Iran capable of producing new biotechnology products at an industrial level. Also as part of that agreement, more than 30 Iranian scientists were to be sent to Cuba to receive training for this project. However, for reasons that have not been disclosed, as of the beginning of 2007, this project had not been launched, despite the claim by an Iranian source in early February 2007 that, "The Project will be inaugurated by Dr. Ahmadinejad, the respected President of the Islamic Republic of Iran on Feb. 5th, 2007."[149] Surprisingly, the vaccine will not be produced at the Pasteur Institute but instead at the "Karaj Production and Research Complex;" Karaj is located approximate 160 km northwest of Tehran and is more know for its nuclear facilities. Research has not disclosed whether vaccine production actually had been accomplished by the time of this writing (January 2008).

A collaborative economic relationship between the two countries was formalized by the creation in 1995 of the Cuba-Iran Intergovernmental Mixed Commission (CIIMC), which continues to meet annually to discuss economic and scientific exchanges and partnerships. Of course, Cuban-Iranian trade in biotechnology does not occur in isolation but rather as part of a diverse and expanding relationship between the two states.[150] In addition to biotechnology, bilateral trade involves agricultural products, industrial machinery, textiles, fisheries, transportation, and sports.[151] According to an Iranian official commenting in 2004, "The exchange includes Iranian purchase of sugar and medicine from Cuba, while Iranian export to Cuba consists of raw material for textiles, plastics, sugar cane production machinery, and electrical parts."[152]

In 2001, Iran extended a $10 million loan to Cuba to "promote bilateral trade cooperation."[153] Between 2002 and 2006, Cuban and Iranian officials repeatedly discussed a € 20 million credit to Cuba for development of its agricultural sector. In 2003, Iranian agriculture minister Mahmoud Hojjati tied the credit directly to the transfer of Cuban biotechnology to Iran. According to the *Islamic Republic News Agency* (IRNA), Hojjati hoped that the credit "would offer a clear response to Iran's proposal for biotechnological cooperation with Cuba in the field of agriculture… Cuba is ready to provide Iran with the technology for production of hepatitis vaccines."[154] In 2005, Cuba and Iran folded the credit into a memorandum of intent covering three areas: "Bank cooperation in order to make use of a 20 million Euro credit from Iran; cooperation in food production on land freed up by the sugar industry; and the acquisition of materials and equipment to combat the affects of the drought in Cuba."[155] Seven months later, however, a press release from the office of Iranian President Mahmoud Ahmadinejad referred to the loan and stated the countries would "expand cooperation in the areas of sugar industry, fishery, biotechnology, sports, transportation, development projects, investment, tourism,

information technology, and communications and water resources."[156] These activities appear mostly to benefit Cuba by enabling it to bypass U.S. sanctions and, in the process, gain substantial income in hard currency.

The biotechnology collaboration between Cuba and Iran might be fading, however. No mention of Cuba, for example, was made in the two annual statements issued by the Pasteur Institute in Tehran in 2006 and 2007 regarding the establishment of a hepatitis B vaccine manufacturing plant at Karaj.[157] Indeed, there is no mention of Cuba or Cuban research institutions anywhere on the extensive Pasteur Institute website.

Whatever the specific reasons behind the Cuban-Iranian trade in biotechnology, it takes place in the context of global politics.[158] Two broader motives might drive trade relations between the two countries, at least to some extent. The first is that both countries have adversarial relationships with the United States and may wish to cooperate in endeavors that harm U.S. interests. Thus, during a visit to Iran in 2001, Castro asserted, "Iran and Cuba, in cooperation with each other, can bring America to its knees. The U.S. regime is very weak, and we are witnessing this weakness from close up."[159] Similarly, Iranian First Vice President Parviz Davoudi recently described Cuba as the "standard-bearer" of Latin America in recognizing and standing up to "colonialist powers."[160] Cuba's political alignment with Iran against the United States may also be timely because Cuba plays a leadership role in the Non-Aligned Movement,[161] of which Iran is also a member.

A second motive could stem from Cuba's weak economy, which has confronted serious difficulties since Castro came into power in the early 1950s. The country's economy was bolstered, however, by substantial financial assistance from the Soviet Union.[162] After the Soviet Union was dissolved in December 1991, the Soviet aid stopped, as did Cuban exports to markets in Eastern Europe.[163] The results were disastrous: Cuban imports fell by 50 percent, gross domestic product by 30 percent, and per capita caloric intake by 24 percent.[164] Cuba was forced to decrease its substantial subsidies to the biotechnology industry,[165] although the sector continued to advance by relying on "materials and resources stockpiled during the pre-1990 heavy investment period."[166] As of 2001, Cuba's once state-of-the-art biotechnology center, the CIGB, had received virtually no capital improvements in 10 years.[167] As a result of these pressures, the "technological gap between Cuba and industrialized countries continued to widen" throughout the 1990s.[168] The claim has been made that Cuba recently decided to deemphasize biotechnology, while investing more in the tourism industry to attract capital from foreign sources.[169] Of course, it is possible that the Cuban government is supporting both industries; it would make little sense for Cuba to stop marketing biotechnology products that have already been developed, such as vaccines.[170]

After the breakup of the USSR, Cuba transitioned from one financial angel, the Soviet Union, to another, Iran. (Venezuela under President Hugo Chavez seems to be filling a similar economic and political role today, but the Cuba-Venezuelan relationship is of recent origin and thus not fully developed.) Of course, Iran is not the only developing country with which Cuba collaborates in biotechnology.

Cuba claims to export biotechnology products to 50 countries,[171] but this does not mean that it has meaningful collaborations with all of these parties. Based on open sources, in addition to Iran, Cuba appears to have extensive collaborations in biotechnology with China and India, and lower-level collaborations with six additional countries: Belarus, Malaysia, Mexico, Pakistan, Taiwan, and Vietnam. The latter collaborations tend to involve joint scientific research or agreements to collaborate that mostly have not led to significant results. For example, during a

session of the Belarusian-Cuban Commission on Trade and Economic Development held in Minsk in May 2004, the two countries agreed to collaborate in medicine and biotechnology. Belarusian officials indicated particular interest in Cuban vaccines.[172] However, as far as research reveals, there has been no announcement since the agreement was signed on concrete follow-up actions.

On November 25, 2004, the Malaysian company Bioven Holdings Sdn Bhd signed an agreement with CIMAB in Havana under which Bioven was granted exclusive rights to market Cuban vaccines in the Southeast Asian region and to manufacture a shrimp growth stimulator called Acuabio 1. The agreement also covered cooperation in managing clinical trials of three new Cuban cancer vaccines. In return, Cuba will purchase Malaysian palm oil.[173] In July 2005, however, it was reported that Bioven would not proceed with the clinical trials because of a failure to secure investors for the project.[174] This situation does not appear to have improved during by the time of this writing.

Cuba also established friendly relations with Pakistan by providing substantial medical and humanitarian assistance to Pakistan after a devastating earthquake in October 2005. The assistance included "32 field hospitals and two relief camps . . . staffed by more than 2,400 doctors, paramedics, and physiotherapists. Tons of medicines and medical equipment were also dispatched by Cuba… About 30 amputee patients received treatment in Cuba."[175] (At the time, Cuba claimed to have 2,823 doctors and paramedics working in 70 countries.) In August 2006, representatives from Cuba and Pakistan met in Islamabad to develop "a plan to increase links in higher education particularly in the field of biotechnology."[176] It was also announced that Cuba was offering 1,000 fully-funded medical scholarships to Pakistani students. As of this writing, there are no concrete signs of a Cuban-Pakistani collaboration in biotechnology. However, two CIGB products, Heberon Alfa R (an interferon to treat hepatitis B and C) and Heberbiovac (a vaccine against hepatitis B) are being marketed in Pakistan.[177]

4. Cuba's export controls

Only limited open-source information has been found on Cuban laws and regulations pertaining to biotechnology export controls.[178] As for Cuban biosafety and biosecurity regulations, for a long time the Cuban government was mute on this subject, allowing the CIGB deputy director Carlos G. Borroto to only state that "Cuban regulations on the use of transgenesis [sic] techniques are the strictest in the world."[179] It has not been possible to verify Borroto's assertion.

In 2004, in response to a UN Security Council resolution pursuant to Resolution 1540, the Cuban government provided detailed information on its biosafety and biosecurity laws and regulations.[180] According to the document, these laws are comprehensive, strict, and appropriate to ensure effective levels of biosafety and biosecurity.

As for laws and regulations that pertain directly to the subject of this study, the Cuban report presented to the Security Council regarding its implementation of Resolution 1540 states:

> With regard to border controls, a list of agents and equipment is being drawn up in conjunction with the national custom service for inclusion in the harmonized product classification system. Once this work is concluded, the national customs service will verify that each listed agent or piece of equipment has the corresponding authorization.

> The State System of Accounting and Control established under CITMA [Ministry of Science, Technology and the Environment] resolution No. 2/2004 makes it mandatory to obtain safety clearance for activities related to transfers of material and equipment, whether national or international. The import and export of agents and equipment must be authorized in advance by the national authority, which issues such authorization either together with or independently of the biosafety license, as appropriate.
>
> CITMA resolution No. 2/2004 on rules for accounting for and control of biological agents, equipment and related technology, lists the biological agents and equipment that are subject to control and special authorization.[181]

In 2005, Cuba added to its report with further details regarding its BW export controls.[182] In brief, it noted an extensive array of Cuban regulations pertaining to export licensing, but noted that work on border controls and enforcement agency regulations was "under way." It further stated that control lists were being updated and regulations providing for periodic list updating were being drafted. The report also noted, however, that Cuba's export control system had no "catch all" provisions (requiring licensing of items not on control lists, but which the exporter has reason be believe may be used in a WMD program); no re-export controls (requiring Cuba's prior approval before a recipient may retransfer a licensed item received from Cuba); and no controls over the transfer of "intangible technology," a term that includes production processes and other know-how, all of which are of particular relevance to the biotechnology sector.

C. India

1. India's possible offensive biological warfare activities and biodefense program

India ratified the BWC on July 15, 1974. The text of its declaration upon signing the treaty on January 15, 1973, included the following statements:

> India has stood for the elimination of both chemical and bacteriological (biological) weapons…. The Government of India would like to reiterate in particular its understanding that the objective of the Convention is to eliminate biological and toxin weapons, thereby excluding completely the possibility of their use, and that the exemption in regard to biological agents or toxins, which would be permitted for prophylactic, protective or other peaceful purposes, would not, in any way, create a loophole in regard to the production or retention of biological and toxin weapons.[183]

India has not been accused by any state of pursuing an offensive BW program. However, India supports a strong biodefense establishment consisting of nine facilities that are publicly known. All operate under the authority of the Indian Ministry of Defence's Research and Development Organisation.[184] These are described immediately below.

> Defence Bio-Engineering and Electro Medical Laboratory (DEBEL), Bangalore. This Laboratory is mostly involved in developing personal protective equipment of many types, including protections against chemical and biological materials.[185]

Defence Institute of Psychological Research (DIPR), Delhi. DIPR conducts research in military psychology dealing with personnel selection, placement, and training.[186]

Defence Research Laboratory (DRL), Tejpur. This laboratory focuses its research and development studies on control of malaria, quality of drinking water and plant materials for human and animal consumption.[187]

Field Research Laboratory (FRL). The FRL has several facilities and is located in the high-altitude desert region called Ladakh, in the states of Jammu and Kashmir. Since this region does not possess geo-climatic conditions suitable for usual agriculture, the FRL is engaged in the development of appropriate agro-technologies for the region.[188]

Institute of Nuclear Medicine and Allied Sciences (INMAS), Delhi. The Institute was established to study the consequences of the use of nuclear and other weapons of mass destruction, but has expanded its scope so it now develops radioisotopes for peaceful medical applications and other aspects of nuclear medicine and allied sciences, such as non-invasive imaging and thyroidology.[189]

Defence Research and Development Establishment (DRDE), Gwalior. The DRDE is India's oldest defense institution, having been established in 1947. Its mission is also the nearest to the focus of this study since it conducts research and development on defenses against hazardous chemical and biological agents, as well as associated toxicological problems. In recent years, it has undertaken work in the fields of synthetic and analytical chemistry, protective devices, process technology development, pharmacology and toxicology, microbiology, entomology, biochemistry, biotechnology, virology, and electron microscopy.[190]

As can be realized from even a rudimentary survey of the work programs of the nine defense institutions, if there were to be any suspicions about illicit BW work in India, the DRDE would be the most likely of the nine known Indian defense institutes to be involved in such work.

2. India's biotechnology capabilities

India has a biotechnology infrastructure that is probably larger than China's and growing at a faster rate. In India, about 300 college-level educational and training institutes offer degrees and diplomas in biotechnology, bioinformatics, and related fields. These institutes produce each year about 300,000 graduates with master's degrees and 1,500 with PhDs. Industrial biotechnology has emerged a major sector of the Indian economy, generating revenues of about $5 billion in 2006. This sector expected to continue growing, generating one million jobs through industrial products and services by 2010. The Indian bio-pharmaceuticals industry alone has the potential to generate $2 billion in 2007 and aims to reach $5 billion by 2010. The overall biotechnology sector is currently expanding at the rate of about 30 percent annually, while agricultural biotechnology is growing at about 50 percent.[191]

India has promoted the growth and development of biotechnology since 1977, when it established the Center for Cellular and Molecular Biology.[192] The Sixth Five-year Plan (1980-1985) was the first national policy document to mention biotechnology explicitly. It proposed strengthening the nation's capabilities in immunology, genetics, communicable diseases, and

other areas. The National Biotechnology Board (NTBT) was established in 1982 for the purpose of "identification of priority areas and for evolving a long-term plan for the country in biotechnology." The "Long-term Plan in Biotechnology for India," released in April 1983, set priorities for the country's biotechnology to fulfill national objectives such as food security, health and hygiene, and protection of the environment. It also bears mentioning that India joined the negotiations to establish the ICGEB in 1982, and in 1984 its member states selected New Delhi to be the headquarters of one of the two components that comprise this organization (the other and main component is located in Trieste, Italy). India, as is the case of Cuba, has been exceedingly active members of the ICGEB (China has an ICGEB affiliated center in Beijing, but its activity level is fairly low).

In 1986, the Indian government established the Department of Biotechnology (DBT) under the Ministry of Science and Technology, replacing the NTBT. In response to increased demand for highly trained personnel, the new department began supporting education in biotechnology by instituting and supporting masters-level and doctoral degree programs at several universities around the country.[193] The governmental University Grants Commission also promoted higher education in biotechnology by providing funds to universities for the creation of new programs, upgrading facilities, and so forth. Currently the DBT is tasked with promoting Indian biotechnology by:

- Collecting and disseminating information;
- Developing biosafety guidelines and promoting biotechnology education and R&D;
- Fostering university and industry interaction;
- Establishing research institutes; and
- Approving proposed biotechnology projects.[194]

The DBT actively promotes "industrial clusters" that foster synergies between academic and industrial institutions. Technologies developed with government funding at national laboratories or research institutes are often commercialized in the private sector through technology-transfer and licensing arrangements.[195]

Since its inception, the DBT has funded a total of 1,841 R&D projects.[196] The agency's budget allocation has also increased steadily over the past two decades, from $96 million in FY1987-88 to $385 million in FY2004-05. The Tenth Five-Year Plan saw a shift to increased funding of medical biotechnology and away from the previous emphasis on agricultural biotechnology.[197] Other Indian government institutions fund research in related areas of science and technology. For example, the Council of Scientific Industrial Research (CSIR) runs a nationwide network of more than 40 research laboratories, including the Center for Cellular and Molecular Biology and the Institute of Microbial Technology. The Indian Council of Medical Research, under the Ministry of Health, also funds research on communicable diseases.[198] In general, the government's emphasis in biomedical research has been on infectious and chronic diseases, cancer, and stem cell research, as well as development of diagnostic kits.[199]

In 2001, India had 176 biotechnology-based companies, 25 percent of which were in the health and medicine field. By 2003, the number of biotech companies had increased to approximately 401, of which 32.9 percent focused on agricultural biotechnology and 35.4 percent were health-oriented.[200]

In 2003, the Indian government was urged to create a national biotechnology policy. Proponents argued that such a policy was needed to plan for future expenditures to support the

industry.[201] In response, a draft national biotechnology policy was released in the spring of 2006 that emphasized the following national priorities:

- Increasing scientific and technical human resources in all areas relevant to biotechnology, especially in academia and industry, by improving the quality of education through standardization of undergraduate and postgraduate curricula;
- Improving infrastructure necessary for biotechnology R&D, including creating depositories of biological materials and animal facilities for testing vaccines;
- Promoting industry and trade through government support in the competitive international business environment and driving innovation through venture capital;
- Establishing biotechnology "parks" (combining research laboratories, manufacturing and quality control facilities, and animal testing labs) where public/private partnerships can thrive.

This draft national policy was criticized by Indian NGOs (such as the Gene Campaign, an agriculture advocacy group) for being hastily put together and reflecting the interests of biotechnology industry rather than of farmers and consumers.[202] Nevertheless, the draft policy is still in effect.

For the past 20 years, Indian pharmaceutical companies have manufactured generic drugs more cheaply than in Western countries. Approximately 40 percent of the therapeutic proteins developed by Western companies have lost their patent protection, opening up possibilities for Indian companies to claim an expanding share of the world's drug market. One Indian expert claims that, "India has the largest number of FDA-approved GMP facilities outside the U.S."[203] A major new development in Indian pharmaceutical market is the production of biosimilars. As the Indian pharmaceutical industry's capability to develop and produce biosimilars increases, it should be in a position to capture market share now belonging to name-brand drugs developed in the United States and other industrialized nations.

The online directory "IndiaMart" lists 584 Indian companies that export laboratory equipment.[204] When we searched for companies that produce and export major items of dual-use biotechnology equipment, the list shortens considerably; specifically, just seven Indian companies claim to manufacture fermenters. However, when each of these was checked out, only four actually presented data on their fermenters while the others did not buttress their claims in any way or did so in a fashion that was not credible. For example, under the heading "fermenter" one company presented a photo of a spray dryer. As for the actual four, they are as follows:

- Amar Equipments Private Limited, Mumbai, (http://www.indiamart.com/amarequipments/index.html). The company claims to manufacture fermenters that range in size from 2 to 100 liters, as well as industrial-scale high pressure reactors in size from 50 to 1000 liters. It is not certain whether the latter are suitable for fermenting microorganisms or are used only for chemical synthesis.

- Srujan Enterprises, Pune, (http://www.indiamart.com/srujanenterprises/index.html). The company claims to manufacture one type of fermenter whose capacity is 50 liters for pharmaceutical applications.

- Shree Biocare India, Gujarat, (http://www.indiamart.com/shreebiocareindia/). The company claims to manufacture "optimum quality fermenter," for use in "large-scale fermentation and in the commercial production of antibiotics and hormones." However, the company provides no specifics as to capacity or other parameters.
- Scigenics (India) Private Limited, Chennai (http://www.scigenics.in/index.htm). This company is the most impressive of those we found in India in terms of product line and international presence. As for fermenters, the company markets two lines of laboratory-sized fermenters. The first line features autoclavable fermentation chambers with respectively 31 and 51 liters capacity; while the second line is comprised of in situ sterilizable chambers having capacities of 31, 51, 71, 101, and 141 liters. Moving up to the industrial scale, Scigenics manufactures and sells what appears to be a robust 1,000 liter fermenter. However, the principal value of this fermenter is that it can be linked with other 1,000 liter ferments in what are termed "banks," and which are controlled by an advanced supervisory computerized system. At this time, the company claims that its supervisory system can handle a bank containing up to 20 of the 1,000 liter fermenters (see Photo 1).

Photo 1: A bank of three Scigenics (India) 1,000 liter fermenters set up to ferment microorganism for enzyme production.

3. *India's trade relationships in biotechnology, including with states of proliferation concern*

The DBT website lists numerous countries with which India has an "ongoing bilateral collaborations" in biotechnology, namely, Australia, Belarus, Brazil, China, Denmark, Germany, France, Israel, Iran, Mauritius, Mongolia, Russia, Switzerland, Singapore, Sri Lanka, Sudan, Syria, Sweden, the United Kingdom, the United States, and Vietnam. The Department's most recent annual report (2005-6) also describes governmental collaboration with a number of

international partners, including the following additional countries: Cyprus, Finland, Norway, Ukraine, and Venezuela.[205] Many of the foregoing partner-countries are members of the AG and hence are of lesser concern with regard to India's sharing of dual-use knowledge and materials. However, a substantial number of India's biotechnology partners do not participate in the AG, including Belarus, Brazil, China, Iran, Israel, Mauritius, Mongolia, Russia, Singapore, Sri Lanka, Sudan, Syria, Venezuela, and Vietnam. These collaborations may therefore present potential proliferation concerns, especially those with Iran and Syria, believed by the United States to be pursuing offensive BW activities.

As noted in the China section, above, professional associations, such as FABA, provide opportunities for industry scientists to meet and explore potential partnerships with one another.[206] India was one of the founding members of FABA and has been one of its more active members. Industrial tradeshows also provide a platform for Indian and foreign biotechnology companies to connect and plant the seeds of cooperation. For example, the Biotechnology India International 2005 exhibition was attended by companies from China, France, Germany, Russia, and Switzerland.[207]

Because of the Indian biotechnology sector's relatively low costs, highly skilled workforce, and expanding market, it is expected "to grow into a major R&D hub for biotechnology companies from across the world."[208] Indian biotechnology companies already have extensive international ties and often engage in joint ventures with foreign firms. These collaborations either involve developing products based on technology transferred from abroad, or jointly developing new technologies with foreign partners. Often these partnerships are with companies from AG member countries, such as the joint venture between the Indian company Panacea Biotec and Novartis (U.K.) to develop and market combination vaccines for viruses such as hepatitis B. Nevertheless, India has also established a number of joint ventures with companies and research institutes from countries outside the AG. Some examples include:

- Biocon has a joint venture with CIMAB (Havana, Cuba) to develop antibodies and cancer vaccines.
- Biocon is negotiating with the Center of Molecular Immunology (Havana) to "market a select range of biotech products in India."[209]
- Key Pharma has a joint venture with Heber Biotech (Havana) to produce recombinant streptokinase, recombinant interferon, and gamma and alpha interferons.
- Key Biogenetics (a division of Key Pharma) plans a joint venture with Heber Biotech to produce cardiological, immunological, and oncological drugs in India.
- Lifecare Innovations is collaborating with a consortium led by the South African Council for Scientific and Industrial Research to develop anti-tuberculosis products;
- Unnamed Indian and Israeli companies are collaborating in biotechnology.[210]
- Unnamed Indian companies are collaborating with firms from Brazil, South Africa, and Syria.[211]

While these collaborations are not necessarily of proliferation concern, they indicate an increasing pattern of interaction between the Indian private sector and international partners. In addition, some Indian biotechnology companies have established foreign subsidiaries to foster international partnerships. For example, Bharat Serums & Vaccines (BSV) has a U.S. subsidiary, BSV BioSciences of San Jose, CA.

Several overseas foundations and international organizations are involved in funding Indian biotechnology R&D and providing technology transfer to the private sector, especially for the development of vaccines to combat infectious diseases of global importance. For example, UNICEF, the Bill and Melinda Gates Foundation, the Malaria Vaccine Initiative, and others have collaborated with Indian biotechnology companies on various projects.

4. India's export controls

Although India is not a member of the AG, it has an equivalent system of export controls on dual-use equipment and technologies relevant to BW development and production. Such exports are regulated in section 3D of the Special Chemicals, Organisms, Materials, Equipment, and Technology (SCOMET) List, which is part of the Export Policy in the Indian Tariff Classification. Additionally, pursuant to UN Security Council Resolution 1540, the Indian Parliament passed the Weapons of Mass Destruction and their Delivery Systems (Prohibition of Unlawful Activities) Bill—commonly known as the WMD Act—on May 13, 2005. Included in this Act is a "catch-all clause" that prohibits the export of any good or technology from India if the exporter has reason to believe it is intended to be used in a WMD program.[212] The Act is binding on Indian citizens at home and abroad and on foreign nationals residing in India. Punitive measures for violations range from five to 15 years imprisonment. The preamble of the law reiterates India's commitment to the BWC.[213]

India has taken a rhetorical stance against "discriminatory" treaties and their associated supplier groups (especially the Nuclear Nonproliferation Treaty and the Nuclear Suppliers Group) and has therefore declined to join the AG. Recent U.S. official statements indicate that attempts to align India's export controls with those of the AG are occurring on a bilateral rather than a multilateral basis.[214] The U.S. goal is to link a strengthening of India's biological export controls to the expansion of bilateral trade in nuclear and other high technologies.[215]

The United States and India confer over dual-use export controls within the U.S.-Indian High Technology Cooperation Group (HTCG), which was formed in 2002 to strengthen bilateral trade in high technologies. When Indian export controls were discussed by the HTCG during a meeting in Washington, D.C., on February 23, 2007, U.S. Assistant Secretary of Commerce for Export Administration Chris Padilla stated that Indian export controls comply with a majority of items on the AG control lists. Industry representatives who attended the private sector dialogue section of the meeting suggested that India should harmonize its export controls completely with those of the AG.[216] The Bureau of Industry and Security in the U.S. Department of Commerce has also established a procedure for regulating dual-use exports from the United States to India.[217]

Despite these developments and earlier efforts to encourage strict Indian export controls, in February 2003, the U.S. government imposed sanctions on an Indian company, NEC Engineers Private, Ltd., and an Indian citizen, Hans Raj Shiv, for having "engaged in chemical/biological weapons proliferation activities that require the imposition of measures as described in section 81(c) of the Arms Export Control Act (22 U.S.C. 2798(c)) and section 11C(c) of the Export Administration Act of 1979 (50 U.S.C. app 2410C(c))."[218] In addition, in 2006, the United States sanctioned two more Indian chemical companies, Balaji Amines and Prachi Poly Products, but did not reveal specific reasons for imposing the sanctions. For its part, Balaji Amines, a leading Indian producer of chemicals used primarily in the pharmaceutical and agricultural industries, asserted that its supply of "certain products" to an Iranian pharmaceutical company had ceased in December 2005. Balaji Amines denied that it was at fault and called on

the Indian government for help in removing the sanctions.[219] The Indian government has yet to respond officially to the United States sanctions.

Note: For more data on Chinese and Indian biotechnology initiatives, see Appendix I.

III. BW Proliferation Concerns Associated with China, Cuba, and India

In this section the information populating the case studies is applied in analysis to answer the four issues presented above in the Introduction. In addition, concluding thoughts are provided on the country in question and nonproliferation.

A. China

1. Does China have access to previously developed technology for BW?

According to the U.S. government, China operated an offensive BW program before it ratified the BWC, and appears to be still involved in activities that are contrary to the BWC. If these allegations are true, China certainly would possess BW know-how and technology. Conversely, if these allegations are incorrect, China is nevertheless likely to posses BW know-how and technology due to the activities of its sizeable defensive BW program. The reason, as noted, is that a country cannot effectively defend itself against adversaries armed with biological weapons unless it knows how biological weapons function and can be deployed. It follows that the Chinese military is likely to have developed biological weapons if for no other purpose than to realistically test its defenses against them. However, if the history of other BW programs is a guide, the Soviet BW program being an especially noteworthy and appropriate example, China is highly unlikely to have shared BW and BW-related expertise or material with other nations or subnational groups.[220]

It is reasonable to assume, however, that China has shared some of its biotechnological expertise with foreign partners, including with scientists from countries that the U.S. government considers "of proliferation concern," such as Cuba, Iran, North Korea, and Syria. Yet, there is no evidence from open sources suggesting that the Chinese government has made, or is making, a deliberate effort by to assist other countries seeking to acquire BW-related equipment and know-how to support a BW program. However, if such an effort were under way, it would be highly classified and subject to strong concealment measures. Accordingly, only a highly effective national intelligence service could detect such illicit transfers.

2. What BW-relevant dual-use capabilities might be available for export from China's civilian biotechnology and pharmaceutical sectors?

From the information presented above it is clear that China has a huge biotechnology infrastructure that is growing at what appears to be an exponential rate. Like other developing economies, China's investment in basic research is low; instead, the impetus for applied R&D comes from whatever its scientists and engineers can glean from the international scientific literature, as well as training they may have received abroad. Despite this shortcoming, Chinese accomplishments in agricultural biotechnology are impressive, and those in health-related fields do not lag far behind. With these limitations in mind, it would appear that China's civilian biotechnology and pharmaceutical sectors could develop, produce, and export the full range of

dual-use capabilities listed by the AG, from pathogens to computer-controlled fermenters. In addition, given its expertise in agriculture, dual-use know-how and items related to animal husbandry and plant agriculture probably are available for export.

3. *What evidence is there, from past behavior or from the status of bilateral relations, to indicate that China is prepared to share BW-relevant technology or commodities with one or more state of proliferation concern?*

Before 2002, the Chinese government did not monitor exports of dual-use biotechnology equipment and materials to prevent transfers to countries that the AG considered of proliferation concern, such as Cuba, Iran, Iraq, Libya, North Korea, and Syria. Chinese government officials speaking off the record before 2002 maintained that China had the right to trade in civilian items and technologies with any country it chose, including those listed above. They claimed to treat every country equally and not discriminate between "good countries" and "countries of proliferation concern." Apparently, the Chinese government did not share in the U.S. perception of possible threats posed by the indiscriminate marketing of dual-use technologies. Most likely, in the pre-2002 era, the Chinese government did not *knowingly* support BW acquisition programs in these countries, if they existed, but it might have done so unknowingly. The reason for this possibility is that given China's traditional reluctance to interfere in the domestic affairs of other nations, and the fact the Chinese government has pegged all measures of success to economic growth, Chinese enterprises were free to sell dual-use biotechnology equipment and supplies as part of what the government considered normal trade, but might not have been so.

The imposition of U.S. sanctions against a series of Chinese firms for exports of AG list items to Iran, however, indicates that some BW-relevant dual-use items may have continued to flow from China to at least one state of proliferation concern even after Beijing began to tighten its export control system in this area.[221] (U.S. statements regarding the imposition of these sanctions speak of goods controlled by the AG, which may have involved only those relevant to chemical weapons, leaving the public record ambiguous on this point.)

4. *If evidence is found that BW-sensitive items are being exported by China, is the export a matter of state policy or of illicit activity by entities not under state control?*

Despite various accusations, no conclusive evidence appears in the publicly available record establishing that China is deliberately exporting BW-sensitive items to states of proliferation concern or any of its many biotech companies are doing so. Nevertheless, given China's weak enforcement of the export-control regulations, Chinese companies could export dual-use equipment fairly easily without government approval or knowledge. Further, the probability that the illegal exports would be detected and the company involved punished remains quite low.

As noted, the U.S. government has sanctioned several Chinese companies under various U.S. chemical and biological weapons sanctions laws and other laws penalizing WMD and missile transfers to states of concern. Because the U.S. government does not always reveal why a person or entity is being sanctioned, it is not possible to determine if dual-use biotechnology items were a reason for the sanctions, even if the item at issue is described as one on the AG list. Based on the names of the sanctioned parties and information on their websites (if available), it appears that the sanctions were related to chemical or missile items rather than to biotechnology, but this conclusion remains uncertain.

The number of Chinese companies and persons targeted by U.S. nonproliferation sanctions has fluctuated significantly over time. In 1997, ten Chinese entities were sanctioned under the chemical and biological weapons sanctions laws; none had been sanctioned before this date. No Chinese entity was sanctioned between the end of 1997 and the end of 2001. However, eight were sanctioned in 2002, but none has been sanctioned since January 1, 2003.

The situation with sanctions imposed under the Iran and Syria Nonproliferation Act (formerly the Iran Nonproliferation Act) of 2000, as amended in 2005, is more complicated. One Chinese entity was sanctioned under this Act in 2001, 12 in 2002, five in 2003, 21 in 2004, four in 2005 (these sanctions still remain in effect); two in 2006; and three in 2007.[222] One of the entities sanction in 2007, Zibo Chemet Equipment Co., Ltd., manufactures dual-use CW and BW equipment, but publicly available documents do not reveal the specific exports that triggered the U.S. penalties. The sharp decline in new sanctions since 2004 may indicate that the export control regime, described above, imposed by the Chinese government is working, at least as far as the U.S. government is concerned. In other words, Chinese companies appear to be adhering to the strengthened Chinese export laws and, for that reason the U.S. government has no cause to impose sanctions.

Another issue, which is peculiar to China, concerns enterprises owned by the People's Liberation Army, which is in many ways an entity unto itself. As noted in the 2005 report by the Center for International Trade and Security, "PLA influence over company management and production should not be underestimated, though the extent to which this influence may affect individual military-related transfers is unclear."[223] Thus, enterprises owned by the PLA could be selling dual-use equipment and supplies that are approved by the government and that end up in the hands of legitimate end-user, but they also might be executing sales that are unconstrained by the central government's export control system and where end-users of the imported products are not known or may be engaged in illicit activities. Such sales would be very difficult for the Chinese export control officials – and for U.S. intelligence agencies – to detect. As far as we are aware, not of the entities sanctioned by the United States were PLA related.

5. Conclusions regarding China and BW proliferation

It is clear from the foregoing that China has the capability to assist virtually any aspect of a foreign BW program. China is also known to have scientific collaborations in the biotechnology field with Iran through Federation of Asian Biotech Associations and Developing Country Vaccine Manufacturing Network and with Cuba (which, in turn has close biotechnology ties to Iran). Over the years, moreover, China has been accused of providing BW-related commodities to a number of states of proliferation concern, although the public record remains ambiguous. It is also clear that China's export control system, while imperfect, is improving and that the number of Chinese entities sanctioned by the United States for selling items controlled by multilateral supplier groups has been declining.

China has important political ties (and formerly a military alliance) to North Korea and significant trade relations with Iran, including significant purchases of Iranian oil. Beijing has also opposed attempts at the UN to impose strong international sanctions on both countries seeking to curb their nuclear and missile programs.

Against this background, what can one conclude about the BW proliferation threat, if any, China poses to the United States and to the international community? While the threat remains significant, it appears that U.S. and international pressures on China to adopt a responsible export policy are achieving results. Moreover, although China is on much friendlier

terms with Iran and North Korea than is the U.S., China has no strategic imperatives that might lead it to deliberately support BW programs in either of these states or in Syria. On the other hand, seemingly benign interactions in the context of international collaborations – for example on vaccine production – could provide a mechanism for the transfer of important dual-use know-how relevant to BW production. In addition, segments of China's industry have sometimes provided dual-use exports to questionable end-users, and the drive for profits could lead them down this path again.

A separate concern deserving attention is the underground production of botulinum toxin in China, for sale through criminal networks. This activity raises the possibility that the toxin might be clandestinely manufactured in larger quantities for terrorist organizations.

B. Cuba

1. Does Cuba have access to previously developed technology for BW?

Based on existing evidence, it is not possible to satisfactorily answer the question posed immediately above. The ambiguous finding by the U.S. Intelligence Community – that the United States "continues to believe that Cuba has the technical capability to pursue some aspects of an offensive biological weapons program" – leaves the matter completely up in the air and may mean no more than that it has a capable civilian biotechnology industry. At the moment, except for the statements of Roberto Ortega and earlier, now repudiated allegations by John Bolton, there is little in the public record to establish that Cuba has mastered the weaponization of BW agents or their dispersal through advance delivery systems. Further, despite accusations made by the Cuban government that its human, animal, and plant populations have been the victims of biological attacks by the United States or its agents, Cuba appears to have foregone acquiring a program to defend against BW.

On the other hand, as listed above on page 24, a number of questions remain about some aspects of Cuban behavior with respect to its biotechnology sector that call for further investigation. Thus even though the better conclusion at this time, based on the open literature appears to be that Cuba does not have either an offensive BW program or a significant biodefense capability, the matter is far from fully resolved. Accordingly, while it does not appear that Cuba could export know-how or commodities to support the military dimensions of a BW program, this conclusion must remain tentative.

2. What BW-relevant dual-use capabilities might be available for export from Cuba's civilian biotechnology and pharmaceutical sectors?

It is clear that Cuba has a powerful biotechnology research, development, and manufacturing infrastructure. Yet Cuba's applied R&D in biotechnology is strongly biased in favor of vaccines. According to a leading Cuban immunologist, "Vaccines are 29 percent of the worldwide biotechnology pipeline but more than 50 percent in the Cuban biotechnology pipeline."[224] Another large fraction of Cuban biotechnology focuses on therapeutic agents such as streptokinase, interferons, etc. Cuba also has a minimal capability to manufacture biotechnology equipment, certainly far less than China or India. Accordingly, if the Cubans are providing assistance to countries of BW proliferation concern, it is chiefly by transferring relevant information and know-how and/or by transferring relevant equipment obtained from others.

3. *What evidence is there, from past behavior or from the status of bilateral relations, to indicate that Cuba is prepared to share BW relevant technology or commodities with one or more state of proliferation concern?*

The Cuban government claims to be exporting biotechnology products to some 40 or 50 nations. (Cuban sources vary on the number.) Yet no country enjoys as extensive and deep collaboration with Cuba in all aspects of biotechnology that is comparable to Iran's. Neither Cuba nor Iran has revealed any details of the collaboration or hinted at any illicit activity. Nevertheless, under the Iran and Syria Nonproliferation Act, in 2006, the U.S. government has sanctioned one Cuban research institute, the CIGB (presumably, this sanction also applies to CIGB's commercial arm, Heber Biotec).[225] The U.S. government has not provided any specific reasons as to why the sanction was imposed, beyond the relevant language in the Iran and Syria Nonproliferation Act. As summarized by the U.S. Department of State, the Act, "provides for penalties on entities for the transfer to Iran since January 1, 1999, of equipment and technology controlled under multilateral export control lists (Missile Technology Control Regime, Australia Group, Chemical Weapons Convention, Nuclear Suppliers Group, Wassenaar Arrangement) or otherwise having the potential to make a material contribution to the development of weapons of mass destruction (WMD) or cruise or ballistic missile systems."[226]

Given that CIGB is Cuba's premier biotechnology research institute and its subsidiary Heber Biotech is Cuba's major exporter of biotechnology products, one or both entities appear to have exported something to Iran that made "a material contribution" to an Iranian WMD program. Clearly, the only WMD program of relevance in this instance would be a BW program. Since finished pharmaceutical products have no BW applications and CIGB does not manufacture biotechnology equipment, the most likely dual-use items that Cuba may have provided to Iran are pathogens or toxins on the AG control list, or know-how and information having BW relevance. Surprisingly, the Cuban government has never issued a public denial or protest in response to the U.S. sanctions. For all these reasons, the situation warrants further monitoring. It will be particularly interesting to see if the U.S. government renews the sanction against CIGB after it expires in September 2008. A decision to renew could well be an important indicator of possible illicit Cuban-Iranian trade in biotechnology.

Drawing conclusions about the Cuba-Iran commercial relationship is problematic. Unlike the other two case countries, Cuba is openly hostile to the U.S., so much of what it does in the area of international trade must be considered in this light. Questions that come up in this regard include: Is Cuba's export of biotechnology equipment and materials to Iran, another avowed enemy of the United States, part of the normal trade between the two nations or is it intended to circumvent the U.S. economic blockade on Cuba and, perhaps, the sanctions imposed on Iran? Might some of the information and know-how that Cuba provides to Iran be applied in ways that harm U.S. interests?

It is difficult for outsider research to answer these types of questions. Castro's assertion cited above, that "Iran and Cuba, in cooperation with each other, can bring America to its knees"[227] might be bombast or it could signal an alliance whose aim is to weaken the United States by overt and covert means. Thus, Iran's efforts to acquire capabilities in biotechnology may be part of a covert program to develop and produce biological weapons (or its aim may be to develop and produce vaccines). Yet if Tehran is seeking BW, no foreign government is likely to learn about it except by accident or through superb intelligence work.

The foregoing leads to two conclusions regarding whether Cuba has supplied, or is supplying, dual-use biological equipment for illicit purposes: one focused on Iran and the second

on the rest of the world. Starting with Iran, there are three possible explanations for Cuban-Iranian trade in biotechnology. The first is that Iran needs hepatitis B vaccine, interferon, streptokinase, and other drugs to enhance the ability of its health system to prevent and treat diseases. Over the longer term, it makes sense for Iranian biomedical scientists to develop and manufacture these drugs domestically, so purchasing the underlying technologies is a logical choice. Therefore, the mere possibility that the technology could be misused for BW purposes is not, in itself, sufficient reason to accuse Cuba of having violating BWC's Article III by having supplied BW-related expertise or material to Iran.

The second possible rationale for Iran's biotechnology trade with Cuba is that, with or without Cuba's knowledge, Tehran is pursuing a hedging strategy of developing a BW capability in secret, but not engaging in large scale BW production activities,. For the present, the imported technologies would be used for peaceful purposes, but if the Iranian government decided in the future to acquire biological weapons, it would own the technologies necessary for the task. Officially, the Cuban government asserts that it opposes any illicit uses of biotechnology. According to Deputy Minister of Foreign Affairs Rafael Dausa, "In Iran, Cuban experts will participate directly in the production process, ensuring that it is not diverted to prohibited purposes."[228] This implicit recognition of risk suggests that Cuba fully appreciates that the technology could be diverted and is seeking to minimize this possibility.[229]

The third possibility is that, as the United States has charged, Iran, with or without Cuba's knowledge, is actively pursuing a BW capability at this time and is exploiting dual-use technologies obtained from Cuba to support this effort. [230] If Cuban officials knew for sure that Iran were importing biotechnology with the intent of acquiring BW, then Cuba would be in violation of Article III of the BWC. Yet without the defection of a senior Cuban or Iranian official, it is probably impossible to know the extent to which Havana is aware of Iranian intentions, whatever they may be. Perhaps for this reason, neither the United States nor any other BWC party has accused Cuba of violating Article III of the BWC, not withstanding Washington's decision to impose sanctions on CIGB.

It can be realized from the foregoing that despite having much information on biotechnology in Cuba, the publicly available literature does not permit a determination of whether Cuba has supplied, or is supplying, dual-use biological equipment to Iran with the intent of assisting a latent or active BW program. The Cuban-Iranian relationship in biotechnology remains a major proliferation concern, even though it appeared to be diminishing in 2007. However, the situation could change in 2008; if Iran is dissuaded from acquiring nuclear weapons, it could decide to place greater priority on acquiring a robust BW program in which Cuban technology might play a substantial role.

Looking beyond Iran, there is no sign that Cuba is supplying BW-related dual-use biotechnology know-how or items to any states of proliferation concern. Yet, because of the dual-use nature of biotechnology, by sharing vaccine-related know-how and technologies through FABA to such countries as Pakistan and Sri Lanka, the Cuban government may inadvertently be supplying the governments of these countries with the means for acquiring BW programs in the future.

4. *If evidence is found that BW-sensitive items are being exported by Cuba, is the export a matter of state policy or of illicit activity by entities not under state control?*

Since Cuba does not have a significant private biotechnology sector, it must be presumed that an official of the Cuban government has approved its various biotechnology interactions

with Iran, including that for which the United States sanctioned CIGB. Whether such activities had the approval of senior leaders, mid-level officials, or only more junior managers, is not clear from open sources, however. Presumably, the imposition of U.S. sanctions means that any future transactions of this type will receive the attention senior Cuban decision-makers.

5. Conclusions about Cuba and BW proliferation

What biological weapons proliferation threats does Cuba pose to the United States and the world community? In the end, this question turns on the nature of Cuba's relations with Iran in the biotechnology sector. If ties are extensive – including Cuban training of hundreds of Iranian scientists, joint vaccine production and similar projects in Iran, transfers to Iran of pathogens, and Cuban synthesis of DNA components for Iranian gene-splicing work – then the contribution to an Iranian BW program could be considerable, even if Cuba has not, itself, mastered the most demanding elements of the biological weaponization process. Given the intense opposition to the United States that Havana and Tehran both share, at the very least there is cause for concern that rather than tightly limiting its biotechnology trade with Iran, Cuba will continue this commerce with few, if any, restraints. On the other hand, if the two states' joint project to build a vaccine plant at Iran's Pasteur Institute is off, the relationship between Cuba and Iran in biotechnology could be fading.

C. India

1. Does India have access to previously developed technology for BW?

As far as we can discern, India has never supported an offensive BW program. Nevertheless, for reasons described earlier, India is likely to possess BW know-how and technology due to the activities of its sizeable defensive BW program. Indeed, Indian military laboratories may well have developed biological weapons so as to be able to realistically test defenses against them. As is the case with other defensive BW programs, India is highly unlikely to share its BW-related expertise or material with other nations or subnational groups.

2. What BW-relevant dual-use capabilities might be available for export from India's civilian biotechnology and pharmaceutical sectors?

Without doubt, India has a large biotechnology infrastructure (possibly even larger than that of China), which is growing at a rapid pace. Much of this infrastructure is based in the pharmaceutical industry. A recent survey by *Nature Biotechnology* identified four main categories of products and services in the Indian health biotechnology sector: (1) the development, manufacture, and marketing of affordable vaccines for hepatitis B, measles, diphtheria, pertussis, and other infectious diseases prevalent in the developing world; (2) the manufacture of therapeutic proteins like insulin through the use of efficient genetic engineering methods; (3) the development of novel products, such as combination vaccines that protect against multiple diseases and bacteriophages for use against multi-drug resistant bacteria; and (4) contract services for drug discovery, manufacturing foreign products, and conducting clinical trials for large multinational corporations.[231]

India's capabilities in major dual-use biotechnology equipment manufacture appears to be quite a bit less substantial than that of China, but nevertheless meaningful in terms of being

able to equip its own biotechnology industry and having some capacity for export. But judging from how fast the Indian biotechnology sector is expanding, we can safely assume that in the not too distant future Indian equipment manufacturers will be competing strongly with Chinese companies for the growing markets in Asia and other parts of the world for biotechnology equipment. We estimate that in a few years, the United States and other industrialized countries will be supplying only highly sophisticated biotechnology equipment to specialized niches of the world biotechnology industry, with the lower-end equipment markets having been taken over by Chinese and Indian companies.

If one combines the expertise in vaccine and protein development and production with India's growing industrial prowess related to biotechnology equipment, it would appear that India has dual-use capabilities available for export in all aspects of pathogen (and toxin) engineering, formulation, propagation, and packaging. This kind of expertise and know-how could be relatively easily adapted for weaponization purposes especially by entities with more advanced biotechnology capabilities like many in Iran. On a lower capability level, Indian-made equipment, such as fermenters and dryers, would be welcome additions, for example, to BW acquisition programs operated by countries with lower domestic biotechnology capabilities, such as Syria and Iran, as well as well-financed terrorist groups.

3. *What evidence is there, from past behavior or from the status of bilateral relations, to indicate that India is prepared to share BW-relevant technology or commodities with one or more state of proliferation concern?*

India has civilian biotechnology collaborations with Syria and Cuba that might lead to dual-use technology transfers of BW concern from India to these states; in the case of Cuba, such transfers might be retransferred to Iran. Indeed, one Indian joint venture with Cuba is with Heber Biotech, the commercial arm of CIBG, the entity sanctioned by the United States for dealings with Iran. Few details of such relationships have come to light publicly, however, and there is no specific evidence indicating that sensitive transfers have taken place in this context. India's growing attention to export controls, moreover, increases the likelihood that exports to these countries will receive added scrutiny in the future. India appears to have no strategic reasons for wishing to improve BW capabilities in any of the states of proliferation concern.

4. *If evidence is found that BW-sensitive items are being exported by India, is the export a matter of state policy or of illicit activity by entities not under state control?*

While the Indian government is highly unlikely to provide assistance that might actively support the proliferation of biological weapons, private entities in the country's poorly regulated private sector might be willing to sell their wares to dubious end-users, while attempting to by-pass India's still nascent export control system. As noted earlier, the United States has sanctioned some half dozen Indian individuals and entities since 2002 for making WMD-relevant exports to Iran. Whether such incidents will continue or taper off further as India's export control system gains strength remains to be seen. Further to this point, the *Nature Biotechnology* survey noted above characterizes Indian health biotechnology firms as being in a "relatively early stage in their innovative R&D programs" but strongly committed to R&D and moving toward compliance with international intellectual property rights norms and treaties.[232]

5. Conclusions regarding India and BW proliferation

India has significant BW-relevant biotechnology capabilities and certain potentially sensitive collaborations with Syria and Cuba. Despite these factors and the U.S. sanctioning of a small number of individuals and entities in India, however, New Delhi's growing commitment to international export control norms and lack of strategic ties to countries of proliferation concern make it quite unlikely to be a significant source of support for BW program in such countries.

IV. CONCLUSIONS

A. Limitations and Accomplishments of the Study Design

This study, which mined open sources, has not produced information that allows the authors to reach a definitive conclusion on the question whether the Chinese, Cuban, and Indian governments, or companies that operate in these countries, have sold biotechnology dual-use items to proliferant nations. When the project began, its staff expected to be able to access unclassified data suggestive of illicit international trade in dual-use biotechnology equipment and materials. Yet despite the use of various search strategies in several languages, no such information was uncovered. A large amount of data was collected on the biotechnology capabilities of the three case countries, however, as well as on international collaboration and trade among research institutions and companies in China, Cuba, India, and Iran. Yet information about the details of these relationships was rarely available, and then only when research institutions were involved. In no case was it possible to obtain details of commercial arrangements between these countries. Furthermore, no Chinese or Indian companies admitted to having dealings with any state that the United States considers a country of BW proliferation concern. Commercial arrangements involving illicit transactions would be likely be even more hidden from view than legitimate ones.

The study has, however, developed a framework for analysis that can be widely utilized by specialists operating in both the unclassified and classified realm. Of particular importance, this analytical approach, by providing specific benchmarks for monitoring the status of national biotech capabilities, can be used to provide early warning of the emergence of additional second-tier supplier states. This, in turn, can be used to prioritize both intelligence collection and diplomatic initiatives to encourage the effective international export controls.

In addition, the study has shown that open source data-mining can provide important base-line information regarding second-tier supplier state capabilities and relationships. Such base-lines can provided a solid foundation for, and give direction to, further analysis with classified sources.

B. China, Cuba, India

The three case studies show a pattern of collaboration on apparently non-military, dual-use biotechnology projects between each of the second-tier supplier states and states of proliferation concern. There was no evidence to suggest, however, that the two supplier states with the greatest access to know-how and commodities with strictly military BW applications (China and India) have shared any of this with proliferant states. Moreover, given that underlying relationships between these two suppliers and the proliferant states do not include close military or strategic ties, such transfers would seem inherently unlikely.

The Cuban and Indian governments appear to have approved dual-use projects with Iran, and India may also have at least one with Syria. Entities in all three second-tier supplier states considered here have been sanctioned by the United States for providing Iran with AG-list commodities that could "materially" contribute to a BW capability, but it is not clear whether such exports were licensed and thus were approved by the supplier-state government or were made in violation of the relevant nation's export controls. The supplier-proliferant relationship that appears to be the strongest is between Cuba and Iran, reflected in a number of projects and in the two states' shared hostility to the United States. If the Pasteur Institute vaccine production project in Tehran has been cancelled, this could reflect a diminution of this relationship. Table 3 summarizes these data.

Table 3:
Capabilities and Propensities of China, Cuba, India to Provide BW-Relevant Know-How and Commodities to States of Proliferation Concern

Country	Current BW Program	Past BW Program	Biodefense Program	Dual-Use BW-Relevant Know-How	Manufacture of Dual-Use BW-Relevant Equipment	Gov't Approved Dual-Use Projects with, Transfers to Proliferant States	Private Dual-Use Projects with, Transfers to Proliferant States	Alliance, Strategic Ties to Proliferant State	Close Diplomatic Ties to Proliferant State	Important Economic Relations With Proliferant State	Export Controls
China	Possible	Probable	Yes, significant capability	Yes, significant capability	Yes, significant capability	No major gov't-to-gov't projects w/ Syria, Iran, DPRK. Some with Cuba.	10+ cases since 2000; approval of PRC gov't not clear	No.	Yes. Historical ally of DPRK. Relations now more cautious. (Also, opposes new UN sanctions on Iran)	Yes. Iran (oil)	Yes, AG list. Enforce-ment capabilities uncertain.
Cuba	Has relevant capabilities	Some allegations	None apparent	Yes, significant capability	No. Relies on imported equipment	Yes. On-going BW-relevant trade, projects with Iran	Yes. Scale not clear; "private" entities in Cuba extension of government	No	Yes. Shares common hostility with Iran to the U.S.	Yes. Extensive direct investment, financing provided by Iran	Yes. Scope, effectiveness uncertain
India	None alleged	None alleged	Yes, significant capability	Yes, significant capability	Yes, significant capability	Yes. Iran, Syria	Yes. Syria, Iran, Cuba. May be tapering off.	No. Some joint military exercises w/ Iran.	No.	Moderate with Iran (e.g., IPI pipeline)	Yes. AG list. Enforcement capabilities uncertain

C. Export Controls and New Challenges Ahead

The study's review of BW-relevant export controls highlights that considerable progress has been made in encouraging the three second-tier supplier states to adopt such controls, along with declared policies opposing exports that could contribute to BW proliferation. U.S. diplomacy has played a major role in this regard, through the development and subsequent promotion of UN Security Council Resolution 1540; bilateral negotiations leading to enhanced export controls in China and India; and the use of targeted sanctions, which have forced senior policy-makers in these two countries and in Cuba to pay greater attention to sensitive exports by entities within their borders. Enforcement appears to remain a problem in the case of China and India, and it is not yet clear whether Cuba will adopt a more cautious attitude towards biotechnology exports to Iran in the future.

Nonetheless much has been accomplished, and it is quite possible that illicit trafficking by entities in these states can be curtailed, although the danger cannot be eliminated that for reasons of greed or survival some entities remain eager to supply dual-use biotechnology and equipment to countries of concern.

A related positive development is that the requirement of UN Security Council Resolution 1540 that all states adopt effective export controls appears to have begun altering attitudes towards the AG and other supplier-state regimes. Since much thought has gone into crafting the AG control list (and that of the Nuclear Suppliers Group and the Missile Technology Control Regime) states intending to adopt effective export control measures are likely to rely on these pre-existing commodity rosters rather than develop new ones, which might be challenged as incomplete. Eventually, Resolution 1540, in combination with the supplier group lists, may emerge as a universal export control system of the type China and India, among others, have pressed for.

Still, great challenges remain. As additional states seek to build their biotechnology sectors, for example, the cadre of second-tier supplier states will grow, creating new opportunities for sensitive exports to states of concern. For example, Class III biosafety cabinets made by Esco Biotech can now be purchased from distributors in over 50 countries.[233] These safety cabinets, as well as fermenters, centrifuges, dryers, and milling equipment, can be purchased without background checks from online suppliers of second-hand equipment, such as "Laboratory Equipment Mall" and eBay. Purchases of second-hand equipment are not only less traceable by national and international trade control agencies than purchases of new equipment, but the used items are substantially cheaper than even new equipment manufactured by Chinese and Indian companies. Similarly, the possibility that illicit programs or terrorist groups will contact criminal organizations in the former Soviet Union and contract with them to purchase second-hand equipment that once was used in the Soviet BW program cannot be discounted.

Moreover, the BW area, by its nature, presents a particularly difficult area for export controls, since much of what is needed by a state of proliferation concern is know-how, including processing techniques and data relevant to weaponization. Controlling such "intangible technology transfer," which can be transmitted in face-to-face meetings at conferences, through training, or over the Internet, is one of the most challenging problems for export control systems.

It is also likely that as their biotechnology sectors grow, India and China – like the first-tier suppliers before them – will become the targets of external illicit smuggling rings. Using the standard tools of false end-use statements, anonymous middlemen, and circuitous shipping routs, such rings may find it a good deal easier to defeat export controls in the second-tier supplier

states than in more advanced countries. While the main driving force for this development is the trade in black-market drugs that are made cheaply in, for example, China and India, and sold in rest of the world, the same illegal means could be used for a trade in dual-use items of BW concern.

Unintended transfers may also occur as second-tier supplier states interact with one another. China, India, and Iran all belong to the Federation of Asian Biotechnology Associations (FABA), which provides a venue for facilitating technological trade and collaboration among these nations, a venue that also might be easily misused (see Figure 5). The illustration below indicates how dual-use commodities and skills transferred to one second-tier supplier state that is not considered a state of urgent proliferation concern may be transferred onward to one that is. FABA is only one of many settings in which the stage can be set for such transfers.

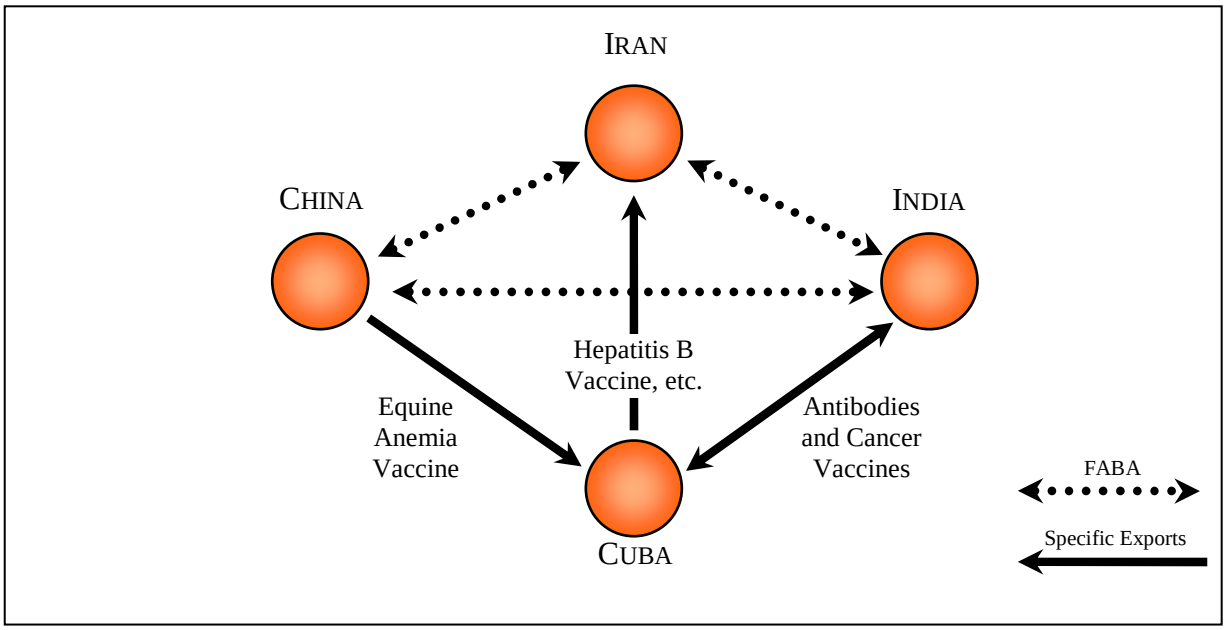


Figure 5: Select Trade in Dual-use Biotechnology Items between China, Cuba, India, and Iran

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In the end, the cases of China, Cuba, and India highlight the considerable challenges ahead. As additional states follow their example and build substantial biotechnology sectors of their own, the challenges of restraining BW proliferation are likely to grow at a disturbing pace. It is too early to judge whether effective diplomatic tools will be available to meet this challenge.

Appendix I

Biotech initiatives in China and India[234]

Biotech initiatives in China and India		
Details	**Priorities**	**Measures**
China (2006-2010) Estimate from previous program 2000–2005: RMb13 ($1.6) billion The next plan is expected to have a budget increased by several fold.	●Health. Screening for major genetic diseases, develop biotech drugs and vaccines focusing on major diseases in China.	●Fiscal incentives such as policy guidelines enabling biotech firms to get bank loans on a priority basis and schemes to provide government grants. Also, the tax policies will certainly be revised to allow more research facilities to remain tax free for longer than the current 3-years.
	●Agriculture. Advancing commercialization of genetically modified rice, wheat and cotton as well as developing salt-resistant crops and sand-resistant plants. Develop biofertilizer.	●Support the coordination of biotech research resources.
	●Support biotech-based manufacturing, particularly when the products, such as one that replaces polyethylene, reduce China's reliance on imported petroleum products.	●Increase financial support to biotech including venture capital.
	●Biofuels. Breeding and increasing acreage of crops spreading new plants for bio-alcohol and bio-diesel.	●Promote industrialization, support several major biotech parks.
	●Environment. Supporting biotech antipollution measures.	●Legislative efforts to write a biosafety law, which is especially important for agbiotech applications.
	●Supporting biotech ancillary service, including contract research organizations.	●Increase financial support to biotech including venture capital.
		●Promote industrialization, support several major biotech parks.
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India (2006–2010) $400 million	●Agriculture. Crop improvement with equal emphasis on genetically modified (GM) hybrids and new varieties and transgenic farm animal breeding.	●Massive manpower development program to ensure availability of scientists and technicians for biotech industry.
	●Food biotechnology. Development of tools for evaluating food safety; diagnostic kits for detection of GM foods and food-borne pathogens.	●Strengthening link between industry and academic institutions by enacting Indian version of the Bayh-Dole Act, allowing companies to patent and commercially exploit innovations generated in academic institutions from government funding. A network of universities and industries facilitating pooling of resources, called "Bio-Edu-Grid," is planned.

	●Medical biotechnology. High priority to basic and applied research in molecular and cellular biology, genomics, proteomics, systems biology, stem cell biology, RNA interference; tissue engineering; biosensors. Regenerative and genomic medicine with emphasis on stem cell research.	●Fiscal incentives such as policy guidelines enabling biotech firms to get bank loans on a priority basis and schemes to provide government grants (up to Rs. 5 million [$100,000]) to support early-stage innovative research of small biotech firms and low interest (2%) loans for product development. In addition, exemption of tax on revenue generated through contract research/R&D.
	●Diagnostics for screening and early detection of infections and chronic diseases.	●Simplifying regulatory and procedural formalities by replacing the multiple agencies at present by a single National Biotechnology Regulatory Authority.
	●Bio-resources. Develop technologies to convert animal, plant and microbial and marine bio-resources into commercially useful products.	●Promoting and supporting new facilities including at least ten biotech parks by 2010 and depositories of biological materials and genetically modified organism test facilities in partnership with industry.
	●Environment. Eco-restoration of degraded habitats; conversion of toxic chemicals into harmless byproducts; bioremediation of wastes.	●Attracting overseas companies by removing all hurdles in contract research and collaborations and allowing 100% foreign investment in biotech sector.
	●Industrial biotech. For the production of useful chemicals including bio-pesticides and bio-fuels.	
	●Nanobiotech. Developing biomaterials for drug delivery and controlled release.	
	●Bioinformatics and information technology–enabled biotechnology	

REFERENCES AND ENDNOTES

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[2] U.S. Department of State, *Adherence to and Compliance with Arms Control, Nonproliferation and Disarmament Agreements and Commitments*, Washington, D.C.: U.S. Department of State, August 2005, pp. 15-32. Such concerns about BW proliferation are reinforced by the fact that all three states have engaged in or are currently engaged in activities to pursue other types of weapons of mass destruction (WMD): Iran is subject to UN sanctions because of its suspect nuclear activities related to the production of nuclear-weapon materials and is accused by the United States of developing advanced chemical weapons; Syria is widely believed to possess stocks of chemical weapons, and a site near Syria's border with Turkey was attacked by Israel in September 2006, allegedly because it housed a secret nuclear facility; and North Korea tested a nuclear weapon in October 2006, leading to the imposition of UN sanctions, and is believed to have extensive stocks of chemical warfare agents.

[3] See Australia Group Website, www.australiagroup.net/. Russia has not been invited to join the Australia group, reportedly because of some members' concerns that Russia continues to maintain certain elements of the Soviet Union's offensive BW program. Russia is not known, however, to have provided BW-relevant matériel to states of proliferation concern.

[4] United Nations Security Council Resolution 1540, April 28, 2004.

[5] The name 'Australia Group' derives from the fact that the first meeting of states took place in the Australian Embassy in Paris. Australia chairs the annual AG plenary sessions, which always are held in Paris, France.

[6] AG participants are Argentina, Australia, Austria, Belgium, Bulgaria, Canada, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Commission, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Republic of Korea, Latvia, Lithuania, Luxembourg, Malta, Netherlands, New Zealand, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine, U.K., and U.S. In its communications the AG tends to avoid the use of the word 'member' since this word implies that the AG is a formal organization with a legal basis, using instead the word "participant" or "participants."

[7] For a historical overview of the AG, see *20 Years of Australia Group Cooperation, 1985-2005* (Romania: National Agency for Export Control, April 2005), http://www.australiagroup.net/en/20years.pdf (accessed January 3, 2008).

[8] AG control lists in the chemical and biological areas is divided into six categories - chemical weapons precursors, dual-use chemical manufacturing facilities and equipment and related technology, dual-use biological equipment, biological agents, plant pathogens, and animal pathogens. The AG list can be found at: http://www.australiagroup.net/en/agcomcon.htm (accessed September 30, 2007).

[9] John Hart, personal communication to Raymond A. Zilinskas, March 2001. It has not been possible to update this information because of the classified nature of the subject matter.

[10] BWC, Article III.

[11] BWC, Article X.

[12] India, moreover, under a July 2005 agreement with the United States on nuclear cooperation has pledged to adopt strict nuclear and missile export controls consistent with the guidelines of the supplier groups for these sectors, suggesting that it opposition to export controls of this type may be moderating. See, The White House, "Joint Statement Between President George W. Bush and Prime Minister Manmohan Singh," July 18, 2005, http://www.whitehouse.gov/news/releases/2005/07/20050718-6.html. (accessed January 3, 2008).

[13] Syria, which has signed but not ratified the BWC, is bound by its signature under international law not to act in a matter that would undermine the fundamental purposes of the treaty.

[14] Atlas and Dando, 2006.

[15] Huxsoll, et al., 1989.

[16] Figure 2 was adapted from D.L. Huxsoll, C.D. Parrott, W.C. Patrick III, "Medicine in defense against biological warfare," *Journal of the American Medical Association* 262 (1989), pp. 677-679.

[17] U.S. Department of State, Bureau of International Security and Nonproliferation, "Nonproliferation Sanctions" (2007): http://www.state.gov/t/isn/c15231.htm (accessed September 30, 2007). The eight are: Executive Order 13382; Iran and Syria Nonproliferation Act; Executive Order 12938, as amended; Iran-Iraq Arms Nonproliferation Act of 1992; Missile Sanctions Laws; Chemical and Biological Weapons Sanctions Laws (the Chemical and Biological Weapons Sanctions Laws is a package comprised of three individual laws: Arms Export Control Act, Export Administration Act, and Chemical and Biological Weapons Control and Warfare Elimination Act); Sanctions for the Transfer of Lethal Military Equipment; and Iran Nonproliferation Act of 2000.

[18] Office of the Secretary of Defense, *Proliferation: Threat and Response*, August 2001; http://www.fas.org/irp/threat/prolif00.pdf (accessed November 20, 2007).

[19] Paula DeSutter, "Congressional Testimony on China," U.S.–China Commission, July 24, 2003, http://www.uscc.gov/hearings/2003hearings/written_testimonies/03_07_24/tesut.htm (accessed September 13, 2007).

[20] Paula DeSutter, "The administration's perspective on China's record on nonproliferation," testimony before the U.S.–China Economic Security Review Commission, Washington, D.C., September 14, 2006; http://www.state.gov/t/vci/rls/rm/ (accessed March 20, 2007).

[21] "Current and Projected National Security Threats to the United States," Lieutenant General Michael D. Maples, U.S. Army, Director, Defense Intelligence Agency, Statement for the Record, Senate Select Committee on Intelligence Committee, January 11, 2007, http://intelligence.senate.gov/070111/maples.pdf; see also U.S. Department of State, *Adherence to and Compliance with Arms Control, Nonproliferation and Disarmament Agreements and Commitments*, Washington, D.C.: U.S. Department of State, August 2005, http://www.state.gov/t/vci/rls/rpt/51977.htm. (The report contains the following finding: "The United States reaffirms its judgment that China maintains some elements of an offensive BW capability in violation of its BWC obligations. Despite China's BWC CBM declarations to the contrary, indications suggest that China maintained an offensive BW program prior to acceding to the Convention in 1984.")

[22] Nuclear Threat Initiative, "The Australia Group," http://www.nti.org/db/china/agorg.htm (accessed August 28, 2007).

[23] Ibid.

[24] John Hart, private communication to Raymond A. Zilinskas, May 10, 2007.

[25] *International Export Control Observer*, "China: Moving toward the Next Level," no. 10, March/April 2007: http://www.cns.miis.edu/pubs/observer/pdfs/ieco_10e.pdf (accessed October 25, 2007).

[26] Zhang Yan, "Statement by the Director-General of the Department of Arms Control and Disarmament of Chinese Foreign Ministry at 1st Committee of UNGA 60th Session on Nuclear Disarmament and Non-proliferation," 2006; http://www.fmprc.gov.cn/ce/ceun/eng/xw/t215948.htm (accessed April 11, 2007).

[27] China, "The Seminar on Implementing the UN Security Council Resolution 1540 in Asia and the Pacific Held in Beijing," July 13, 2006; http://www.fmprc.gov.cn/eng/zxxx/t263849.htm. (accessed October 25, 2007).

[28] R. Jeffrey Smith, "China may have revived germ weapons program, U.S. officials say," *Washington Post*, February 24, 1993, p. A4.

[29] Milton Leitenberg, *Biological Weapons Arms Control*, from *Project on Rethinking Arms Control*, (College Park, MD: Center for International and Security Studies at Maryland, 1996).

[30] William Broad and Judith Miller, "Soviet Defector Says China Had Accident at a Germ Plant," *New York Times*, April 5, 1999, p. A3.

[31] Nuclear Threat Initiative, "China and Chemical and Biological Weapons Nonproliferation," http://www.nti.org/db/china/cbwpos.htm, (updated June 6, 2003).

[32] Eric Croddy, "China's Role in the Chemical and Biological Disarmament Regimes," *Nonproliferation Review* 9 (Spring 2002), p. 26.

[33] Ibid.

[34] People's Republic of China, *PRC Report on Anti-Biological Warfare R&D* (in Chinese), submitted to the United Nations Department of Disarmament Affairs, August 1, 1992.

[35] The Academy of Military Sciences, "Homepage," (2004-2005); http://web.medkaoyan.net/4/2/1125300580787.html (accessed October 12, 2007).

[36] Anonymous, "The ASA international laboratory series: The Institute of Pharmacology and Toxicology: Beijing," *ASA Newsletter* 5 (October 11, 1995), pp. 3-4.

[37] Zhang Baoshen, "Military toxicology: Survey of status quo and development" (in Chinese), *Renmin Junyi* (*People's Military Surgeon*) 3 (1995), pp. 5-6.

[38] Liao Yingchang, "New trends in biological weapons and medical prevention research for them" (in Chinese), *Renmin Junyi* (*People's Military Surgeon*) 40 (1997), pp. 6-8.

[39] Wu Yali, "A record of attacks on key problems in preventing and curing chemical neurotoxicants – a visit to the Chinese Academy of Military Medical Sciences" (in Chinese), *Guangming Ribao* (Beijing), August 5, 1989, p. 3.

[40] Anonymous, "Shenzhen slated for PLA Medical Academy bio-industry base," radio broadcast over Beijing *Xinhua*, June 28, 1998, 0041 GMT.

[41] Ibid.

[42] People's Republic of China, 1992.

[43] Yu Liqian and Gao Aisu, "A PLA 'Antibiological Warfare' unit" (in Chinese), *Jiefangjun Bao* (Beijing), October 21, 1994, pp. 5-6.

[44] Wong Mei, "'Ming Pao' Profiles Beijing's Profit-Making Anti-Biological Warfare Unit" (in Chinese), *Ming Pao* (Hong Kong), December 27, 1994, p. A4.

[45] Ibid.

[46] Ibid; Liqian and Aisu, 1994.

[47] Mei, 1994.

[48] People's Republic of China, 1992.

[49] Croddy, 2002.

[50] Charles R. Smith, "Chinese Germ Warfare Ignored by Department of State," NewsMax.com, October 10, 2001, http://www.newsmax.com/archives/articles/2001/10/10/192312.shtml, (accessed August 7, 2007).

[51] Interestingly, China's Ministry of Commerce issued a statement on September 11, 2007, reminding Chinese companies that "Chinese enterprises and government institutions may not allow representative of foreign governments to visit or conduct inspections for export control purposes on their premises without first getting permission from MOFCOM" (in Chinese); see http://qiaojia.mofcom.gov.cn/aarticle/gonggao/200709/20070905141321.html (accessed October 25, 2007).

[52] Smith, 2001.

[53] Stephen D. Bryen, "Prepared Statement before the U.S. Senate Subcommittee on International Security, Proliferation, and Federal Services of the Committee on Governmental Affairs," June 11, 1997, http://www.fas.org/spp/starwars/congress/1997_h/s970611b.htm (accessed April 16, 2007).

[54] Harbin Veterinary Research Institute, Facility Website, http://www.hvri.ac.cn/home_e.asp?hid=202, (accessed March 24, 2007).

[55] Elizabeth Rosenthal, "Success of Horse Vaccine in China Raises Hope in Fight Against AIDS," *New York Times*, August 21, 1990.

[56] Food and Agriculture Organization, "Vaccine Producers and Suppliers: China," http://www.fao.org/ag/AGAinfo/programmes/en/empres/documents/docs/vaccine_producers.pdf (accessed March 10, 2007).

[57] *Nature Biotechnology*, published online January 5, 2006; http://www.nature.com/news/2006/060102/fig_tab/nbt0106-7_T1.html (accessed September 28, 2007).

[58] Ibid.

[59] Robert Yuan, "China Cultivates its Healthcare Industry," *Genetic Engineering News* 27(12) (2007), pp. 49, 51.

[60] Robert Yuan, "Pharmaceutical Operations Expand in China," *Genetic Engineering News* 27(8) (2007), pp. 52, 59.

[61] Matthew Chervenak, "An Emerging Biotech Giant? Opportunities for well-informed foreign investors abound in China's growing biotech sector," *China Business Review Online Edition*, May-June 2005; http://www.chinabusinessreview.com/public/0505/chervenak.html (accessed March 5, 2007).

[62] *China Business News*, "Biotechnology next in line to be China's fastest growing industry," (April 16, 2007); http://www.interfax.cn/displayarticle.asp?aid=23281&slug=CHINA-HEALTH-BIOTECH (accessed September 14, 2007).

[63] Chen Zhiyong, "China Not Reaping Benefits of Innovation Spending," *SciDev.Net* (August 29, 2007); http://www.scidev.net/news/index.cfm?fuseaction=printarticle&itemid=3857&language=1 (accessed September 3, 2007).

[64] Ibid.

[65] Shanghai Ritai Medicine Equipment Project Co., Ltd., "Brief Introduction" (2006); http://www.ritai-fermenter.com/ (accessed September 29, 2007).

[66] Ibid.

[67] *China Business News*, 2007.

[68] Robert Yuan, "China Looks to Accelerate Globalization," *Genetic Engineering News* 27(9) (2007), pp. 14, 16.

[69] Davoudi, 2007.

[70] Ibid.

[71] Nuclear Threat Initiative, "China Biological Overview," http://www.nti.org/db/china/cbwpos.htm (accessed March 19, 2007); Nuclear Threat Initiative, "Chinese Export Control Issues," http://www.nti.org/db/china/cwcorg.htm, (accessed March 29, 2007).

[72] Center for Nonproliferation Studies, "Chemical and Biological Weapons: Possession and Programs Past and Present," http://cns.miis.edu/research/cbw/possess.htm (updated April 9, 2002).

[73] "Confronting Noncompliance with the Biological Weapons Convention," Paper Submitted by the United States, Sixth Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, November 24, 2006, document BWC/CONF.VI/WP.27, http://www.wilpf.int.ch/disarmament/BWC/WP27.pdf?OpenElement (accessed January 3, 2008).

[74] Office of the Secretary of Defense, 2001.

[75] U.S. Department of State, *Iran Nonproliferation Act of 2000*, http://www.state.gov/t/isn/c15234.htm, (updated January 10, 2007).

[76] Susan Krause, "U.S. Sanctions Nine Companies Under Iran Nonproliferation Act," Bureau of International Information Programs, U.S. Department of State, December 28, 2005, http://usinfo.state.gov/xarchives/display.html?p=washfile-english&y=2005&m=December&x=20051228125201ASesuarK0.4326593 (accessed March 25, 2007).

[77] Quoted in Nuclear Threat Initiative, "Syria Biological Profile," http://www.nti.org/e_research/profiles/Syria/Biological/3345_3346.html (accessed April 4, 2007).

[78] Gao Pei, "First Sino-Cuban Biotechnology Joint Venture Lays Foundation for its Plant in Beijing" (in Chinese), *Beijing Xinhua Domestic Service*, September 26, 2002.

[79] Lilliam Riera, "Cuban and Chinese experts discuss biotechnological products in cancer therapy, *Granma* May 11, 2006; http://politicalaffairs.net/article/view/3408/1/167 (accessed September 30, 2007).

[80] Nuclear Threat Initiative, "Cuba Biological Profile: Biological Facilities"; http://www.nti.org/e_research/profiles/Cuba/Biological/3487_3488.html (accessed September 7, 2007).

[81] *People's Daily Online*, "China, Cuba to strengthen bilateral relations," November 22, 2004; http://english.people.com.cn/200411/22/eng20041122_164712.html, (accessed April 2, 2007).

[82] Naryanan Suresh, "FABA helps India, Pakistan shake hands in biotech," *BioSpectrum*, February 9, 2006, http://www.biospectrumindia.com/content/bioEvents/10602092.asp (accessed September 7, 2007).

[83] Federation of Asian Biotech Association, "About Us," http://www.biofaba.org/aboutus.htm (accessed April 16, 2007).

[84] World Health Organization, "Developing Country Vaccine Manufacturer's Network," (updated February 6, 2006), http://www.who.int/immunization_supply/network/en/ (accessed January 3, 2008).

[85] World Health Organization, *Reports of a Meeting of International Public Sector Vaccinology Institutions*, WHO/V&B/00.30, March 16-17, 2000.

[86] Since 100 units is equivalent to 25 nanograms (0.000000025 grams) of botulinum toxin, it would take the contents of 100 vials, each of which costs approximately $300, to kill one 70 kilogram person by injection. Source: Edward J. Schantz and Eric A. Johnson, "Properties and use of botulinum toxin and other microbial neurotoxins in medicine," *Microbiological Reviews* 56(1), March 1992, pp. 80-99.

[87] Chemical and Biological Arms Control Institute, "Updated Assessment of Proliferation Potential of the Pharmaceutical Product Marketed as Botox®," Washington, D.C.: Chemical and Biological Arms Control Institute, 2001.

[88] A "biosimilars" is defined as "a biopharmaceutical that is produced using a different cell line or master cell bank and/or different process, yet meets criteria for comparability in clinical activity [with a existing name drug]." See BioPharm International, "Guide to BioTerminology 2nd edition," (August 6, 2006); http://www.biopharminternational.com/biopharm/article/articleDetail.jsp?id=362006&pageID=5 (accessed October 8, 2007).

[89] Lanzhou Institute of Biological Products, "Brief Introduction of Lanzhou Institute of Biological Products" (2005) ; http://www.vacmic.com/qyjj/Enindex.htm (accessed October 15, 2007)

[90] Mitchell Brin, "2007 Update: New products and novel emerging therapeutic targets," paper presented at the 44th Annual Interagency Botulism Research Coordinating Committee Meeting, held October 14-18, 2007, in Asilomar, California.

[91] As this report was in its last stages of completion, a new publication of relevance and importance appeared that we could not include due to a looming deadline: Amy E. Smithson (editor), *Beijing on Biohazards: Chinese Experts on Bioweapons Nonproliferation Issues*, Center for Nonproliferation Studies, Washington, D.C., September 19, 2007; http://www.cns.miis.edu/pubs/week/070917.htm (accessed September 30, 2007).

[92] Jonathan E. Davis, *Export Controls in the People's Republic of China 2005*, Center for International Trade and Security, University of Georgia, 2005.

[93] Nuclear Threat Initiative, "China Biological Overview."

[94] Ibid.

[95] Davis, 2005.

[96] Ibid, p. x.

[97] Ibid.

[98] Chervenak, 2005.

[99] Nuclear Threat Initiative, "Cuba Profile: Introduction," June 2007; http://www.nti.org/e_research/profiles/Cuba/index.html (accessed January 3, 2008).

[100] Jonathan B. Tucker, "Assessing the U.S. Bioweapons Allegations Against Cuba," U.S.-Cuba Cooperative Security Project, World Security Institute, January 10, 2005; http://www.wsicubaproject.org/cubanbiotech_05.cfm (accessed January 3, 2008).

[101] Raymond A. Zilinskas, "Cuban allegations of biological warfare by the United States: Assessing the evidence. *Critical Reviews in Microbiology* 25 (1999), pp. 173-227.

[102] Steven R. Weisman, "In Stricter Study, U.S. Scales Back Claim on Cuba Arms," *New York Times*, September 18, 2004, p. 5.

[103] Ben Friedman, "Cuba: Bioweapons Threat or Political Punching-Bag?" Center for Defense Information, May 22, 2002; http://www.cdi.org/terrorism/cuba-pr.cfm (accessed January 3, 2008).

[104] Jeffrey Lewis, "Cuba BW Effort Revisited," web posting citing the *Report of the Select Committee on Intelligence on the U.S. Intelligence Community's Prewar Intelligence Assessments on Iraq*, ArmsControlWonk website, September 20, 2004; http://www.armscontrolwonk.com/35/cuba-bw-effort-revisited (accessed January 3, 2008).

[105] Gonzalez, David, "Carter and Powell Cast Doubt on Bioarms in Cuba," *New York Times*, May 14, 2002, p. A3.

[106] Ibid.

[107] Council on Foreign Relations, "State Sponsors: Cuba," December 2005; http://www.cfr.org/publication/9359/states_sponsors.html (accessed January 3, 2008).

[108] U.S. Department of State, "Country Reports on Terrorism 2005: Chapter 6 – State Sponsors of Terrorism Overview," April 28, 2006; http://www.state.gov/s/ct/rls/crt/2005/64337.htm (accessed January 3, 2008).

[109] Weisman, 2004.

[110] At least some of the concerns regarding Cuba stem from its inclusion on the Department of State's list of "state sponsors of terrorism." According to department, there are four reasons for Cuba's status: (1) failing to participate actively in the War on Terror or to speak out against Al Qaeda; (2) interacting with other state sponsors of terror, such as Iran and North Korea; (3) providing safe haven for fugitives from the U.S.; and (4) providing a safe haven for terrorist groups. See U.S. Department of State, "Country Reports on Terrorism 2005." While providing safe haven to fugitives and terrorists is not trivial, it should be noted that most of the American fugitives harbored by Cuba arrived during the 1970s. Moreover, most of the groups on the Department of State list are not recognized as terrorists in Europe and Latin America and have easily identifiable offices in capital cities. Additionally, providing *safe haven* is not the same has *sponsoring* terrorists with money, weapons, and supplies. Indeed, the Department of State admits that it is "not aware of specific terrorist enclaves in the country." (Of course, the Department of State's classified assessment may provide other reasons for its categorization of Cuba as a state sponsor of terror.)

[111] *Tehran Mehr News Agency*, "Iran To Produce Hepatitis B Vaccine With Cuban Help," Open Source Center document IAP20061017950074, October 17, 2006.

[112] Frances Robles, "Ex-insider: Cuba has bioweapons: A former top Cuban military official said Cuba is manufacturing biological weapons," *Miami Herald*, February 28, 2007, p. 12A.

[113] Ibid.

[114] Tucker, 2005.

[115] Glenn Baker, ed., *Cuban Biotechnology: A First Hand Report*, Washington, D.C.: Center for Defense Information, 2003.

[116] Tucker, 2005.

[117] Ibid.

[118] Ibid.

[119] Ibid.

[120] Ibid.

[121] Ibid.

[122] Halla Thorsteinsdóttir, Uyen Quach, Douglas K Martin, Abdallah S Daar, and Peter A Singer, "Cuba – Innovation through Synergy," *Nature Biotechnology* 22 (Supplement) (December 2004), pp. DC3-DC7.

[123] Zilinskas, 1999.

[124] Thorsteinsdóttir et al., 2004.

[125] Ibid.

[126] Nuclear Threat Initiative, "Cuba Profile: Introduction."

[127] Thorsteinsdóttir et al., 2004.

[128] Ibid.

[129] Chen May Yee, "Cutting-Edge Biotech in Old-World Cuba," *Christian Science Monitor*, April 17, 2003.

[130] Francisco Machado, "Biotekhnologiya na Kube (in Russian)," Centre for Genetic Engineering and Biotechnology, November 18, 2004; http://www.pircenter.org/cuba2004/data/Biotecnologia_Cuba_2004.pdf (accessed October 12, 2007).

[131] Thorsteinsdóttir et al., 2004.

[132] Jose de la Fuente, "Wine into Vinegar – the Fall of Cuba's Biotechnology," *Nature Biotechnology* 19 (2001), pp. 205-7.

[133] Ibid.

[134] U.S. Department of State, "Country Reports on Terrorism 2005."

[135] Yee, 2003.

[136] James Murphy, "U.S. imposes sanctions on foreign sales of WMD to Iran," *Jane's Defence Industry* (September 1, 2006); http://www8.janes.com/ (accessed September 20, 2007).

[137] Thorsteinsdóttir et al., 2004.

[138] Ibid.

[139] *Agence France-Presse*, "Cuban Biotechnology Sector After Foreign Markets, May 22, 2006, Open Source Center document #FEA20060522023153.

[140] CancerVax Corporation, Security and Exchange Commission Filings Form 10-Q, August 13, 2004; http://www.micromet.de/en/sec/asp/secText.asp?secTextLink=2943493+%26+doc=+%26+attach=ON (accessed August 28, 2007).

[141] Tucker, 2005.

[142] *Agence France-Presse*, "Cuban Biotechnology Sector After Foreign Markets," radio broadcast on May 22, 2006, Open Source Center document FEA20060522023153.

[143] Augustine Lage, "On the cross-fertilization between biotechnology and immunology: current situation in Cuba," *Vaccine* 24 (April 2006), pp. Suppl. 2:S2-3-6.

[144] Aleksey Lyashenko, "Russia: Commentator Says U.S. Carrying Out 'Secret War' Against Cuba (in Russian)," *Krasnaya Zvezda*, July 25, 2003.

[145] Nuclear Threat Initiative, "Cuba Biological Profile," March 2007; http://www.nti.org/e_research/profiles/Iran/Biological/2305_2375.html (accessed October 12, 2007).

[146] Ministerio de Relaciones Exteriores de la República de Cuba, "Archivo General (in Spanish)," http://www.cubaminrex.cu/Regionales/Articulos/AfricaNorteMedioOriente/ANMO_Iran.htm (accessed September 16, 2007).

[147] de la Fuente, 2001.

[148] Nuclear Threat Initiative, "Biological facilities: Pasteur Institute," August 2003; http://www.nti.org/e_research/profiles/Cuba/index.html (accessed October 12, 2007).

[149] Pasteur Institute of Iran, "The Interview with Director of Pasteur Institute of Iran (IPI) on the inauguration of Hepatitis B Vaccine Project," February 3, 2007: http://www.pasteur.ac.ir/4.12.85.htm (accessed October 25, 2007).

[150] See Ministerio de Relaciones Exteriores de la República de Cuba, 2007, for a listing of Cuban-Iranian diplomatic and political events during 2005 – July 2007; http://www.cubaminrex.cu/Regionales/Articulos/AfricaNorteMedioOriente/ANMO_Iran.htm (accessed October 12, 2007).

[151] Tehran IRNA, "Iran Voices Dissatisfaction Over State of Bilateral Trade With Cuba," Open Source Center document IAP20040414000151, April 14, 2004.

[152] Ibid.

[153] *Financial Times Information*, "Iran-Cuba Iran Grants Cuba $ 10 Million Loan," Global News Wire, EFE News Services Incorporated, January 23, 2001.

[154] *Tehran IRNA*, "Iranian Credits Help Cuba Develop Agriculture," Open Source Center document IAP20031005000122, October 5, 2003.

[155] *Havana Granma*, "Cuba and Iran Sign Memo of Intent To Expand Cooperation" (in Spanish), Open Source Center document LAP20050121000064, January 21, 2005.

[156] Presidency of the Islamic Republic of Iran, "Havana Stress Closer Ties in All Areas," http://www.president.ir/eng/ahmadinejad/cronicnews/1384/05/30/index-e.htm (accessed October 11, 2007).

[157] Pasteur Institute, 2007; "The hepatitis B Vaccine Plant was visited by Dr. Lankarani, the respected Health Minister of the Islamic Republic of Iran," October 8, 2006; http://www.pasteur.ac.ir/news/28.7.85.htm (accessed January 3, 2008).

[158] Cuban Transition Project, "Staff Report. Cuban Policy in the Middle East: A Cuba-Iran Axis?", Institute of Cuban and Cuban-American Studies, University of Miami, 2004: http://www.cartadecuba.org/cuba-iran_axis.htm (accessed September 16, 2007).

[159] *Agence France-Presse*, "Fidel Castro had 'Free and Frank' Talks with President Khatami in Tehran," Tehran, May 8, 2001.

[160] *Iranian News Agency*, "Iran is willing to develop cooperation with independent states," February 28, 2007, http://www2.irna.com/en/news/view/line-22/0703016805002041.htm (accessed October 12, 2007).

[161] Roger Hearing, "Doing Business at Non-Aligned Summit," BBC News, Havana, September 19, 2006.

[162] At the time of the Soviet Union's dissolution in December 1991, Cuba was estimated to owe the USSR approximately $26 billion, far ahead of the second largest debtor, Mongolia, estimated to be $10 billion in

debt; see RIA Novosti, "Russian lawmakers ratify deal to restructure Cuba's debt," November 16, 2007; http://en.rian.ru/russia/20071116/88363132.html (accessed January 3, 2008).

[163] Thorsteinsdóttir et al., 2004.

[164] Ibid.

[165] Nuclear Threat Initiative, "Cuba Biological Profile."

[166] de la Fuente, 2001.

[167] Ibid.

[168] Ibid.

[169] Ibid.

[170] A Cuban source claims that by 2005, its international trade earned almost $10 billion, which means it was at the same level as before the economic crisis that began in 1991 (*Agence France-Presse*, 2006).

[171] *ACAN-EFE* (Panama City), "Cuba Says It Exports Biotechnology to More Than 50 Countries," October 13, 2004, Open Source Center document #SAP200410013000123.

[172] *Minsk Belarusian Television I*, "Belarus, Cuba Agree to Cooperation in Medicine and Biotechnology (in Russian)," broadcast on May 19, 2004, Open Source Center document # CEP20040519000275.

[173] Mikhail Raj Abdullah, "Malaysia's Bioven Teams up with Cuban Biotech Institutes," *Bernama* (November 25, 2004): www.biznewsdb.com (accessed September 18, 2007).

[174] Koh Lay Chin, "Hunt for Local Investors," *New Straits Times* (July 11, 2005): www.biznewsdb.com (accessed September 18, 2007).

[175] Qudssia Akhlaque, "Pakistan and Cuba agree to boost ties," *Karachi Dawn* (Internet Version) (May 25, 2006); http://www.dawn.com/2006/05/25/top18.htm (accessed September 18, 2007).

[176] *Karachi Dawn* (Internet Version), "More links with Cuba in education planned," September 1, 2006, Open Source Center document #SAP20060901081004.

[177] M. Khalid Rahman, "Dispelling myths: Cuban biotechnology setting milestones," *Karachi Dawn* (Internet Version) (October 7, 2006); http://www.dawn.com/weekly/science/archive/061007/science2.htm (accessed September 18, 2007).

[178] Dr. Jonathan Benjamin-Alvarado, and expert on Cuban export regulations in the nuclear area, reports making several attempts to learn about Cuban regulations pertaining to biosecurity and biotechnology export controls, but always being rebuffed (personal communication, October 9, 2007).

[179] *Havana AIN*, "Measures on Transgenesis are Strict in Cuba" (in Spanish), December 10, 2003, Open Source Center document #LAP20031211000030.

[180] Government of Cuba, "Note verbale dated 28 October 2004 from the Permanent Mission of Cuba to the United Nations addressed to the Chairman of the Committee: National report of the Republic of Cuba on the implementation of Security Council resolution 1540 (2004)," UN Security Council document number S/AC.44/2004/(02)/50, dated November 15, 2004.

[181] Ibid, paragraphs 3 and 6.

[182] Government of Cuba, "Note verbale dated 23 December 2005 from the Permanent Mission of Cuba to the United Nations addressed to the Chairman of the Committee, [responding to the Chair's request to provide information according to a uniform matrix]," UN Security Council document number S/AC.44/2004/(02)/50/Add.1.

[183] Government of India, "Declaration made upon signature and reiterated upon ratification of the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction. Opened for Signature at London, Moscow and Washington," April 10, 1972; http://www.icrc.org/ihl.nsf/NORM/344297D0DA8EC94BC1256402003FAB4D?OpenDocument (accessed January 3, 2008).

[184] Research and Development Organisation, "Home page," October 30, 2006; http://www.drdo.org/index.shtml (accessed September 20, 2007).

[185] Defence Bio-Engineering and Electro Medical Laboratory, "Historical background," December 23, 2005: http://www.drdo.org/labs/dls/debel/history.shtml (accessed September 20, 2007).

[186] Defence Institute of Psychological Research, "Historical background," August 5, 2007; http://www.drdo.org/labs/dls/dipr/index.html (accessed September 20, 2007).

[187] Defence Research Laboratory, "Historical background, January 15, 2007; http://www.drdo.org/labs/dls/drl/index.shtml (accessed September 20, 2007).

[188] Field Research Laboratory, "Background history," November 14, 2006; http://www.drdo.org/labs/dls/frl/index.shtml (accessed September 20, 2007).

[189] Institute of Nuclear Medicine and Allied Sciences, "Historical background," February 2, 2006; http://www.drdo.org/labs/dls/inmas/history.shtml (accessed September 20, 2007).

[190] Defence Research and Development Establishment, "Historic background," December 26, 2005; http://www.drdo.org/labs/dls/drde/history.shtml (accessed September 20, 2007).

[191] Sarah E. Frew, Rahim Rezaie, Stephen M Sammut, Monali Ray, Abdallah S Daar, and Peter A Singer, "India's health biotech sector at a crossroads," *Nature Biotechnology* 25 (April 2007), pp. 403-417.

[192] Centre for Cellular and Molecular Biology, "Home Page," http://www.ccmb.res.in/, (accessed March 20, 2007).

[193] Sachin Chaturvedi, "Dynamics of Biotechnology Research and Industry in India: Statistics, Perspectives, and Key Policy Issues," Organisation for Economic Cooperation and Development (OECD), Directorate for Science, Technology, and Industry (STI) Working Paper 2005/6, May 31, 2005.

[194] Utkarsh Palnitkar, "Biotechnology in India," Ernst & Young, 2002; http://www.altassets.com/casefor/countries/2002/nz2910.php, (accessed March 20, 2007).

[195] Indian Department of Biotechnology. "Technologies Transferred," 2006; http://dbtindia.nic.in/techtransfer/techmain.html, (accessed August 28, 2007).

[196] Indian Department of Biotechnology, "Fact Sheet"; http://dbtindia.nic.in/factsheet/factsheetmain.htm, (accessed August 3, 2007).

[197] Chaturvedi, 2005.

[198] Ibid.

[199] Ibid.

[200] Ibid.

[201] P.M. Bhargava, "Why and what should be our biotechnology policy?" *BioSpectrum* (June 11, 2003); http://www.biospectrumindia.com/content/future/10306111.asp (accessed October 12, 2007).

[202] Suman Sahal, "Biotech Policy: secretive and hasty," *India Together* (April 29, 2006); http://www.indiatogether.org/2006/apr/agr-btpolicy.htm (accessed October 12, 2007).

[203] Sue Pearson, "Biosimilars Market Ripe for Expansion: Can Innovation Drug Design Stem the Rising Tide?" *Genetic Engineering News* 27(9) (May 1, 2007), pp. 1, 58.

[204] IndiaMart, "Laboratory Equipment and Lab Testing Equipment," http://dir.indiamart.com/indianexporters/laboratory-equipment.html (accessed January 3, 2008).

[205] Indian Department of Biotechnology, *Annual Report 2005-2006*; http://dbtindia.nic.in/annualreports/2005-06/annual_report_2005-06.htm (accessed April 4, 2007).

[206] Federation of Asian Biotech Association, "Home Page"; http://www.biofaba.org/genesis.htm (accessed August 28, 2007).

[207] Biotechnology India International, "Exhibitor List," 2005; http://www.biotec-india.com/biotec_exhibitor_list.html (accessed April 7, 2007).

[208] Biotechnology India International, "Exhibitor List."

[209] Anil Urs, "India bio cos look to Cuban tech for growth," *Economic Times* (New Delhi), July 15, 2003, Open Source Center document #SAP20030715000070.

[210] *Jane's Intelligence Digest*, "India-Israel alliance firming up," March 2, 2005.

[211] Urmi A. Goswami, "India emerges as biotech R&D hub," *Economic Times* (New Delhi), October 25, 2002, Open Source Center document #SAP20021025000093.

[212] "Communication from the Resident Representative of India to the International Atomic Energy Agency regarding India's nuclear export policies and practices," INFCIRC/647, International Atomic Energy Agency, June 29, 2005.

[213] Ziad Haider and Souvik Saha, "Analysis of India and Pakistan's Export Control Laws," Henry L. Stimson Center; http://www.stimson.org/southasia/?SN=SA20050713866 (accessed August 28, 2007).

[214] R. Nicholas Burns "Ongoing Efforts To Implement the U.S.-India Civil Nuclear Agreement," U.S. Department of State, March 16, 2006; http://www.state.gov/r/pa/prs/ps/2006/63270.htm (accessed October 12, 2007).

[215] See note 12. India is also aligning its nuclear and missile export controls with those of the relevant supplier groups.

[216] *Inside U.S. Trade*, "U.S., India Working to Agree on India's Export Control Gaps," no. 25, March 2, 2007; http://www.insidetrade.com/secure/dsply_nl_txt.asp?f=wto2002.ask&dh=75086463&q= (accessed October 12, 2007).

[217] U.S. Department of Commerce Bureau of Industry and Security, "U.S.-India Dual-Use Export Control: Policies and Procedures"; http://www.bis.doc.gov/InternationalPrograms/IndialCoopPresentation.htm (accessed March 13, 2007).

[218] U.S. Department of State, Bureau of Nonproliferation, "Imposition of Chemical and Biological Weapons Proliferation Sanctions Against Foreign Persons, Including a Ban on U.S. Government Procurement" *Federal Register* 68 (33), (February 19, 2003), pp. 8068-7.

[219] James Murphy, "US imposes sanctions on foreign sales of WMD to Iran," *Jane's Defence Industry* (September 1, 2006).

[220] During the early 1980s, China is thought to have shared nuclear weapon technology and relevant production know-how to Pakistan, indicating that at least at that time Beijing was not averse to helping a

strategic ally achieve a WMD capability. In the interim, however, China appears to have become more cautious regarding WMD-relevant transfers. Moreover, it does not have relations today with the principal states of proliferation concern that are as strategically important as its relationship of the 1980s was with Pakistan.

[221] Chemical and Biological Weapons Sanctions Laws, U.S. Department of State, providing a comprehensive list of sanctioned entities and relevant laws, http://www.state.gov/t/isn/c15236.htm; Krause, "U.S. Sanctions Nine Companies Under Iran Nonproliferation Act," see note 76.

[222] "Iran and Syria Nonproliferation Act," Bureau of International Security and Nonproliferation, U.S. Department of State, May 10, 2007, http://www.state.gov/t/isn/c20760.htm (accessed February 27, 2008).

[223] Davis, 2005, p. 34.

[224] Lage, 2006.

[225] "Iran and Syria Nonproliferation Act," Bureau of International Security and Nonproliferation, U.S. Department of State, see note 223.

[226] Ibid.

[227] *Agence France-Presse*, "Fidel Castro had 'free and frank' talks with President Khatami in Tehran," Tehran, May 8, 2001.

[228] Tucker, 2005.

[229] For this reason, Jonathan Tucker argues, the "United States could probably exert more influence over Cuba's questionable exports to Iran through active engagement rather than continued confrontation." Ibid.

[230] "Confronting Noncompliance with the Biological Weapons Convention," op. cit.; "Current and Projected National Security Threats to the United States," Lieutenant General Michael D. Maples, U.S. Army, Director, Defense Intelligence Agency, see note 21.

[231] Frew, et al., 2007.

[232] Frew, et al., 2007.

[233] Esco Biotech, "Global Homepage," (2006); http://www.escoglobal.com/biotech/ (accessed October 12, 2007).

[234] *Nature Biotechnology*, 2006.