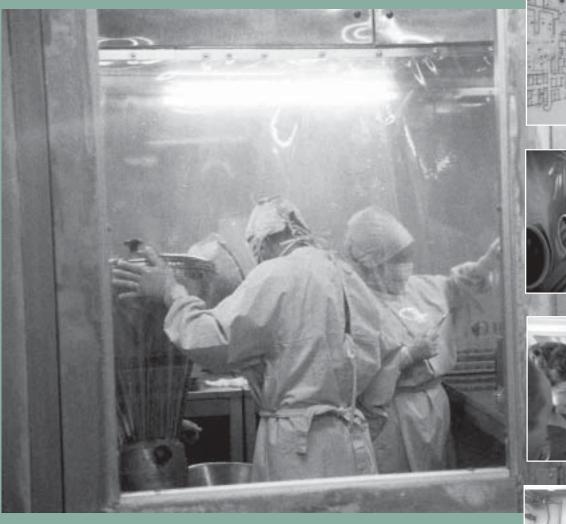
A First-hand Report

Cuban Biotechnology













Edited by Glenn Baker Center for Defense Information

Disclaimer

This report is not an integrated work, but rather a series of impressions reflecting the personal experiences of the individuals who participated. Reports were submitted separately and reflect differing styles. Members of the group were chosen for the diverse range of their collective expertise, and included a former UNSCOM chief inspector, a retired four-star general, a leading infectious disease specialist, senior research scientists, bioweapons policy experts, and former assistant secretaries of Defense and Energy. The differing perspectives brought to bear by this group provide a multi-disciplinary assessment of the Cuban biotechnology sector and the issue of bioweaponry. The views expressed herein are those solely of the authors.

Acknowledgements

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CENTER FOR DEFENSE INFORMATION Washington, D.C.
May 2003

About the U.S.-Cuba Cooperative Security Project

The Center for Defense Information (CDI) is a non-partisan, non-profit organization committed to independent research on global security issues. Since the early 1990's, its U.S.-Cuba Cooperative Security Project has been organizing meetings between senior retired U.S. military personnel and Cuban officials.

The Project's mission is to promote constructive dialogue between the United States and Cuba on military-related issues, aimed at articulating and exploring specific cooperative measures that serve the security interests of both countries. This dialogue is intended to facilitate peaceful U.S.-Cuba military relations both today and in the future.

CDI delegations have gained access to many secure sites in Cuba of great interest in the United States: the mothballed nuclear power plant, secret military tunnels, a Border Guard command center, a former Soviet submarine base, a munitions factory, and now, nine biotechnology production facilities. Future trips will have the opportunity to revisit the biotechnology sector and additional sites of interest, and to extend the dialogue on key security issues between the United States and Cuba.

About the Center for Defense Information

CDI is a non-partisan, non-profit organization committed to independent research on the social, economic, environmental, political and military components of global security. To ensure the ability to provide objective analysis, CDI accepts no government or defense industry funding. Its central aim is to educate the public and inform policymakers about issues of security policy, stratey, operations, weapon systems and defense budgeting, and to produce creative solutions to the problems of today and tomorrow. To encourage the intellectual freedom of staff, CDI does not hold organizational positions on public policy issues. Instead, staff members are dedicated to the concept that the public and political leaders can, and will, make wise choices on complex security matters when provided with facts and practical alternatives. The views expressed in CDI publications are those of the authors.

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The Delegation Members

Dr. Bruce G. Blair President, Center for Defense Information

Dr. Blair served in the U.S. Air Force as a Minuteman missile launch control officer and support officer for the Strategic Air Command's Airborne Command Post (1970-74) before earning a doctorate in operations research from Yale. He is an expert on the security policies of the United States and the former Soviet Union, specializing in nuclear forces and command-control systems. He also has extensively studied the Russian military-industrial economy.

Before becoming president of CDI in 2000, he was a senior fellow in the Foreign Policy Studies Program at the Brookings Institution for 13 years, and a project director for the Congressional Office of Tech-



CDI delegation discusses benefits of information-sharing in the biotech field with directors of Cuban biotechnology centers. From top left, Taylor, Wilhelm, Steinbruner, Coyle, Spielman, Barberia, Krebs, and Blair.

nology Assessment. He is the author of numerous books, including *De-Alerting Strategic Forces* and *The Logic of Accidental Nuclear War*, and is a leading advocate of removing nuclear weapons from hair-trigger alert.

He has frequently testified before Congress and has taught security studies as a visiting professor at Yale and Princeton universities. He was awarded a MacArthur Fellowship Prize in 1999. Dr. Blair has chaired three CDI U.S.-Cuba security conferences in Havana since 2001.

Gen. Charles Wilhelm, USMC (Ret.) Distinguished Military Fellow, Center for Defense Information

Commander in Chief, U.S. Southern Command, 1997-2000. Prior to that he served as Commander, U.S. Marine Forces Atlantic, Europe and South/Commanding General II Marine Expeditionary Force/Commander Marine Striking Force Atlantic and Commanding General, Fleet Marine Force, Atlantic, Camp Lejeune, N.C.

Gen. Wilhelm held a variety of command positions including two tours of duty in Vietnam. From December 1992 to March 1993, while serving as Commanding General, 1st Marine Division, he commanded Marine Forces participating in the U.S.-led coalition during Operation Restore Hope in Somalia, and he served as Deputy Commander of Joint Task Force Proven Force during the Persian Gulf War in 1990-1991. Among many other senior assignments, he was selected in 1990 to serve as deputy assistant secretary of defense in the Office of the Assistant Secretary of Defense for Special Operations and Low-Intensity Conflict; and, in 1994, he assumed duties as Commanding General, Marine Corps Combat Development Command, Quantico, Va.

Gen. Wilhelm was a contributor to the 1998 Dept. of Defense study on Cuba that concluded "Cuba does not pose a significant military threat to the U.S. or to other countries in the region." Today, he is a leading proponent for security cooperation between the United States and Cuba.

During his tenure as commander of Southern Command, Gen. Wilhelm traveled multiple times to every country in his region of responsibility except Cuba, 90 miles from Southcom headquarters in Miami (aside from many trips to the U.S. Naval Base at Guantanamo). Since retiring from the Marine Corps, he has been to Cuba three times as chief military liaison for CDI delegations.

Mr. Terence Taylor

President and Executive Director, International Institute for Strategic Studies U.S. and Assistant Director, IISS

Mr. Taylor was a commissioner to the UN Special Commission to Iraq (1993-95), for which he also conducted missions as chief inspector (1993-97).

He worked as a political affairs officer at UN Headquarters in the Department for Disarmament Affairs (1994-95) and earlier for the United Kingdom Ministry of Defense as a member of the staff for the development of policy on arms control and non-proliferation measures on nuclear, biological and chemical weapons (1985-92). In this capacity, he was a member of the U.K. negotiating team for Nuclear Non-Proliferation Treaty review conferences, the Chemical Weapons Convention and also a member of joint U.S./U.K. inspection teams in Russia investigating the Biological Warfare program.

He is currently working on a study examining the feasibility of setting up a global association for the private biotechnology industry with the object of encouraging high standards of safe and secure operation of facilities and good business practices; and a study of scientific and technological developments in biotechnology to identify for policy-makers the opportunities to be exploited in the interest of public safety and security and on how best to manage the risks arising from this advancing science and technology. (A joint project with the Center for Global Security Research, Lawrence Livermore National Laboratory). He served as a career officer in the British Army.

The Hon. Martha Krebs, Ph.D. Principal, Science Strategies

Assistant Secretary of Energy and Director of the Office of Science, 1993-2000

Dr. Krebs founded Science Strategies, a consulting firm that works with academic and private organizations to identify critical issues and opportunities in science and technology that will affect their research and development activities. Her expertise includes broad familiarity with the physical and life sciences including materials and chemical science, high energy physics, genomics, structural biology, and environmental and ecological science. She also has worked with large and small science and technology institutions, and has served on evaluation teams with respect to both scientific agendas and organizational effectiveness.

Previously, Dr. Krebs was founder and first director of the California NanoSystems Institute at UCLA and University of California-Santa Barbara, which includes molecular-scale bioengineering research addressing medical and pharmaceutical applications.

When she served as U.S. assistant secretary of energy and director of the Office of Science, Dr. Krebs oversaw the \$3 billion basic research program that underlay the department's energy, environmental and national security missions. These included the human genome program, molecular and structural biology, and the characterization of biological organisms relevant to DoE missions, including biowarfare.

She serves on the Board of Trustees for the Institute for Defense Analyses and is a member of the National Research Council's Board on Energy and Environmental Systems.

The Hon. Philip Coyle III

Senior Advisor, Center for Defense Information

Assistant Secretary of Defense and Director, Operational Test and Evaluation, Dept. of Defense, 1994-2001

As an assistant secretary of defense and director, Operational Test and Evaluation (DOT&E) at the Defense Department, Mr. Coyle oversaw operational testing for all major Pentagon weapons programs, including biological weapons detection and protection systems. He served 33 years at Lawrence Livermore National Laboratory, where he was associate director. Mr. Coyle served as principal deputy assistant secretary for defense programs at the Energy Deptartment during the Carter administration.

Mr. Coyle has frequently testified before Congress on weapons testing issues, including missile defense. With more than 40 years of experience in testing and test-related matters, he was selected by *Aviation Week* magazine as one of its "Laurels" honorees for 2000, a select group of people recognized for outstanding contributions in the aerospace field.

Mr. Coyle is the Director of CDI's West Coast office in Los Angeles, Calif.

Dr. John Steinbruner

Professor of Public Policy and Director of the Center for International Security Studies, University of Maryland

Dr. Steinbruner's work has focused on issues of international security and related problems of international policy. He is also a Non-Resident Senior Fellow at the Brookings Institution and an Academic Advisor at the Carnegie Corporation of New York.

Dr. Steinbruner served as director of foreign policy studies at Brookings for 18 years. He is currently vice-chair of the Committee on International Security and Arms Control of the National Academy of Sciences, chairman of the Board of the Arms Control Association, a fellow of the American Academy of Arts and Sciences, and the cochair of its Committee on International Security Studies. He is also a member of the Council on Foreign Relations.

In recent years, he has served on the Defense Policy Board of the Department of Defense and the Carnegie Commission on Preventing Deadly Conflict. He is the author of numerous books, including *Principles of Global Security* and *A New Concept of Cooperative Security*.

Dr. Andrew Spielman (Lt. Cmdr., U.S. Navy, Ret.)

Professor of Tropical Public Health, Harvard School of Public Health and Center for International Development

Dr. Spielman is an expert on zoonotic vector-borne tropical diseases, such as those that cause malaria, dengue, and West Nile fever. He is director of the Malaria Epidemiology Program, Kennedy School of Government, and acting director, Program in Epidemiology of Infectious Diseases, Harvard School of Public Health. Dr. Spielman established many of the fundamental features in the natural history of West Nile fever and Lyme Disease.

His research includes work on pathogens that are listed as potential bio-warfare agents, including those that cause eastern equine encephalitis and tularemia, and mosquito physiology.

Dr. Spielman first went to Cuba in 1956 as a Lt. Cmdr. in the U.S. Navy. He served as Disease Vector Control officer at the U.S. Naval Base at Guantanamo Bay, from 1956 to 1959, witnessing the Cuban Revolution first-hand during that time.

Ms. Lorena Barberia

Program Associate and Cuba Program Director, David Rockefeller Center for Latin American Studies, Harvard University

Ms. Barberia directs the Rockefeller Center's initiatives focused on strengthening the institutional ties of cooperation and exchange between Harvard University and Cuban academic, scientific and research institutions. Her key project areas include: public policy-making and management education, health, economic development, U.S.-Cuba relations, and urban planning and architecture.

Together with faculty at the Program in Infectious Disease and Social Change in the Department of Social Medicine at Harvard Medical School, she recently organized a seminar on the Cuban health system at Harvard University and participated in a conference on the impact of health systems reform in the control and prevention of infectious disease in Latin America, co-sponsored by the Pan American Health Organization and the David Rockefeller Center for Latin American Studies, which took place in Havana in April 2002.

Prior to joining the Rockefeller Center, she worked in Ecuador and Panama as an economist and on research projects at the Harvard Institute for International Development that focused on developing and transition economies.

She holds a Masters in Public Policy from the Kennedy School of Government. Her research focuses on economic policy, and is currently examining remittance flows to Cuba and their impact.

Mr. Glenn Baker

Cuba Project Director, Center for Defense Information

Mr. Baker created the U.S.-Cuba Cooperative Security Project, aimed at developing and expanding U.S.-Cuban dialogue on military and regional security issues, and articulating the specific architecture of future military-to-military cooperation. He has traveled to Cuba six times since 1996 with CDI delegations.

He is also an independent television producer, having written and produced more than 50 documentary episodes broadcast on PBS on global security issues, including three award-winning films on Cuba. Most recently he was executive producer of the FRONTLINE program "Missile Wars," exploring the battle over missile defense, which aired on PBS in October 2002.

Previously he worked at the private National Security Archive, where he was Freedom of Information coordinator and then research analyst evaluating declassified government documents.

Mr. Stephen Sapienza Co-Director, Azimuth Media Video documentation

Mr. Sapienza co-directs Azimuth Media, a documentary production unit specializing in global security issues. He has written and produced more than 40 programs broadcast on PBS in the *America's Defense Monitor* series. With 11 years of experience as a producer, videographer, and editor, he has produced numerous award-winning documentaries on topics as diverse as child combatants in Sierra Leone, the Cuban military, and landmine survivors in Cambodia. Most recently he was producer and editor of "Deadlock: Russia's Forgotten War," a program exploring the war in Chechnya, broadcast on CNN in 2002.

Introduction

by Glenn Baker
Cuba Project Director,
Center for Defense Information

John Bolton, U.S. undersecretary of state for arms control and international security, triggered a furor when on May 6, 2002, he stated, "The United States believes that Cuba has at least a limited offensive biologi-

cal warfare research and development effort." Two days later, I was meeting with a representative from the Cuban Interests Section on an unrelated matter when I posed the question, "How would Cuba respond if CDI asked to bring a group of experts down to learn more about these charges?" I had no expectations of hearing any more about it. But less than two weeks later, I was told that not only was there an interest, but that we were invited to bring anyone, come anytime, and visit anywhere we wanted. Clearly, Bolton's comments had struck a nerve in Havana.

It is easy to see why. In the same speech, Bolton went on to say, "States that renounce terror and abandon WMD [weapons of mass destruction] can become part of our effort. But those that do not can expect to become our targets." Furthermore, Cuba has remained on the State Department's list of sponsors of terrorism since its inception in 1979, despite considerable evidence that Cuba is held to a different standard than other countries due to politics. In the context of the war on terrorism and the new U.S. policy of



CDI President Dr. Bruce Blair (left) and Gen. Charles Wilhelm, former commander in chief of U.S. Southern Command (center), led a group of ten science and policy experts to examine Cuba's biotechnology sector.

pre-emptively attacking nations suspected of possessing WMD, Cuba feels increasingly in the crosshairs. (Cuba's harsh crackdown on dissidents in April 2003 only served to heighten these tensions.)

As I went about identifying and recruiting experts on bioscience and bioweapons, one thing became clear: allegations of biological weapons efforts are extremely hard to either prove or disprove. The means to create germ weapons, unlike nuclear, can be easily concealed or dismantled in a short period of time, and do not require elaborate technical facilities. Any nation with a fairly sophisticated pharmaceutical industry inherently has the **capability** to develop bioweapons, whether or not it has the intention to do so.

Furthermore, it was mutually agreed that the CDI trip in no way constituted "inspections," a term that implies a certain degree of confrontation and an element of surprise. Therefore it became evident that our visit would provide neither the "smoking gun" nor the "clean bill of health" that might put an end to the controversy.

Here's what the trip did do:

- provide a great deal of first-hand information about a subject long on rhetoric and short on fact;
- gauge Cuban openness and transparency on issues related to its biotechnology sector;
- engage American and Cuban scientists and security experts in a much-needed dialogue on how, in the age of terrorism, to balance the need to protect trade secrets in a highly-sensitive industry with the need to establish international confidence in the legitimacy of your work;
- provide a framework for routinized future exchanges in the field that will build confidence on biotech issues and facilitate information-sharing that can lead to scientific advances in both countries.

After extensive research and consultation with a variety of sources in the United States, both official and private, we provided the Cubans with a list of nine

facilities that we wanted to see. Upon arrival, we were handed an itinerary that listed all nine facilities. The Cubans repeatedly stressed that we could go to locations not on the list as well, if we so de-At each center, following a sired. PowerPoint presentation about its mission from the center's director and a jolt of thick Cuban coffee, we donned white coats, foot-covers, and hats and toured the primary facilities. As we toured, we frequently were introduced to mid-level scientists and technicians, who were proud to talk about their work. We then had the opportunity to request to see additional parts of what in many cases are sprawling complexes.

We were permitted to shoot video and take pictures almost everywhere we went. We were not permitted to shoot in the actual production lines, where proprietary information about pharmaceutical products would be compromised. (Smaller groups of three or four individuals did go through these production lines, enduring extremely thorough decontamination showers before and after the tour.) At DAVIHLAB, one staffer attempted to prevent filming in one particular lab, but following our protests, he was overruled and our camera was invited in. At "La Fabriquita," we were told we could not film inside the building, due to Ministry of the Armed Forces regulations, which manages the facility.1 We were permitted to shoot outside and around the building. Ironically, this facility appeared to have the least technological capacity, containing a handful of workers with knives and hoses cutting up shark carcasses and processing the cartilage into powder for nutritional supplements.

The Armed Forces of the Revolution, or FAR, are heavily involved in economic and business interests in Cuba. For more information, go to: www.cdi.org/adm/1319.



Dr. José Manuel Miyar Barruecos (left), secretary of the Council of State, discusses the development of the Cuban biotech sector with Bruce Blair (right), as translator stands by to handle technical terms.

Aside from these instances, we were permitted to roll everywhere, from laboratories filled with test tubes, computers, and scientists, to Biosafety Level 3 labs, to large rooms full of organism fermentors, to animal testing labs, to cold storage chambers. (Often this filming took place through windows designed to protect the room from contaminants.)

At the beginning and end of the trip, we met with a group of about two dozen of Cuba's leaders in the biotechnology field, including Dr. José Manuel Miyar Barruecos, secretary of the Council of State and a close advisor to Cuban President Fidel Castro on scientific and medical issues; Dr. Luis Herrera, director of the Center for Genetic Engineering and Biotechnology (CIGB); Dr. Agustín Lage, director of the Center for Molecular Immunology; Dr. Concepción Campa, director of the Finlay Institute; Dr. Gustavo Kourí, director of the Pedro Kourí Institute, and Dr. Carlos G. Barroto, vice-director of the CIGB. We also met with Castro himself for more than six hours.

Over the course of these meetings and site visits, the role of Cuba's large and advanced biotechnology sector within the context of the national health care system became clear. While the country's commitment to free national health care is well-known, its resources for providing it are extremely limited, especially in the economically difficult times that have followed the loss of Soviet aid. Therefore, an "ounce of prevention" strategy makes particular sense in the Cuban context. Today, Cuba is probably the most vaccinated society on Earth, with citizens receiving immunizations against 13 major diseases prevalent in its tropical climate. One result is that despite its beleaguered economy, Cuba's infant mortality rate (6.2 per 1,000) and average life expectancy (76 years) compare favorably with those of the United States (seven per 1,000 and 76).²

Because we knew our visit would not permit us to make a conclusive statement about the status of any alleged Cuban bioweapons effort, we asked the Cubans to refrain from making any statements that might reflect an attempt to take political advantage of our visit. To my knowledge, they have abided by this request.

Does Cuba have "a limited offensive biological warfare research and development effort"? Sorry. I can't say. Did Cuba display a remarkable degree of openness and goodwill in permitting our group to go where it went and do what it did? Absolutely. Is Cuba open to further visits to its biotech centers by American scientists and bioweapons experts? I would bet the answer would be "yes." It's in our best interest to keep posing such questions to them.

The U.S. figure is skewed slightly higher due to the fact that the United States leads the world in extraordinary medical efforts to save very premature births, some as early as the 20th week of gestation. While deaths in this category are factored into infant mortality figures, in most countries the medical intervention would not have been attempted and it would be categorized as a "fetal mortality."

Individual Reports

The Hon. MARTHA KREBS, Ph.D.
Principal, Science Strategies
Assistant Secretary of Energy and Director of the Office of Science, 1993-2000

I came away impressed with the quality and enthusiasm of the staff of the research organizations, particularly. Their awareness and commitment to their mission to improve the health and nutrition of the Cuban people was also notable. I was struck by the general youth of the staff, often averaging 40 or younger. In the major research facilities, there was significant international collaboration and Cuban scientists had spent significant time training or visiting outside the country. It was interesting to note that they also returned home in significant numbers.

The leadership at these institutions is committed to their designated missions. I was particularly struck by certain of the directors, their prompt expressions of lack of any knowledge of military involvement in the

setting of research and development (R&D) priorities, and their personal sense of obligation to their missions. Most of them were open and their openness affected the reactions of their staff.

The major institutions have fine equipment that allow them to research and produce pharmaceuticals that meet international standards. As a result of the combination of staff and equipment and the character of modern biological research, I cannot say that Cuba is not producing bioweapons. However, I do believe that we heard from the staff and leaders of most of the institutions we visited that they are committed to science and its use for the welfare of the Cuban people. To turn these groups to

a mission of death, would, in my opinion, be pretty difficult. Since this was not an 'inspection' *per se*, there may be other people and places in Cuba who know how to take advantage of the knowledge that we saw and who have a more deadly mission, but I would be surprised.

Description of facilities visited on the Cutting Edge with a Broad R&D and Production Mandate: CIGB, CIM, FINLAY, and IPK

Center for Genetic Engineering and Biotechnology / Centro de Ingeniería Genética y Biotecnología (CIGB)

CIGB has a broad mandate to investigate health and pharmaceutical applications of molecular biology with a special emphasis on recombinant DNA techniques (that



Dr. Luis Herrera Martínez is director general of the CIGB.



The delegation is welcomed to CIGB, the most-visited of the 53 biotechnology facilities in Cuba. Former President Jimmy Carter visited here in May 2002.

permit the isolation, replication, and manipulation of gene fragments). From a scientific perspective, CIGB and CIM are the most modern facilities we visited. CIGB has close to state-of-the-art facilities that can characterize the physical properties of molecules and bulk materials; these facilities include ion mass spectrometry and high-resolution electron microscopy. It has DNA sequencers and oligonucleotide assemblers that permit them to fabricate specific DNA sequences. Staff are also doing research on the structure and function of particular protein molecules using their magnetic resonance facilities. They also participate in foreign collaborations to undertake x-ray scattering experiments.

The CIGB production facility is small but high quality, claiming to meet World Health Organization and Pan American Health Organization requirements and have FDA standards as their goal. The intent is to produce pharmaceuticals for first world markets. The facility has non-active BioSafety Level (BSL)-4 laboratories3 that have never been used at that level. It would take a major investment to bring them into BSL-4 operation.

This facility has both people and equipment that have the requisite skill and capability to contribute to research and production of military bioagents. However, it would require a major change of mindset both at the leadership and working level.

Images at right, from top:

Multiple TV monitors provide views of sterile labs at CIGB.

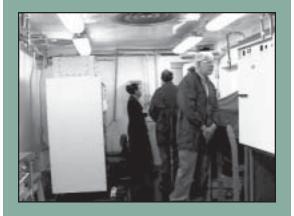
Entering one of the non-active BSL-4 labs at CIGB.

Originally constructed to handle BSL-4 work, these labs have never been used at that level, and would require substantial modifications in order to do so.

Inside the non-active BSL-4 lab.









See Appendix I for a description of Biosafety levels for handling infectious agents.

Center for Molecular Immunology / Centro de Inmunología Molecular (CIM)





CIM is an up-to-date organization with respect to both staff and equipment. Staff and leadership are palpably excited about their mission to use and develop molecular biology to understand various cancers and to develop cancer vaccines. They also work with other institutes on molecular approaches for dengue fever vaccines. Under the framework of their mission, they have a group of theoretical biophysicists modeling antigens and cellular receptors that are related to the particular diseases and cancers that they are investigating. They are also knowledgeable and engaged in using modern bioinformatics databases and techniques, which can accomplish a number of tasks, including the identification of specific genes, protein structures, and protein pathways. They are assembling a cluster-based computing facility (currently 32 processors moving to 64 in the near future) that will allow them to carry out more complicated, independent calculations than they can currently. The cluster is based on ASUS processors from China or Taiwan.

The CIM production facility is modern. Since they produce vaccines based on molecular fragments that are not inherently infectious, their major concern is the quality of the product, not so much the safety of the workforce. We saw here the same awareness of world-class quality control and safety standards as we saw at CIGB and Finlay.



Top: a scientist explains floor plan schematic in CIM control room.

Above: part of the e x t e n s i v e ventilation system at CIM.



Bottom: produced at CIM, EPOCIM is a recombinant product used in the treatment of anemia in HIV-infected patients and cancer patients undergoing chemotherapy.

Carlos J. Finlay Research Institute







The Finlay Institute develops and produces numerous vaccines, including the only vaccine in the world for meningitis B. It is named for Dr. Carlos Finlay, nominated for a Nobel Prize in 1906 for his work identifying the mosquito as the transmitter of yellow fever.

Above middle: Dr. Concepción Campa Huergo, President and Director-General of the Finlay Institute, is also a member of the Politburo; Above right: lab workers handle live organisms in the production line for the Meningococcal (meningitis) B vaccine.





Top: this fermenter is used to produce organisms for the Meningococcal B vaccine, currently undergoing clinical trials in the United Kingdom and Spain; Bottom: midlevel scientists lead a tour through the Institute's very clean observation hallways.

At the Finlay Institute, we mostly saw the facility's two production lines for human vaccines. This is a big operation with more than 900 full-time employees. Although we didn't see the Institute's laboratories. staff is clearly involved in research to develop new vaccines for Meningococcal B&C. Trivalent Antileptospirosis, and new versions of standard vaccines for typhoid, tetanus and combination vaccines. The Institute is working with GlaxoSmithKline4 on the Meningococcal vaccine. The production facility, like the animal vaccine facility, is based on classical cellular fermentation procedures and technologies. The human-use goals, however, result in higher levels of regulation domestically and internationally. Though the facility is 10 years old, it is in great shape. A major issue for all the production labs that we saw is the importation of the fundamental chemicals for various kinds of fermentation nutrients and processing. Much of it comes from the United States, and Cuba has to find ways to bring it in around U.S. restrictions, at cost markups of 3-4 times. We saw this at CIGB and CIM as well. This is a facility with a strong leader, entusiastic staff and equipment that is current and well-maintained.

Cuba partnered with Smith Kline Beecham, which merged in 2000 with Glaxo Wellcome to form the new company, GlaxoSmithKline, a U.S.-U.K. pharmaceutical conglomerate with \$29.5 billion in sales in 2001.

Pedro Kourí Institute of Tropical Medicine / Instituto de Medicina Tropical "Pedro Kourí" (IPK)

We had a very brief visit here. The overview did not give much sense of the quality or research effort of the staff or the equipment.







Facilities with a narrower mandate and more limited capabilities: CENSA, DAVIHLAB, LABIOFAM

National Center for Agricultural and Livestock Health (CENSA)

This is an interesting place insofar as it seems to have a significant history in providing contributions to health innovations for Cuban



health and agriculture. However, we saw very little in the way of modern lab equipment that would support whatever its current work is. The facility itself appears to be quite large, given its current workforce of about 400 full-time employees. We saw some young scientists who were excited about their work. One young man was working on a concept of integrated pest management based on a fungus that grows on rice and can be used to infect an earthworm that causes major damage to an important woody crop. This is a clever idea that eliminates the need for large and costly applications of chemically synthesized insecticides. It is also consistent with much of the strategic approach that Cuba has taken with respect to health and agriculture, which is: grow your own capacity, think sustainably, and minimize imports that require hard currency. We saw nothing here that indicates strong capability for biowarfare. However, the specific laboratories that we visited were surrounded by many empty, underused rooms; the particular research activities that were being carried out looked like they were staged.

From top: built in 1993, IPK structures show the effects of weather. IPK appears to lack the funding base of CIGB, CIM, and Finlay; Dr. Gustavo Kourí, director of the Pedro Kourí Institute, explains the role of the institute founded by his father in 1937, pictured on the wall behind; cold storage for bacteria at the IPK.





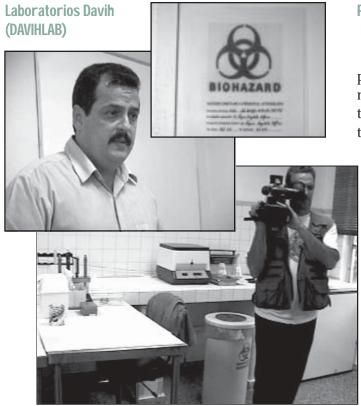






Top left: "Ubre Blanca," or "White Udder," graces the foyer at CENSA. A crossbred Holstein and Zebu, she produced a record-setting 73 liters per day (mean yield).

Left and above: most of the labs and equipment in CENSA appeared to be inactive.



Left: Felipe M. Rolo Gomez is director of DAVIH Laboratories. Above: Cuban cameramen shadowed our camera crew at every turn. Top: sign limiting access to molecular biology lab at DAVIH to the authorized researcher.

This very small facility produces kits that enable standardized testing for HIV. The kits are distributed throughout Cuba; local physicians use them to take individual samples, which are then returned and analyzed at DAVIHLAB. Its laboratory facilities are consistent with quality control needs for the kits and the diagnostic tests that are carried out when the kits are returned. It is not a development lab and relies on labs like CIGB and IPK for any new components for the kits. The lab has a BSL-3 facility associated with an HIV vaccine production facility, where the focus is on protecting both workers and pharmaceutical quality. The staff and leadership here seemed competent and motivated and integrated with colleagues in other institutes.

Pharmaceutical Biological Laboratories / Laboratorios Biológicos Farmacéuticos (LABIOFAM)

LABIOFAM is a large organization that produces products for the agricultural sector, as well as other naturally-derived products with pharmaceutical, nutritional and cosmetic uses. We visited the facilities that produce various vaccines that afflict Cuban agri-

cultural and other domestic animals. These are old facilities, small, dark and not very user-friendly. However, people were very open and willing to take us through facilities that were shut down for annual maintenance. These are classic pharmaceutical production facilities in that they involve the growth of specific cell lines that have been modified to produce antigens that elicit a desired immune response but do not infect with the virulence of the original bacteria or virus.

The most interesting part of the tour was the cold room where we saw the various strains of modified infectious agents that form the basis for cell culture in the factory.

We did not get a sense of the facility's quality control laboratories but there were references to collaborations with CIGB. We drove past a few other LABIOFAM facilities as we traveled around Havana, so what we say about this location may not be applicable to the others.



Dr. José Fraga Castro, president of the LABIOFAM Enterprise Group and a relative of Fidel Castro.



Products on laboratory shelf at LABIOFAM.



A LABIOFAM cold room.



LABIOFAM produces a wide variety of commercial products, distributed around the country by semi truck and trailer.



The grounds of LABIOFAM feature an alligator pool.



A staffer displays a freezer of modified infectious agents in a LABIOFAM cold room.



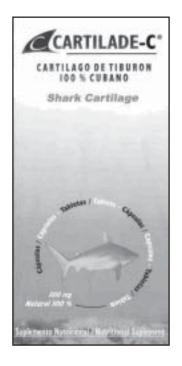
Facilities which were small, of very limited technical capability, and need not have been on the list: "La Fabriquita" and CEBIMAR

Fabrica de Pienso Animal / Special Processing Plant "La Fabriquita"

This facility produces shark cartilage extract for a natural supplement that is used in Cuba for arthritis and as a supplement to other treatments for bone cancers. Like many Cuban industries, it is managed by the military, but has no apparent direct connection to military missions. The workforce is minimally skilled and most manufacturing procedures are manual. The only significant piece of technical equipment is a milling machine that produces micron scale powders, which is significantly larger than militarized anthrax powders. Conversion of this machine for weaponized biologicals is probably not feasible and certainly would be costly; also it would have to be moved to a more controlled and safe environment than where it is now.



This dressing area just inside the doorway was as far as cameras were permitted. We were told this was due to Ministry of the Armed Forces regulations. Just beyond was a large, open area where two employees with knives and water hoses were removing cartilage from shark carcasses.





Above: main building at "La Fabriquita," run by the military, looks like a former barracks. Left: this brochure describes the medicinal uses of the powdered shark cartilage produced at La Fabriquita.



Center for Marine Bioactive Substances (CEBIMAR)

This is another small facility (about 30 staff members) that operates under the aegis of the Ministry for Science, Technology and Environment. Gisela Alonso, deputy minister for the environment, attended the briefings and tour and in a private conversation gave me a broader sense of the civilian science and technology organization of Cuba. Her husband is the president of the Cuban Academy of Science. The facility used to be part of the Cuban Academy, but was spun off with other research activities when the academy was reorganized to focus on expert studies. This follows the model of the U.S. National Academies of Science







and Engineering. The mission of the center appears to be the study of marine organisms for beneficial uses, especially for health. The center has some work on marine-based neurotoxins. It has an enthusiastic staff, but the facilities and equipment are extremely out-of-date. Staffers do a lot with very little, but they are basically a group focused on classical cell and organismal biology. The knowledge of the staff about the organisms they study is the principal asset here.

Above: entrance to CEBIMAR, a modest facility in a residential neighborhood of Havana; Left from top: the assistant director explains CEBIMAR's work in front of chromatography columns; materials preparation at CEBIMAR; microscope with patch-clamp set-up indicates the modest technology at CEBIMAR.

MR. TERENCE TAYLOR
President/Executive Director,
International Institute for Strategic Studies, U.S.
UNSCOM Chief Inspector, 1993-1997

In the context of a short visit, it is difficult to draw firm conclusions about the Cuban pharmaceutical and biotechnology sectors. Nevertheless, a great deal of openness was displayed, even to the extent in some instances commercial proprietary rights were put at risk. Given the composition of the visiting team and context of the visit, the Cubans no doubt assessed that the risk to their proprietary information was low. Clearly the direction from the top level of government was to be as open as possible consistent with safety and, where possible, protecting commercially sensitive data.

International Contacts

There was plenty of evidence of technology transfer in both directions between Cuba and academic and commercial entities abroad – in the form of academic exchanges and conferences and commercial joint ventures. European, Latin American and Canadian universities and companies are the dominant entities involved.

There appeared to be a fair amount of contact with the U.S. academic community reported by most of the facilities visited. There were plenty of manuals and handbooks of U.S. Department of Health and Human Services origin on such matters as basic laboratory techniques in cell culture.

The most substantial joint venture was with the Anglo-American pharmaceutical company

"Given the nature of the range of international contacts and joint ventures, the relatively open system, and the attitude and approach of the staff to their work, it would be very unlikely that there is any work on biological weapons at any of the facilities visited."

- Terence Taylor



CENSA's vast hallways led to laboratories that were for the most part inactive.

GlaxoSmithKline for a meningitis vaccine now undergoing clinical trials in the United Kingdom and Spain. This sector of the Cuban industry has a global reach with 37 'Technology Transfer Projects' being reported in 14 countries including Algeria, Brazil, China, India, Iran, Malaysia, Mexico, Tunisia and the United Kingdom. This range of contacts would be typical for a country with the capabilities in the pharmaceutical and biotechnology area as exists in Cuba.

At the Pedro Kourí Institute of Tropical Medicine (IPK), the director reported that students from 72 countries had attended courses there. There was substantial cooperation with the World Health Organization at most facilities. There was a puzzling lack of joint projects or ventures with Russia, given the history of the relationship between the two countries and Russia's strong biotechnology capability. Whether there are only a few projects or the Cubans preferred not to mention them is not clear; the former seems the more likely.

Capability

In terms of the general capability of the industry, Cuba is strong in the area of anti-viral vaccines and is putting a great deal of effort, with some promising projects, into anti-cancer vaccines (treatment, not prevention). Early investment in research into HIV, particularly in tests to assess the progress of the disease in patients diagnosed as HIV positive and to assess the effectiveness of treatments. The capability in the agricultural sector is strong, although suffering somewhat from a lack of commercial investment in comparison to commercial competitors overseas.

Personnel and Openness



For the most part, the staff appeared very committed and professional in the facilities we visited.

Dr. Lydia M. Tablada Romero is director general of CENSA.



Above: technicians at CENSA use pipettes to collect samples of liquids for subsequent analysis; Below: Terence Taylor (second from right) is shown list of organisms in stock at LABIOFAM, below.



There was a dominant – and in my view – real sense of engagement in a humanitarian mission.

In a few instances, there was more of a display of ideological commitment to the political leadership than others. This was particularly so at the National Center for Agricultural and Livestock Health (CENSA). In addition, the design of the buildings and some parts of the research program at this facility did not seem consistent with stated purpose of the center.

Also, one of the laboratories visited was clearly set up as a show piece – the work engaged in by personnel there did not appear to be real. This does not necessarily mean there were activities of concern being hidden. The research work being undertaken seemed to be the product of whims of the center's director who set up an "old style" of presentation for foreign visitors.

This approach was unusual, and the display of openness was generally impresive at other facilities. For example, when a catalogue of the organisms (viruses and bacteria) held in stock was requested at the Pharmaceutical Biological Laboratories (LABIOFAM), the list was promptly shown to us at the site and a copy later supplied to me after returning to the United States. The list seems consistent with the work declared as being conducted at the facility.

Containment Facilities

The operational containment facilities [one BSL-3 and one BSL-2] appeared to be efficiently operated and appropriate for the activities at the facilities concerned. There was a second BSL-3 not in use. There was also a BSL-4 facility that was apparently constructed in the 1980s, but reportedly never used for its designed purpose. From a tour of the facility, it is clear that it is now being used for storage.

Provisional Assessment

Like many countries with a substantial and modern pharmaceutical and biotechnology industry, Cuba has the capability to run a leading-edge biological weapons program. While we saw no evidence of a weapons program, it has to be remembered that the team was engaged in a brief visit that should not be considered in any way as an inspection. Given the nature of the range of international contacts and joint ventures, the relatively open system, and the attitude and approach of the staff to their work, it would be very unlikely that there is any work on biological weapons at any of the facilities visited. More visits to these and other facilities, with appropriate experts, would do a great deal to raise the level of confidence in this judgment.

GEN. CHARLES WILHELM, U.S. Marine Corps (Ret.)
Distinguished Military Fellow,
Center for Defense Information;
Commander in Chief, U.S. Southern Command, 1997-2000

General Comments/Observations

- 1. We were given access to every facility that we requested.
- 2. The attitude of our hosts was open, cordial and friendly (more so than government officials and armed forces).
- 3. Tours were relatively informal ... directors of each laboratory personally conducted the tours ... no overt "dog and pony shows" ... no indication that facilities had been specially groomed for our visit ... a fair amount of obvious "busy work." Laboratory personnel were reasonably communicative, but directors ran the show.

4. Recurrent themes:

- "All doors are open to you ... you will be permitted to see anything you wish." This took the form of insistence. Were they going to be graded at the end of our trip as to how many facilities we actually visited/entered?
- "Lack of access to American products is penalizing us. We must go to third parties. We incur higher costs."
- "There is no affiliation whatsoever with the military." No Cuban Ministry of the Armed Forces representatives participated in the visit.
- These people have obviously been inspected a lot. They are comfortable with visitors and project the image of a responsible scientific community.





Left: the production facility at the vast CIGB complex as viewed from the seventh floor of the main building. Right: Dr. Andrew Spielman observes lab rat facility at CIGB.

Security at the facilities

Center for Genetic Engineering and Biotechnology (CIGB):

- Permanent staff: 1,245
- 70,000 square meters: two main buildings, a production plant, two animal facilities
- Civilian security guards
- No visible military presence
- Fenced compound with controlled entry
- BSL-3 configured space on the 5^{th} floor but no BSL-3 work being done there
- Laboratories 7A and 7B on the seventh floor could be "theoretically" (their word) configured for BSL-4 work. They are currently used for BSL-2 work on HIV, Dengue and Fowl Pox.

- Stated they needed BSL-4 facilities for DNA recombinant work
- CIGB has seven BSL-2 laboratories
- Most visited facility

"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." - Gen. Charles Wilhelm

Center for Molecular Immunology:

- Director Dr. Agustín Lage is the older brother of Cuban Vice President Carlos Lage
- Under Counsel of State
- Permanent staff: 275
- 15,354 square meters
- One of the newest centers (1994)
- Comparable with U.S. commercial academic lab facilities
- Primary responsibilities: cancer research and mammalian cell research
- No visible military presence
- Minimum security
- 8-foot security wall (3-foot concrete/5-foot steel mesh)



Philip Coyle (left) talks with Dr. Agustín Lage, CIM's director.

National Center for Agricultural and Livestock Health (CENSA):

- Under Ministry of Higher Education
- Staff of 400 (43 percent professionals/scientists;
 26 percent researchers; remainder support);
 58 percent women
- 30,000 square meters
- Non-descript, older facility
- Instruments and appointments appeared obsolete
- No fences, pretty much an open facility
- No visible military presence
- Director came across as an ideologue
- 30 minute drive from Havana

Detection Anti-Virus HIV Laboratory (DAVIH):

- Under the Director of Civil Defense
- 30 "skilled people" work in the BSL-3 labs
- 3,110 square meter fenced compound (6-foot steel mesh) not a security fence as such
- Four BSL-3⁵ labs totaling 132 square meters.
 Donned protective clothing and toured all four labs, followed by a shower.
- Described as counterpart to the Centers for Disease Control (CDC)

Other individual reports refer to DAVIHLAB's BSL-3 facilities as a single lab.

- Strongly encouraged by the Director to observe filtration system (floor above) and water system (floor below). Both appeared ship-shape.
- No evident entry and exit controls
- No visible security
- No visible military presence
- Work in progress was HIV (in vitro HIV surveys) and Hepatitus B
- Produce the antigen for HIV
- Sidebar discussion of HIV: 4,338 AIDS sufferers in Cuba; tracking 206 patients
- Only access controls to BSL-3 spaces were a typewritten access list and conventional locks on a door.

Pharmaceutical Biological Laboratory (LABIOFAM):

- Under Ministry of Agriculture
- More than 40 years old
- Best maintained facility we visited
- 8-foot fence more access control than security
- Uniformed civilian guard force (unarmed)
- No visible military presence
- Badging system in use; had to swipe in and swipe out; more security and better access control than DAVIH Lab
- 97 percent of Cuba's veterinary medicine needs are met by this facility









From top: entrance gate at LABIOFAM; Terence Taylor swipes in with his magnetic card at LABIOFAM gate; Gen. Wilhelm inspects the vaccine freeze dryer at LABIOFAM; the freeze dryer was reported to have a capacity of 180 liters per 24 hours.

Center for Marine Bioactive Substances (CEBIMAR):

- Small facility, founded in 1992
- Located in a residential neighborhood in Havana, no security/unfenced
- Very rudimentary facility, comparable to a high school science lab in rural Alabama
- Research only (three nationally funded projects, five internationally funded projects: Germany, Spain, Middle East)
- No visible military presence

Special Processing Plant ("La Fabriquita"):

- Director name not disclosed
- Under the "Military Hospital System" not Luis Soto Naval Hospital
- No visible uniformed military presence
- Appears to have been a former military facility (barrack-type buildings, two main work spaces, and what appeared to have been a guard shack)
- After questioning, two senior representatives admitted they were military. One owned up to being a Lt. Colonel chemical engineer specializing in food production. The other was more evasive, saying he worked for the military but had no rank ... if true, he may have been a medical officer.
- Lt. Colonel stressed that military doctors do no biological research of any kind
- Facility was actively producing a single product, a medicinal for arthritis and joint ailments extracted/







derived from shark cartilage. Looked more like a food processing plant than a biological laboratory. Product is for commercial sale and export.

Finlay Institute:

- Under the Counsel of State
- Founded 1991
- Staff: 930
- 21,654 square meters
- Mission: research and production of human vaccines
- Currently producing vaccines for meningitis, leptospirosis, typhoid fever and tetanus toxoid
- New plant construction is planned
- Partnership with GlaxoSmithKline
- Output capacity is 100 million doses
- These appeared to be highly resourced facilities
 modern and competitive with U.S. facilities
- Claimed Hepatitis wiped out in Cuba; now selling vaccine to Brazil, Colombia and others

Pedro Kourí Institute of Tropical Medicine:

- Staff: 520
- 30,000 square meters
- Large campus, 20 buildings, including a 140-bed hospital for AIDS patients

Opposite, from top: guard shack and gate at entrance to La Fabriquita; the facility is surrounded by a widely-spaced barbed wire fence; the facility's director declined to provide his name, but stated that he was a Lt. Colonel in the Armed Forces. Right: IPK lobby.

- Established 1937; current complex built in 1993
- 1979 brought a new phase of development for IPK
- Tasked by Castro with work to detect and avoid tropical diseases, collaborate with others (international), and pursue science.
- Heavy emphasis on teaching
- More than 25,000 students over the years, including 47 U.S. students in last five years
- Doing AIDS work with the University of North Carolina



Concluding Comments:

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.

Dr. Spielman did offer the comment that he felt the Cubans were less than forthcoming on some questions concerning genealogy. He did not elaborate, and provided no specifics other than that they were "evasive" and failed to completely answer his questions.

According to the Cubans, they have 53 biotechnical facilities nationwide employing more than 5,000 people. We visited only a small percentage of these, but believe the nine we visited are among the most significant.

The Cuban scientists and researchers pressed us on only two points:

- 1. a need for access to U.S. supplies and equipment;
- 2. the desirability of more robust and frequent exchanges.

We met with Fidel Castro on the last night of our visit. We convened at the Presidential Palace at 21:00 and adjourned at about 03:30. The event was cast in the mold of those I have previously attended: a twohour Castro monologue on a variety of subjects, generally focused on the "good life" in Cuba. On this occasion, he focused most of his comments on a program to reeducate and reemploy Cubans involved in the sugar industry. He spoke of a program, the enrollment growing from an initial 86,000 to its current 113,000, designed to provide new skill sets to the excess workforce from a sugar industry that now employs about 450,000. The monologue was followed by a midnight dinner, during which he spoke continuously. On this occasion, he used our delegation as his rehearsal audience for his presentation at the commemoration of the 40th anniversary of the Cuban missile crisis. He appeared fit and in good health.

DR. JOHN STEINBRUNER Director, Center for International and Security Studies, University of Maryland

In my judgment, we were given a consistent and credible account of the origins and purposes of the Cuban biotechnology complex. Government officials presented it as a commitment to public health in Cuba originally necessitated by the difficulties they encountered in acquiring drugs and vaccines on the international market at affordable prices. Given the substantial investment they have made and the results they have achieved in some instances – most notably, their anti-cholesterol pill and their meningitis vaccine – they have reasonable aspiration for hard currency earnings in international markets. Although they do not use the phrase, "market adaptation" is acknowledged to



A recombinant Hepatitis B vaccine produced at CIGB has been used widely throughout the world.

be their overriding general problem, and they are counting on the biotechnology "complex" – industry as we would term it – to provide material assistance in that regard. The commitment to public health service within Cuba and to international market adaptation

seems to have been recognized and absorbed by the institute directors and the working research staff.

In the course of our meeting with Fidel Castro, he explicitly and forcefully denied that Cuba was undertaking

any biological weapons effort, and I, personally, consider that denial to be inherently credible. Revelation of a clandestine effort of that sort would severely jeopardize Cuba's international market aspirations. I can imagine no countervailing strategic benefit that might override that consideration.

consideration."

I saw nothing in the course of our visit that might bring the denial of a biological weapons program seriously into question. Specifically:

- a. We were given what appeared to be unrestricted access to all of the facilities we visited. That principle was repeatedly stated, and the only qualification I observed was the prohibition of cameras in the production areas.
- b. All of the activities we observed and the personal attitudes we encountered seemed to me to be consistent with the legitimate purposes espoused. In a few instances, individual researchers described lines of scientific inquiry that could be construed to be dangerous and indeed are similar to lines of research in the United States that some have suggested to be potentially dangerous. But in those instances, the Cuban researchers cited thoroughly legitimate purposes, and it seemed to me the potentially destructive applications had not even occurred to them. They seemed very much

like their American counterparts in that regard.

c. The explanation provided for the origin and current status of the BSL-3 facilities are plausible and consistent with what we saw. My understanding

"Revelation of a clandestine effort ... would

severely jeopardize Cuba's international market

aspirations. I can imagine no countervailing

strategic benefit that might override that

- John Steinbruner

is that we saw all those that have been constructed on the island, only one of which is currently being operated under BSL-3 standards. The two that are operating as BSL-2 facilities and the one that is inactive are said to have been con-

structed to comply with the initial U.S. Asilomar standards⁶ and downgraded when those standards were subsequently relaxed. The containment facility that is still operating at the BSL-3 level is engaged in AIDS research, and is used occasionally by the Pedro Kourí Institute and others for experiments that require that level of containment. We were told that there is no facility being operated at BSL-4 on the island.

d. There were access barriers at most of the facilities we visited, but no internal or external security perimeters of the sort that would almost certainly be found at a facility engaged in biological weapons work.

The Asilomar standards were developed to have specific protocols in place for dealing with possible biological dangers arising from research with recombinant DNA molecules. These standards were first established systematically at the 1975 Asilomar conference (Pacific Grove, Calif.) on biohazards from recombinant genetic materials. The major principles are "(1) containment must be an essential part of the experimental design, and (2) the effectiveness of containment should match as closely as possible the estimated risks (in the event risks are not determinable, error should fall on the side of caution)." The original Asilomar standards were considered quite restrictive, and have evolved as technology has developed since their initial establishment.

e. Director Gustavo Kourí of the Pedro Kourí Institute, responsible for the diagnosis and treatment of exotic tropical diseases, stated that the institute had no facility for treating diseases requiring high-level biosafety containment. He implied that there was no such facility on the island, but I am not sure that he actually stated that.

The basis for these impressions is admittedly limited. We visited only nine of the 53 facilities that are said to be part of the biotechnology complex, and there was ample notice given for those visits. There is scope for doubt about facilities we did not see, and about activities at facilities we did see that might have been suspended during our visit. A more definitive judgment would require some combination of sustained presence and periodic visitation at unpredictable times. If the Cuban representation is correct, however, it should be possible to arrange for scientific exchanges that would approximate these requirements.

Given prevailing policy and underlying political attitudes in the United States, the extent of scientific exchange necessary to eliminate residual doubt might have to be accomplished through European interlocutors. I nonetheless have some hope that the American scientific community might be willing and able to undertake a constructive initiative. At any rate, I would personally consider it to be irresponsible to issue charges based on unrevealed evidence without also attempting to arrange for the direct, reassuring access that the Cubans are apparently offering.

MS. LORENA BARBERIA

Program Associate and Director, Cuba Program
David Rockefeller Center for Latin American Studies,
Harvard University

Summary of meetings held during the trip and key issues raised:

1. Both U.S. and Cuban participants repeatedly underscored the importance of scientific exchanges and collaboration in laboratory research as an important step in overcoming suspicions. Joint scientific collaboration has played a key role in confidence building as has been illustrated by Russian-U.S. scientific collaboration after the collapse of the Soviet Union. Publication of findings in peer-reviewed journals and transparency in epidemiological data were also cited as important measures in confidence building, as these emphasize that the purpose of laboratory work is geared toward scientific research and that Cuban officials are not seeking to hide information. Both the U.S. and Cuban delegations commented on Harvard's program of scientific exchange with researchers at the Pedro Kourí Institute and noted that this was one of the only such types of bilateral exchanges underway.

Significant concern was expressed that, contrary to the need for these types of scientific exchanges to increase, U.S. policy was impeding further exchange. Prof. Gustavo Kourí, director of the Pedro Kourí Institute, noted that the areas of collaboration with Harvard laboratories are focused on dengue, tuberculosis, and HIV load viral testing, areas where there is not high concern for bioweapons potential. Based on his experiences in working with Russian scientists, John Steinbruner noted that the next step would be to increase scientific exchange and include sensitive areas, such as anthrax and smallpox.

2. Cuban officials acknowledged that while they undoubtedly have the potential to use biotechnology for harmful purposes, they say do not have the intent to do so. President Fidel Castro reiterated these views

during our dinner meeting, and, as evidenced by the delegation's visit, the country was and indicated that it would be willing to provide open access to its facilities to outside groups.

3. Cuban officials underscored that the biotechnology sector is part of the health system and its benefit is not only measured by economic profits, but also by the impact on disease prevention. Cuban officials stated that the sector is comprised of over 5,000 employees and received more than \$1 billion in R&D investments between 1990 and 1996. In the upcoming

sophisticated practices in biotechnology, including the production of recombinant vaccines and genetically modified seeds. However, there was a significant heterogeneity on the quality and level of research being undertaken across the nine facilities. CECMED, Cuba's agency equivalent to the FDA, regulates safety. (Note: Harvard University has participated in advising the Pedro Kourí Institute on the standards and regulations needed to set up a BSL-3 facility).

The delegation raised concerns related to outside threats and the potential for foreigners to gain access to biotechnology. For example, Cuba currently un-





Lab workers apply labels to products at LABIOFAM, which produces a wide variety of products, from veterinary vaccines to household cleansers to yogurt.

decades, Cuba's biotechnology sector aims to fully supply the health systems' pharmaceutical needs and to an important source of export growth. Eighty percent of Cuba's medicines and vaccines are developed locally (the list of essential medicines totals 808) and the remaining 20 percent are imported (the majority of which are cancer and diabetes drugs). We were told that the Cuban military does not participate in the setting of biotechnology policy or laboratory work.

4. During the site visits to the nine facilities, members of the delegation toured labs and discussed work in progress with scientists. Cuba is engaged in fairly

dertakes contact tracing for infectious disease. When its citizens have been abroad, they are tracked through the family medical doctor to see if any adverse symptoms develop related to infectious disease. However, the country is not equipped to handle an outbreak of a disease such as smallpox or ebola. The Pedro Kourí Institute hospital, which would be the center that is tasked with responding to an outbreak, is not yet set up to handle and fully quarantine patients due to funding constraints. Cuban officials assured the delegation that foreign students studying in Cuban universities do not have access to high security select agents, such as smallpox or eastern equine encephalitis.

5. Collaboration in biotechnology has taken place with the U.S. government (CDC), U.S.-based pharmaceutical companies (GlaxoSmithKline, Acambis) and U.S. universities (Harvard, University of North Carolina-Chapel Hill, University of Massachusetts-Worcester). Noting that "we share common objectives to advance research in cancer, HIV/AIDS, and other diseases," Dr. Concepción Campa, director of the Finlay Institute, explained how her Institute has partnered with GlaxoSmithKline to develop and test the meningitis B vaccine.

Dr. Clare Bloom at the U.S. CDC has also worked with Finlay to make the meningitis B vaccine available in the United States, as this is the only vaccine in the world against this disease (Finlay reported 200 deaths per year in the United States). The CDC is collaborating with the Finlay Institute on the issue of vaccine certification, FDA regulations, and Finlay's clinical trials conducted in Cuba and phase III trials on humans being conducted in Belgium, the United Kingdom and Spain. The CDC is also participating in research related to a polio vaccine with the Pedro Kourí Institute and the Pan American Health Organization (PAHO).

However, Cuban scientists voiced their concern that

these collaborations are impeded by U.S. regulations. Last year, the Treasury Department's Office of Foreign Assets Control (OFAC) issued letters to U.S. participants scheduled to attend a Cuban biotechnology conference, warning them that they would be violating U.S. regulations. After two-and-a-half years of requesting permission, OFAC has granted GlaxoSmithKline permission to partner with Finlay, provided certain conditions are met. GlaxoSmithKline can only pay 50 percent of its investment in cash; the remaining 50 percent must be paid in-kind in medicines and material goods. This restriction on cash transfers was attributed to the U.S. embargo on Cuba. The other restriction – the United States may not permit Cuban-manufactured vaccines to be used on U.S. citizens (the vaccine is in clinical trials in Europe and in the next phase clinical trials will be conducted in the United States), in which case, the Finlay Institute will be required to transfer its technology to GlaxoSmithKline so that the vaccine will be produced by it using Cuban technology.

6. Cuba is also collaborating with Latin America and Europe on biotechnology issues. Cuba is selling





Left: the group was required to don sanitary clothing in most facilities, including here in the Finlay Institute, even to walk down hallways separated by glass from laboratories (right).

vaccines (polio, DPT, measles,) at a low-cost to PAHO for distribution in Latin America. In addition to low cost vaccines, Cuba is hoping to further develop its exports to the region for generic medicines, vaccines and test kits. For example, DAVIH Laboratories (which belongs to Cuba's Civil Defense sector) now produces HIV test kits that are cheaper than U.S.-pro-

duced kits. DAVIH officials said they are exporting test kits to Latin America at a price of \$9 per kit versus \$60 from U.S. pharmaceutical labs. The sub-director of DAVIH laboratories, Dr. Regina Z. Martín García, noted that Cuba is not vio-

"Significant concern was expressed that, contrary to the need for these types of scientific exchanges to increase, U.S. policy was impeding further exchange."

- Lorena Barberia

lating patents with respect to HIV test kits.

Cuba cooperates closely with Brazil in biotechnology policy and participates as a signatory member in discussions with the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (WTO-TRIPS). Cuba has been a signatory to WTO-TRIPS since 1995.

7. In addition to the issues reported in this memorandum, key issues emerged which merit further discussion:

Research takes place within a coordinated process in a cluster of Western Havana. As described by Cuban scientists, "We collaborate to compete internationally." How does coordination work and how are priorities established?

Significant and strategic investments in R&D have been undertaken to develop Cuba's biotechnology sector. What proportion of R&D is dedicated to basic research vs. pharmaceutical production? How strong are the linkages between biotechnology centers and Cuban universities?

The model for the sector is based on a "closed-cycle strategy," where research, production, distribution and marketing are all done within the same firm. Is this

effective? What are some of the challenges presented by such an approach?

Cuba's epidemiological data is used to attest to the efficacy of its biotechnology. Should the international scientific community be given greater transparency and access to data collection and reporting?

Biotechnology requires continued investments in

R&D and cutting-edge innovations. Are the investments paying off? Cuban officials noted that they face stiff competition internationally by large multinational pharmaceuticals and "monopolistic" dominance of the industry. How does Cuba

compete in such an environment? How is Cuba utilizing joint venture alliances with foreign pharmaceutical firms to compete?

The Hon. PHILIP COYLE, III
Senior Advisor, Center for Defense Information
Assistant Secretary of Defense and Director, Operational
Test and Evaluation, Deptartment of Defense, 1994-2001

To prepare for the visit, CDI conducted research on Cuban biotechnology facilities that could be seen as suspect, that is, facilities that might be capable of both legitimate medical research and pharmaceutical production, or biological weapons.

- We provided the Cuban government with a list of nine major facilities, ranked in order of priority. Our Cuban hosts never quibbled with our agenda nor balked at the sites we designated. Over the course of four very full days, we visited all nine facilities. All presentations and tours were filmed and recorded.
- In making this trip, we recognized that production of bioweapons does not require large facilities, and facilities can be converted to other uses. Biotechnology equipment and reagents are readily available and not expensive compared to the facilities required for nuclear weapons. Modern biotechnology permits rapid modification of bioagents which can frustrate medical intervention. Worker protection requires sophisticated facilities.
- The Cuban health care system is quite different from that in the United States. Biotechnology research institutions are integrated within the health care system along with pharmaceutical production and health delivery institutions. There is a major, long-term government commitment to health care. The health mission includes agricultural species and permeates institutions operated by other agencies.
- Technology transfer is less of an issue than in the United States because both the researchers who

- produce knowledge and the production workers who use it tend to be in the same organization.
- The commitment to biotechnology was made in the late 1970s. The emphasis is on vaccines with a focus on children, tropical diseases and cancer. The survival rate of Cuban children under 5 years old compares favorably with developed countries with 10 to 20 times the per capita income.
- World Health Organization, Pan American Health Organization and FDA standards are met or exceeded.
- Our Cuban hosts could not have been more welcoming or open. They took us to their laboratories and production facilities. They showed us proprietary information about the Cuban pharmaceutical industry, information that U.S. companies would likely not have shared had the situation been reversed. When a door was padlocked, they opened it; when a door was sealed they broke the seals. At every stop, they repeatedly asked us to see more, to spend more time, to open another door.



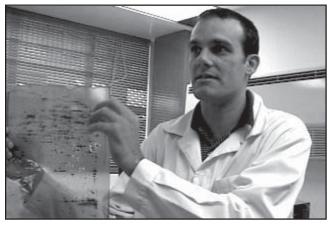
At the CIGB, our guides broke the seal on a door to permit us to investigate this area where unused equipment is stored.

- They urged us to talk with their staff. In any tour, visit, or inspection, the ability to speak with the staff members is very important. Where the leaders of an institution may be sophisticated enough to show only its best face, everyday workers are not so adroit. In my experience, talking with regular employees cuts through to the heart of what an institution is really all about.
- In biotechnology, Cuba has a young diverse workforce. Many are trained abroad, but they return to Cuba; there is no apparent "brain drain." The workforce is enthusiastic and clear about their institutional missions. The leaders also are committed to the health missions of their institutions. Senior R&D leaders are also senior political voices.
- Cuba had every incentive to welcome our visit. Biotechnology and pharmaceutical research, development and production are becoming an important part of the Cuban economy. Cuba sells pharmaceuticals and vaccines to 30 countries around the world.
- Cuban research scientists are interested in and capable of collaboration with U.S. institutions, and some individual and institutional arrangements exist. Recent restrictions on personnel and research exchanges with "sensitive countries" have affected American research visits to Cuba.
- The commitment of the workers in Cuban biotechnology institutions to the health of the Cuban people is palpable. The health of Cuban livestock, poultry, and crops is also part of this commitment.
- To support their commitment to biotechnology, Cuban pharmaceuticals are developed and tested to the standards of the World Health Organization and the Pan American Health Organization.



Scientists answer questions at Institute Pedro Kourí.

- With respect to clinical trials, Cuba meets current European standards that are tougher in some regards than the standards of the U.S. Food and Drug Administration. Cuba is working to meet all <u>other</u> U.S. FDA requirements as well.
- Cuba had every incentive to welcome our visit. Biotechnology and pharmaceutical research, development and production are becoming an important part of the Cuban economy. Cuba sells pharmaceuticals and vaccines to 30 countries around the world.



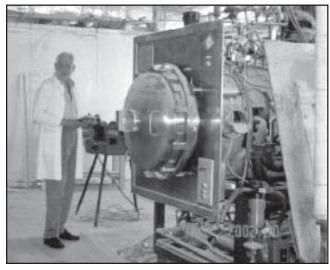
A scientist at CIGB explains the mass spectrometry process.

"Our Cuban hosts could not have been more welcoming or open ... They showed us proprietary information about the Cuban pharmaceutical industry, information that U.S. companies would likely not have shared had the situation been reversed."

- Philip Coyle

- Several of the institutions were planned with BSL-4 facilities in keeping with the U.S. Asilomar recommendations, but none are operated at a BSL-4 level, and only one is used as a BSL-3. BSL-4 facilities are 16 years old and are used at a significantly lower hazard level.
- After we left, Castro could have proclaimed that a U.S. inspection team had just visited and cleared Cuba of these accusations that they are developing biological weapons. Understanding the limitations of our visit, he didn't.
- Does Cuba have the capability to develop biological weapons? Cuba has the capability to develop sophisticated medicines and vaccines, so certainly Cuban scientists could do the technical work required for biological weapons. In this regard, Cuba is no different than the United States, which has more than enough capability in biotechnology to develop advanced medical treatments, and if it wanted biological weapons.
- The human and physical resources we saw are capable of making bioweapons if they chose to divert those resources from health missions, but they are not motivated to do so. Current facilities would need substantial and costly alterations.
- In talking with the researchers and production people at the Cuban facilities, we saw that they were truly incredulous at our questions about bioweapons. The idea that they would do such work had not occurred to them, and was an astonishing suggestion to them, just as workers at a phar-

- maceutical plant in New Jersey would be equally incredulous at such questions.
- We saw no indications that the Cuban military influenced the biotechnology research agenda in Cuba.
- Can we say for sure that Cuba is not building biological weapons? Of course not. No restrictions were placed on where we went, but we did not go everywhere. We were only in Cuba for four days, and spent our time in and around Havana where the major Cuban biotechnology facilities are located. Cuba is 750 miles long and consists of over 3,700 other small islands. Obviously we couldn't see all that in four days, or even four years. But when we asked to visit, our request was accepted



New pharmaceutical production facilities for recombinant vaccines are under construction at CIGB.

immediately, and we have been invited back for other visits.

- There is a strong opportunity for research collaborations of mutual technical benefit to U.S. and Cuban institutions. Such collaborations can provide significant informal communication mechanisms to U.S. and Cuban political leadership.
- In future visits, continued scientist-to-scientist interactions will be important. With scientistto-scientist collaborations between countries, it is clear whether someone is experienced and expert in a field. Scientist-to-scientist interactions cut through to true purposes, and cut through allegations made by non-scientists for political purposes.

Appendix I Facilities visited (in order seen)

Center for Genetic Engineering and Biotechnology / Centro de Ingeniería Genética y Biotecnología (CIGB)

Ave. 31 e/ 158 and 190, Cubanacán, Playa, Apdo. 6120, Habana 10600

Phone: (53-7) 271-3313, (53-7) 271-6032

Fax: (53-7) 33-1779 Web: www.cigb.edu.cu

Director General: Dr. Luis Herrera Martínez

Vice Director: Dr. Carlos G. Barroto

Center for Molecular Immunology / Centro de Inmunología Molecular (CIM)

Calle 15 esq. 216, Siboney, Playa, Ciudad de la Habana

P.O. Box 16040, Ciudad de la Habana 11600

Phone: (53-7) 2714335 and 2713357 Fax: (53-7) 335049

Web: www.cim.sld.cu

Director General: Dr. Agustín Lage

National Center for Agricultural and Livestock Health (CENSA)

Carretera de Jamaica and Autopista Nacional, San Jose de Las Lajas, Apdo. 10, La Habana

Phone: (5364)6633206 and 63014 Fax: (5364)638897 and 98104 Email: comercial@censa.edu.cu

Director General: Dr. Lydia M. Tablada Romero

Laboratorios DAVIH (DAVIHLAB)

Carretera de Jamaica and Autopista NationalOcho Vias, San Jose de Las Lajas, La Habana

Phone: (53-7) 574009 Fax: (53-7) 574152

Email: <u>DAVIHLAB@infomed.sld.cu</u> Director: Dr. Felipe M. Rolo Gómez

Pharmaceutical Biological Laboratories / Laboratorios Biológicos Farmacéuticos (LABIOFAM)

Calle 19 # 1166 e/ 16 and 18, Vedado, Centro Habana

Phone: (53-7) 33 4757 Fax: (53-7) 33 3703

Web: www.labiofam-sa.com Email: negocios@labnet.com.cu Director: Dr. José A. Fraga Castro

Appendix I continued ...

Center for Marine Bioactive Substances (CEBIMAR)

Loma y 37, Alturas del Vedado, Plaza de la Revolución, Ciudad de La Habana 10600

Phone: (53-7)811298, 819300, 819650

Email: cebimar@unepnet.inf.cu

Director: Dr. Anoland Garateix Fleites

Fabrica de Pienso Animal / Special Processing Plant "La Fabriquita"

Commercial agent: Codeme S.A.

Centro de Negocios Miramar – Edificio Habana

Oficina 101, piso 1, Ave 3ra. e/ 78 y80, Playa, Cuidad de La Habana

Phone: (53-7) 242159 Fax: (53-7) 242800

Email: codeme@infocex.cu

Carlos J. Finlay Research Institute

Ave. 27 No. 19805, La Cornonela, La Lisa Apdo. 16017 CP 11600, Ciudad de la Habana

Phone: (53-7) 208-6086, 208-0976

Fax: (53-7) 208-6075

Email: comercial@finlay.edu.cu

President & Director General: Dr. Concepción Campa

Pedro Kourí Institute of Tropical Medicine / Instituto de Medicina Tropical "Pedro Kourí" (IPK)

Autopista Novia del Mediodia, Km 6½ e/ Autopista Nacional y Carretera Central

La Lisa. Apdo. 601, Marianao 13, Cuidad de la Habana

Phone: (53-7) 336051 Fax: (53-7) 215957

Email: ciipk@infomed.sld.cu Director: Dr. Gustavo Kourí

APPENDIX II Summary of Recommended Biosafety Levels for Infectious Agents

BSL	AGENTS	PRACTICES	SAFETY EQUIPMENT (Primary Barriers)	FACILITIES (Secondary Barriers)
1	Not known to consistently cause disease in healthy adults.	Standard Microbiological Practices	None required	Open bench top sink required
2	Associated with human disease, hazard = percutaneous injury, ingestion, mucous membrane exposure	BSL-1 practice plus: Limited access Biohazard warning signs "Sharps" precautions Biosafety manual defining any needed waste decontamination or medical surveillance policies	Primary barriers = Class I or Class II BSCs or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials; PPEs: laboratory coats; gloves; face protection as needed	BSL-1 plus: Autoclave available
3	Indigenous or exotic agents with potential for aerosol transmis- sion; disease may have serious or lethal consequences	BSL-2 practice plus: Controlled access Decontamination of all waste Decontamination of lab clothing before laundering Baseline serum	Primary barriers = Class I or II BCSs or other physical containment devices used for all open manipulaions of agents; PPEs: protective lab clothing; gloves; respiratory protection as needed	BSL-2 plus: Physical separation from access corridors Self-closing, double-door access Exhausted air not recirculated Negative airflow intolaboratory
4	Dangerous/exotic agents which pose high risk of life-threatening disease, aerosol-transmitted lab infections; or related agents with unknown risk of transmission	BSL-3 practice plus: Clothing change before entering Shower on exit All material decontaminated on exit from facility	Primary barriers = All procedures conducted in Class III BSCs or Class I or II BSCs in combination with full-body, air-supplied, positive pressure personnel suit	BSL-3 plus: Separate building or isolated zone Dedicated supply and exhaust, vacuum, and decon systems Other requirements outlined in the text

From "Biosafety in Microbiological and Biomedical Laboratories (BMBL) 4th Edition," published by the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, and National Institutes of Health, May 1999.

APPENDIX III Bioweapons and Cuba: A Chronology

1960: Shortly after coming to power, Fidel Castro delivers a speech linking Cuba's future to the achievements of its scientists. Soon after, the groundwork is laid for a research base modeled on the U.S. National Institutes of Health.

1981: Castro becomes intrigued by the cancer-fighting capacity interferon is believed to possess, and over the next 15 years pumps more than \$1 billion into the development of a biotechnology cluster on Havana's western outskirts. Today, it is considered perhaps the most advanced biotech sector in the developing world, and Cuban children are immunized against 13 diseases using locally produced vaccines.

1999: Soviet defector Ken Alibek publishes <u>Biohazard</u>, a book about the Russian bioweapons program, and includes two pages on Cuba, in which he says Soviet Gen. Yory Kalinin "was invited to Cuba in 1990 to discuss the creation of a new biotechnology plant ostensibly devoted to single cell protein. He returned convinced that Cuba had an active biological weapons program." The book sets off an uproar in south Florida.

June 22, 1999: U.S. officials express skepticism about <u>Biohazard</u>'s allegations. "We have no evidence that Cuba is stockpiling or has mass-produced any BW agents," a State Deptartment spokesman says. Another official, speaking anonymously, states, "We don't see any signs of production facilities ... With all the intelligence we get from defectors and other means, there's never been evidence."

May 9, 2001: During a visit to Iran, Fidel Castro gives a speech at Tehran University. Agence France Press reports that he said, "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." Over the next 18 months, this quotation will be cited in virtually every hard-line speech on Cuba delivered by an American politician. Castro denies making the statement. A year later, research by Nelson Valdes of the University of New Mexico shows that it was not reported by the Iranian News Service, the Cuban media, the BBC Monitoring Service, or the U.S. government's Foreign Broadcast Information Service. A careful review of all 26 pages of the four speeches Castro delivered in Iran does not turn up the quotation or anything close to it. Even after it proves to be a fabrication, U.S. officials continue to quote it.

October 2001: Jose de la Fuente, a Cuban defector who had been the director of research and development at the Center for Genetic Engineering and Biotechnology in Havana, publishes an article in which he describes Cuban-Iranian cooperation in biotechnology and describes as "profoundly disturbing" Cuba's sharing of certain vaccine technology with potential dual use with Iran: "There is no one who truly believes that Iran is interested in these technologies for the purpose of protecting all the children of the Middle East from hepatitis, or treating their people with cheap streptokinase when they suffer sudden cardiac arrest." ("Wine Into Vinegar: The Fall of Cuba's Biotechnology," in *Nature Biotechnology*, Vol. 19, No. 10, October 2001.)

Nov. 19, 2001: At the review conference of the Biological Weapons Convention in Geneva, John Bolton, U.S. undersecretary of state for arms control, delivers a speech listing six countries of concern: Iran, Iraq, Libya, North Korea, Sudan, and Syria. He does not mention Cuba.

March 19, 2002: In a Senate hearing on CBW threats, Carl Ford, assistant secretary of state for intelligence and research, testifies about CBW capabilities of eight countries, including Cuba. He states, "The United States believes that Cuba has at least a limited developmental offensive biological warfare research and development effort. Cuba has provided dual use biotechnology to other rogue states. We are concerned that such technology could support BW programs in those states. We call on Cuba to cease all BW-applicable cooperation with rogue states and to fully comply with all of its obligations under the Biological Weapons Convention." Buried in assessments of CBW capabilities of seven other countries, almost no one notices his statement.

May 6, 2002: Six days before former President Jimmy Carter is scheduled to travel to Cuba, Bolton, in a speech before the Heritage Foundation entitled "Beyond the Axis of Evil," makes the exact same statement as Ford, except he drops the word "developmental" and says, "The United States believes that Cuba has at least a limited offensive biological warfare research and development effort." He offers an extensive critique of the Cuban government with these comments. He goes on to say, "States that renounce terror and abandon WMD (weapons of mass destruction) can become part of our effort. But those that do not can expect to become our targets." Almost everyone notices his statement. This is seen as the "match in the haystack" statement in this ongoing story.

May 7, 2002: U.S. Secretary of Defense Donald Rumsfeld states, "I have not seen the intelligence that apparently led Undersecretary Bolton to make those remarks." Pentagon officials say that the subject simply had not been on Rumsfeld's radar screen and there was no urgency about it in the building.

May 9, 2002: On National Public Radio, Gen. Charles Wilhelm, USMC (ret.), the former commander in chief of U.S. Southern Command, whose purview included Cuba, stated "During my three year tenure, from September 1997 until September 2000 at Southern Command, I didn't receive a single report or a single piece of evidence that would have lead me to the conclusion that Cuba was in fact developing, producing or weaponizing biological or chemical agents."

May 11, 2002: In a speech responding to Bolton's allegation, Castro calls it "... a sinister lie. We demand proof. Let them produce even the tiniest piece of evidence! They do not have any, and they cannot have them because they simply do not exist. They should not be hiding behind the alleged sensitivity of their sources, when there is actually not an atom of truth in what they are saying. ... The only truth in Bolton's lie is that Cuba is 90 miles from the continental territory of the United States."

May 12, 2002: U.S. Secretary of State Colin Powell, attempting to clarify Bolton's accusation, states: "We didn't say it actually had some weapons, but it has the capacity and capability to conduct such research."

May 13, 2002: Former President Jimmy Carter, while touring a major biotechnology center in Havana, states that Bush administration intelligence officials had assured him, in response to specific questioning, that they had no evidence that Cuba had provided other nations with technology suitable for weapons of mass destruction.

May 21, 2002: The State Department releases "Patterns of Global Terrorism," its annual terrorism survey. Responding to critics who claim the report's 77-word section on Cuba contained no specific charges and had not changed in more than a decade, State expands the Cuba section to 47 lines. The report still makes no mention of biological warfare research.

Later the same day, in a Senate hearing on Cuba, Sen. Byron Dorgan (D-ND) asks witness Otto Reich, then assistant secretary of state for Western Hemisphere Affairs, why the report contains no reference to Cuban bioweapons:

Sen. Dorgan: But has the State Department failed to include it in their May 2002 "Patterns of Global Terrorism?"

Mr. Reich: I do not know who publishes that particular document.

Sen. Dorgan: The State Department.

Mr. Reich: Which part of the State Department?

Sen. Dorgan: The United States Department of State. Bureau of Arms Control, I'm told.

Mr. Reich: That's John Bolton's office, sir.

Sen. Dorgan: So why would he omit that?

Mr. Reich: It could very well be that it went to print before — remember, he made his speech on May —

Sen. Dorgan: It's dated May.

Mr. Reich: But they go to print a long time before, sometimes two months before. Bolton made his remarks on May the 6th.

<u>Sen. Dorgan</u>: I think I made the point. I appreciate your yielding. My point is that this seems to originate mysteriously but it doesn't appear in the reports. State Department's never heard of it. But let me yield back.

Mr. Reich: What do you mean, State Department has never heard of it? You mean Defense Department?

<u>Sen. Dorgan</u>: No, State Department. This is a State Department publication that we just received on Capitol Hill. Patterns —

Mr. Reich: It's incomplete.

Sen. Dorgan: It's what?

Mr. Reich: It's incomplete. Must be incomplete, because that comes out of the Bureau of Arms Control, which is headed by John Bolton, who is the one who made the speech.

Sen. Dorgan: Would you alert him then that there is something going on that he doesn't include in his report?

Mr. Reich: Absolutely. He may be watching this right now.

Sen. Dorgan: This will be very helpful to him then, won't it?

(Note: The report is published by the State Dept.'s Office of Counterterrorism)

May 23, 2002: Gen. Gary Speer, the acting commander in chief of Southern Command, tells reporters he has seen no evidence that Cuba was producing biological weapons, and that he was "surprised Bolton raised the subject." "I think what Mr. Bolton said in his statement, it kind of got reported as an accusation that the Cubans were ... that we had evidence that they were actually producing bio-weapons. And I'm not sure that's the case ... They pride themselves on their biomedical advances and it kind of fits into the purpose for which that is used."

June 5, 2002: Ford testifies before the Senate again. Sen. Chris Dodd complains that Powell refused to send Bolton to the hearing instead of Ford. Characterizing Cuba's bioweapons activities as an "effort" rather than a "program," he is asked to explain the difference:

<u>Ford:</u> "I would take some exception to the characterization that there's not much difference between a program and an effort. There really is a difference. We've never tried to suggest that we have the evidence, the smoking gun to prove proof positive that they had a program. A program suggests to us something far more substantial than what we see in the evidence. But we feel very confident about saying that there is — they're working on an effort that would give them a limited BW offensive capability."

July 22, 2002: As the House of Representatives prepares to vote on a bill sponsored by Rep. Jeff Flake, R-Ariz., that would loosen travel restrictions to Cuba, Rep. Lincoln Diaz-Balart, R-Fla., circulates a "Dear Colleague" letter that states, "... please read the enclosed statement on the Cuban Dictatorship's biological weapons program by John Bolton ..." Bolton's statement repeats previous charges, and adds, "No one is more frustrated than I am over how little I can say publicly about Cuba's BW effort. We clearly have major – and legitimate – 'sources and methods' concerns here. Even as I was preparing this statement, a U.S. intelligence community analyst emailed a member of my staff expressing concern about the consequences of providing 'feedback' to Cuba on how much we know about its BW effort." Diaz-Balart's letter encourages colleagues to vote for the Goss Amendment, which would keep the travel ban in place until, among other things, the president certifies that Cuba is not developing biological weapons.

July 23, 2002: The House passes the Flake Amendment, which would prevent the Treasury Department from spending money to enforce the travel ban. The Goss Amendment loses by a vote of 182-247. Voting against it are 15 of the 20 members of the House Select Committee on Intelligence, including six Republicans. These members would presumably have had access to the same intelligence on Cuba that Bolton did.

Oct. 6-9, 2002: A Center for Defense Information-sponsored delegation of scientists, a former UN chief weapons inspector, military experts and videographers tours nine biotechnology centers of its choosing in Cuba. The delegation is given unrestricted access to the facilities.

Oct. 31,2002: Otto Reich, then-assistant secretary of state, speaking at the Heritage Foundation, quotes Bolton's charge, again dropping the word "developmental":

"Cuba is a state sponsor of terror. We believe that Cuba has, quote, 'at least a limited offensive biological warfare, research and development effort,' unquote. And we know that Cuba has shared dual- use biotechnologies with other state sponsors of terrorism.

I repeat this, because two U.S. officials, Undersecretary of State John Bolton, undersecretary for arms control, science and technology, and Assistant Secretary of State Carl Ford, assistant secretary for intelligence and research, both have made the statement in the press and in testimony, and yet the first reaction of some of the people in the press is to say, 'We don't believe it.'

Three — four, now — U.S. officials have made this statement that Cuba has at least a limited offensive biological warfare research and development effort, and we base this on information that we have."

April 30, 2003:

The State Department releases its annual report on international terrorism, "Patterns of Global Terrorism 2002." Again it includes no mention of a Cuban bioweapons effort.

— Compiled by Glenn Baker



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