

Denial of Food and Medicine

The Impact of the

U.S. Embargo on

Health & Nutrition

in Cuba



A Report from the American Association for World Health
Executive Summary

March 1997



DENIAL OF FOOD AND MEDICINE:
THE IMPACT OF THE U.S EMBARGO
ON HEALTH AND NUTRITION IN CUBA

An Executive Summary

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The American Association for World Health

The American Association for World Health (AAWH) was founded in 1953 as a private, nonprofit charitable and educational organization, and serves as the US. Committee for the World Health Organization (WHO) and the Pan American Health Organization (PAHO). Its purposes are to inform the American public about major health challenges that affect people both here and abroad, and to promote cooperative solutions that emphasize grassroots involvement. In carrying out its mission, AAWH works with a variety of public and private health-related organizations, including the Department of Health and Human Services/Centers for Disease Control and Prevention, as well as with WHO and PAHO. AAWH's work is supported by dues payments from institutional and personal members, by charitable contributions from corporate sponsors, and by foundation grants. Guidance is provided by the association's officers and board of directors.



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The U.S. embargo against Cuba has been in place since the early 1960s. It is one of the few embargoes of recent years that explicitly includes foods and medicines in its virtual ban on bilateral commercial ties. Prompted by our 40-year commitment to international health, especially in the developing world, and by the tightening of the embargo since 1992, the American Association for World Health (AAWH) launched a study of the impact of U.S. policy on the health of the Cuban population.

Over a twelve-month period between 1995 and 1996, a multi-disciplinary research team traced the implications of embargo restrictions on health care delivery and food security in Cuba. The team reviewed key U.S. regulations and their implementation, conducted a survey of 12 American medical and pharmaceutical companies and documented the experience of Cuban import firms with the embargo. The team assessed the impact of U.S. sanctions on health in Cuba through on-site visits to 46 treatment centers and related facilities; it conducted 160 interviews with medical professionals and other specialists, government officials, representatives of non-governmental organizations, churches and international aid agencies. In October 1996, the AAWH sent a delegation of distinguished medical experts to Cuba to validate the findings of the draft report through first-hand observation.

The full report of more than 300 pages is the first comprehensive study of its kind. We are pleased to make it available to those who wish more detailed information than this Executive Summary offers. Neither document includes specific policy recommendations. Both are intended to provide a factual basis for informed decision-making on Cuba, and indeed on the wisdom of including food and medicine in any embargo as a means to achieve foreign policy objectives. The AAWH hopes that our findings will temper debate and enhance public knowledge and policy.

Peter G. Bourne, M.D.
Chairman of the Board
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Summary of Findings

After a year-long investigation, the American Association for World Health has determined that the U.S. embargo of Cuba has dramatically harmed the health and nutrition of large numbers of ordinary Cuban citizens. As documented by the attached report, it is our expert medical opinion that the U.S. embargo has caused a significant rise in suffering-and even deaths-in Cuba. For several decades the U.S. embargo has imposed significant financial burdens on the Cuban health care system. But since 1992 the number of unmet medical needs-patients going without essential drugs or doctors performing medical procedures without adequate equipment-has sharply accelerated. This trend is directly linked to the fact that in 1992 the U.S. trade embargo-one of the most stringent embargoes of its kind, prohibiting the sale of food and sharply restricting the sale of medicines and medical equipment-was further tightened by the 1992 Cuban Democracy Act.

A humanitarian catastrophe has been averted only because the Cuban government has maintained a high level of budgetary support for a health care system designed to deliver primary and preventive health care to all of its citizens. Cuba still has an infant mortality rate half that of the city of Washington, D.C.. Even so, the U.S. embargo of food and the de facto embargo on medical supplies has wreaked havoc with the island's model primary health care system. The crisis has been compounded by the country's generally weak economic resources and by the loss of trade with the Soviet bloc.

Recently four factors have dangerously exacerbated the human effects of this 37-year-old trade embargo. All four factors stem from little-understood provisions of the U.S. Congress' 1992 Cuban Democracy Act (CDA):

- 1) **A Ban on Subsidiary Trade** Beginning in 1992, the Cuban Democracy Act imposed a ban on subsidiary trade with Cuba. This ban has severely constrained Cuba's ability to import medicines and medical supplies from third country sources. Moreover, recent corporate buy-outs and mergers between major U.S. and European pharmaceutical companies have further reduced the number of companies permitted to do business with Cuba.
- 2) **licensing** Under the Cuban Democracy Act, the U.S. Treasury and Commerce Departments are allowed in principle to license individual sales of medicines and medical supplies, ostensibly for humanitarian reasons to mitigate the embargo's impact on health care delivery. In practice, according to U.S. corporate executives, the licensing provisions are so arduous as to have had the opposite effect. As implemented, the licensing provisions actively discourage any medical commerce. The number of such licenses granted-or even applied for since 1992-is minuscule. Numerous licenses for medical equipment and medicines have been denied on the grounds that these exports "would be detrimental to U.S. foreign policy interests."
- 3) **Shipping** Since 1992, the embargo has prohibited ships from loading or unloading cargo in U.S. ports for 180 days after delivering cargo to Cuba. This provision has strongly discouraged shippers from delivering medical equipment to Cuba. Consequently shipping costs have risen dramatically and further constricted the flow of food, medicines, medical supplies and even gasoline for ambulances. From 1993 to 1996, Cuban companies spent an additional \$8.7 million on shipping medical imports from Asia, Europe and South America rather than from the neighboring United States.
- 4) **Humanitarian Aid** Charity is an inadequate alternative to free trade in medicines, medical supplies and food. Donations from U.S. non-governmental organizations and international agencies do not begin to compensate for the hardships inflicted by the embargo on the Cuban public health system. In any case, delays in licensing and other restrictions have severely discouraged charitable contributions from the U.S.

Taken together, these four factors have placed severe strains on the Cuban health system. The declining availability of foodstuffs, medicines and such basic medical supplies as replacement parts for thirty-year-old X-ray machines is taking a tragic human toll. The embargo has closed so many windows that in some instances Cuban physicians have found it impossible to obtain life-saving medicines from any source, under any circumstances. Patients have died. In general, a relatively sophisticated and comprehensive public health system is being systematically stripped of essential resources. High-technology hospital wards devoted to cardiology and nephrology are particularly under siege. But so too are such basic aspects of the health system as water quality and food security.

Specifically, the AAWH's team of nine medical experts identified the following health problems affected by the embargo:

- 1) **Malnutrition** The outright ban on the sale of American foodstuffs has contributed to serious nutritional deficits, particularly among pregnant women, leading to an increase in low birth-weight babies. In addition, food shortages were linked to a devastating outbreak of neuropathy numbering in the tens of thousands. By one estimate, daily caloric intake dropped 33 percent between 1989 and **1993**.
- 2) **Water Quality** The embargo is severely restricting Cuba's access to water treatment chemicals and spare-parts for the island's water supply system. This has led to serious cutbacks in supplies of safe drinking water, which in turn has become a factor in the rising incidence of morbidity and mortality rates from water-borne diseases.
- 3) **Medicines & Equipment** Of the 1,297 medications available in Cuba in **1991**, physicians now have access to only 889 of these same medicines — and many of these are available only intermittently. Because most major new drugs are developed by U.S. pharmaceuticals, Cuban physicians have access to less than 50 percent of the new medicines available on the world market. Due to the direct or indirect effects of the embargo, the most routine medical supplies are in short supply or

entirely absent from some Cuban clinics.

- 4) **Medical Information** Though information materials have been exempt from the U.S. trade embargo since 1988, the AAWH study concludes that in practice very little such information goes into Cuba or comes out of the island due to travel restrictions, currency regulations and shipping difficulties. Scientists and citizens of both countries suffer as a result. Paradoxically, the embargo harms some U.S. citizens by denying them access to the latest advances in Cuban medical research, including such products as Meningitis B vaccine, cheaply produced interferon and streptokinase, and an AIDS vaccine currently under-going clinical trials with human volunteers.

Finally, the AAWH wishes to emphasize the stringent nature of the U.S. trade embargo against Cuba. Few other embargoes in recent history — including those targeting Iran, Libya, South Africa, Southern Rhodesia, Chile or Iraq — have included an outright ban on the sale of food. Few other embargoes have so restricted medical commerce as to deny the availability of life-saving medicines to ordinary citizens. Such an embargo appears to violate the most basic international charters and conventions governing human rights, including the United Nations charter, the charter of the Organization of American States, and the articles of the Geneva Convention governing the treatment of civilians during wartime.

The Human Toll

The cost of the embargo in human terms can be calculated both statistically and anecdotally. Here are some highlights from the report:

- Surgeries dropped from 885,790 in 1990 to 536,547 in 1995, a glaring indicator of the decline in hospital resources. Surgical services face shortages of most modern anesthetics and related equipment, specialized catheters, third generation antibiotics and other key drugs, sutures, instruments, fabric for surgical greens, air conditioning equipment and disposable supplies.
- The deterioration of Cuba's water supply has led to a rising incidence of water-borne diseases-such as typhoid fever, dysenteries and viral hepatitis. Mortality rates from Acute Diarrhea1 Disease (ADD), for instance, increased from 2.7 per 100,000 inhabitants in 1989 to 6.7 per 100,000 inhabitants in 1994. Amebic and bacillary dysentery morbidity rates showed marked increases during the same period.
- The U.S. embargo is limiting the access of Cuban AIDS patients to a variety of medicines. The AAWH found that the embargo was directly responsible for up to six month delays in AZT treatment for a total of 176 HIV patients in Cuba at a time when AZT was the only approved medication heralded for slowing the progress of the virus. As one AIDS professional told the AAWH, "The problem is that our patients don't have the time to wait."
- AAWH visited a pediatric ward then on its 22nd day without metoclopramide HCl, a drug used in combination with others such as betamethasone for pediatric chemotherapy. Without this drug's nausea-preventing effects, the 35 children in the ward were vomiting an average of 28-to-30 times a day.
- Heart disease is the number one cause of death in Cuba. Mortality rates for men and women have increased since 1989: with 189.3 deaths per 100,000 in 1989 and 199.8 deaths per 100,000 in 1995. In one instance Cuban cardiologists diagnosed a heart attack patient with a ventricular arrhythmia. He required an implantable defibrillator to survive. Though the U.S. firm CPI, which then held a virtual monopoly on the device, expressed a willingness to make the sale, the U.S. government denied a license for it. Two months later the patient died.
- In 1993 the U.S. Treasury Department denied a license, ostensibly for reasons of foreign policy, to the German subsidiary of Pfizer to sell Cuba one pound of the active ingredient methotrexate for trials of an anti-cancer drug.
- Some 48 percent of the 215 new U.S. medications in phase I-II 11 FDA trials in 1995 are specifically for breast cancer. None will be fully accessible to Cuban women as long as the embargo remains in place.
- Cuban children with leukemia are denied access to new, life-prolonging drugs. For example, the FDA has already approved Oncaspar (pegaspargase), patented by the U.S. company Enzon for patients allergic to L-Spar (L-asparaginase). Both drugs produce longer remission when included in treatment for lymphoblastic leukemia (ALL). However, L-Spar has an allergy rate of 40 percent for first-time use and 70 percent for relapsed ALL patients. Further, Oncaspar is less traumatic to a child suffering from ALL, since it requires only one-sixth the

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number of injections of L-Spar. But the embargo deprives Cuban children of this innovation. Left untreated, this type of leukemia is fatal in two to three months.

- In general, the embargo effectively bans Cuba from purchasing nearly one half of the new world class drugs on the market.

Chronology of the U.S. Embargo

<p>March 1960: President Dwight D. Eisenhower approves a plan of covert action and economic sabotage against Cuba. In the first months of 1960, the U.S. government waged a campaign to prevent Cuba from receiving loans and credits from Western European and Canadian institutions. A consortium of European banks, under pressure from the U.S., canceled plans to negotiate a \$100 million loan to Cuba.</p>	1960
<p>July 1960: President Eisenhower canceled the unfulfilled balance of the Cuban sugar quota to the US. for 1960.</p>	
<p>August 1960: Cuba issued Resolution Number 1 under Law 851 which ordered the expropriation of twenty-six of the largest United States companies operating in Cuba.</p>	
<p>October 1960: In what the media describes as a “quarantine” of Cuba, the Eisenhower Administration bans U.S. exports to that country — except for foodstuffs, medicines, and medical and hospital supplies. Companies wishing to sell such goods to Cuba can do so under a “general” license (i.e. no specific license application is required). Imports from Cuba continue to be allowed.</p>	
<p>January 1961: The U.S. severs diplomatic relations with Cuba.</p>	1961
<p>April 1961: The Bay of Pigs invasion is launched.</p>	
<p>September 1961: The Foreign Assistance Act of 1961 authorizes the President to establish and maintain “a total embargo upon all trade between Cuba and the U.S.”</p>	
<p>February 1962: The Kennedy Administration extends the embargo to prohibit Cuban imports into the U.S.</p>	1962
<p>March 1962: The embargo is further tightened to prohibit imports into the U.S. from third countries of goods made from or containing Cuban materials.</p>	
<p>August 1962: In order to dissuade third countries, Congress amends the Foreign Assistance Act of 1961 to prohibit U.S. assistance “to any country which furnishes assistance to the present government of Cuba.”</p>	
<p>February 1963: President John F. Kennedy prohibits U.S. government-ourchased cargoes from being transported on foreign flag vessels which after January 1, 1963, had called at a Cuban port.</p>	1963
<p>July 1963: The U.S. Treasury Department produces the Cuban Assets Control Regulations. These regulations-embody the essential features of the U.S. economic embargo against Cuba that has been in effect ever since, including a freeze on all Cuban-owned assets in the United States and a prohibition on all non-licensed financial and commercial transactions between Cuba and the United States and between Cuban and U.S. nationals (including the spending of money by U.S. citizens in the course of travel to Cuba).</p>	

- 1964** **May 1964:** The Commerce Department revokes its prior general license policy for export to Cuba of foods, medicines and medical supplies. The Commerce Department adopts a broad policy of denying requests for commercial sales of food and medicine to Cuba and permits only limited humanitarian donations.
- July 1964: The Organization of American States (OAS) passes a resolution obliging its members to enforce a collective trade embargo on Cuba. The resolution excludes sales of foodstuffs, medicines and medical equipment. The United States, however, persists in its policy of denying licenses for such sales.
- 1974** July **1974:** The Treasury Department liberalizes its Cuban regulations, among other things, to allow the importation of Cuban books and records and to liberalize restrictions on travel to Cuba by scholars and journalists.
- July **1975:** The OAS repeals its regional trade embargo against Cuba, prompting the Ford Administration to end the ban on third-country subsidiary trade with Cuba and instead requiring only that U.S. companies obtain individual licenses for transactions involving their overseas subsidiaries.
- 1975** **March 1977:** The Carter Administration removes restrictions on travel to Cuba by U.S. citizens.
- 1982** **April 1982:** The Reagan Administration severely restricts the travel of U.S. citizens to Cuba.
- October 1992:** President George Bush signs the Cuban Democracy Act (CDA) which outlaws subsidiary trade with Cuba and imposes severe restrictions on foreign ships that visit Cuba before attempting to enter U.S. ports. The CDA also gives the Treasury Department for the first time the authority to levy civil fines up to \$50,000 for violations of the embargo.
- 1992** **March 1996:** The Cuba Liberty and Democratic Solidarity Act (the "Helms-Burton Act") becomes law. The Act seeks to impede economic recovery under the present Cuban government by deterring foreign investment. Among other measures, the Helms-Burton Act allows foreign companies to be taken to court in the United States if they are "trafficking" in former U.S. citizen-owned properties in Cuba nationalized by the government of President Fidel Castro. ("Trafficking" is expansively defined to include not just direct investment in such properties but also any activities involving such properties that "benefit" the so-called "trafficker.") In addition, the Act "codifies" the existing Cuban Asset Control Regulations. Any modification of those regulations is intended, henceforth, to require an act of Congress.
- 1996**

Current Embargo Restrictions

The bulk of U.S. prohibitions against trade with Cuba are set forth in regulations enforced by the Treasury Department's Office of Foreign Assets Control and the Commerce Department's Bureau of Export Affairs. These include a ban on U.S. exports to Cuba, Cuban imports into the U.S. and even third-country U.S. subsidiary transactions with Cuba. Also banned are family remittances, credits and the transfer of money or property by U.S. nationals to Cuban nationals.

Several provisions of the U.S. embargo constitute major obstacles to any kind of medical commerce for humanitarian purposes:

- Direct flights between the two countries are banned.
- Entry is denied to U.S. ports by any ship which has docked in Cuba during the prior 180 days. U.S. ports are also closed to third-country vessels carrying "goods in which Cuba or Cuban nationals have an 'interest' whatever the cargo's origin or destination. This prohibition applies to a third-country vessel carrying third-country goods which incorporate even trace amounts of Cuban-origin products or produce."
- Re-exports to Cuba of U.S.-origin goods and technical data are banned.
- Exports are banned to Cuba by third-country companies of goods containing 20% or more U.S.-origin components; individual licenses are required for those goods containing over 10% U.S.-origin components.

On paper a procedure exists under which application can be made to the U.S. Departments of Treasury and Commerce for licenses to sell (or even donate) medicines and medical equipment to Cuba. In reality, these licensing procedures are a charade. Ostensibly, licensing should have opened a window in the embargo for medical commerce. As implemented, however, by the Treasury and Commerce Departments, licensing has closed this window. The complexity of these procedures and their arbitrary interpretation have created inordinate delays and costs which pose an insurmountable obstacle to commercial interests. For all practical purposes an absolute ban exists on sale of medicines and medical equipment to Cuba by U.S. companies and their foreign subsidiaries. Licenses are also required for humanitarian donations that can only go to non-governmental organizations, of which there are very few in Cuba. Under no circumstance is the sale of food authorized.

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Cuba's Health and the Embargo

Such a stringent embargo, if applied to most other countries in the developing world, would have had catastrophic effects on the public health system. Cuba's health-care system, however, is uniformly considered the preeminent model in the Third World.

The Cuban constitution makes health care a right of every citizen and the responsibility of the government. The system is based on universal coverage and comprehensive care, essentially free of charge to the population. Over the years, the central government has placed a top priority on public health expenditures in

the national budget and allocated considerable human resources to public health strategies that have earned praise from the World Health Organization, the Pan American Health Organization, UNICEF and other international bodies and individual health care authorities.

Consequently, in the 1990s Cuba's health statistics more closely approximated those of the nations of Europe and North America than of developing countries, with 195 inhabitants per physician, and 95 percent of the population attended by family doctors living in the communities they serve. The infant mortality rate in Cuba is roughly half that in Washington, D.C. Primary care is bolstered with 440 polyclinics; and secondary and tertiary facilities include 284 hospitals and 11 national institutes with inpatient and research capacities.

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Selected Health Indicators

	Cuba	Latin America*
Life Expectancy (1994)	75 years	68 years
Infant mortality (1994)	9.4/1 ,000 live births	38
Under Five Mortality (1994)	12/1 ,000 live births	47
Maternal mortality (1980-92)	39/100,000 live births	178
Access to health services	98% of population	73%

*22 countries of the region.

Source: State of the World's Children, 1996, UNICEF. Note that the 1996 figure for Cuba's infant mortality was down to 7.9.

While the U.S. embargo has always exerted a negative effect on the Cuban economy, its impact-particularly on the health care system-was significantly ameliorated by Cuba's relationship with the Soviet bloc until the 1980s. Besides the obvious advantages of subsidized trade and aid, the relationship also kept 85 percent of Cuban trade outside the reach of the embargo. Havana's inability to obtain U.S. medical supplies was largely offset by imports from the socialist bloc countries and Western Europe. (Nevertheless, a handful of U.S.-produced drugs still could not be obtained from any other source.) In the 1990s, this situation was dramatically reversed: As the socialist bloc crumbled, the embargo suddenly became extremely effective. After 1989, Cuba lost an annual \$4-6 billion in subsidized and bartered trade. Overnight, all imports required hard currency. In a two-year span, the economy contracted by 35 percent, evaporating an annual average growth of 4.3 percent in the previous decade.

Suddenly, Cuba's health system no longer had access to East bloc raw materials for its pharmaceutical industry, and at the same time shortages of hard currency made it increasingly difficult to purchase drugs and medical equipment in Western Europe and elsewhere.

The Cuban Democracy Act (CDA) of 1992, severely aggravated the situation by prohibiting foreign subsidiaries of U.S. companies any trade with Cuba. Ninety percent of that trade was in food and medicines. Business with U.S. subsidiaries had continued to grow well after the Soviet collapse, reaching \$718 million in 1991, the last full year before the CDA cutoff.

To compound matters, the CDA prohibitions were enacted during a period when U.S.firms were particularly active in buy-outsand takeoversofthird-country

The Cuban Democracy Act (CDA) of 1992 severely aggravated Cuba 's ability to purchase drugs and medical equipment by prohibiting-foreign subsidiaries of U.S. companies any trade with Cuba.

medical companies. Many of these companies were prime suppliers to the Cuban health care system. While in some instances Cuba managed to continue such purchases through intermediaries at greatly inflated prices, as a rule Cuban hospitals and physicians had to cope with abrupt cut-offs of key medicines, medical equipment, medical texts, inputs for diagnostics, vaccinations, and pharmaceutical and biotechnology research and development. In 1995, for instance, Upjohn, a major U.S. pharmaceutical company, merged with a Swedish concern, Pharmacia, which since 1970 has logged multimillion dollar sales to Cuba of protein purifying equipment (HPLCs), reagents for clinical laboratories and production plants, chemotherapy drugs, and growth hormones. Though technically Upjohn could have applied for a U.S. export license to continue supplying Cuba with some of these items, the company opted instead to terminate Pharmacia's sales and closed down its Havana office within 3 months of the merger. Cuba suddenly lost another supplier of plates for HIV-tests and other diagnostic kits to screen for hepatitis B and C, when Sybron International of Wisconsin bought out Nunc of Germany. Cuba lost two main sources for pacemakers under similar circumstances,

The human consequences of these decisions are all too evident in the wards of Cuban hospitals. When the AAWH delegation visited the cancer ward at the Juan Manuel Marquez Pediatric Hospital in Havana, our doctors found that oncologists do not have access to U.S.-manufactured cell-site-ports for chemotherapy. (The U.S. is the leading producer of this item.) As a result, nurses and physicians must repeatedly puncture and search for new veins in young children, causing them added pain and suffering. In order to treat one five-year-old girl suffering with sarcoma, doctors were compelled to use the girl's jugular vein because all her other veins had already collapsed. As a result, she developed a hematoma that almost killed her. The child was in excruciating pain. The availability of the cell-site port Implantofix would have prevented the child's suffering. This product, however, is manufactured by Braun Medical, Inc., of Bethlehem, Pennsylvania. Although Braun is associated with a German company and has an affiliate in France, their cell-site-port is produced in the United States and is thus subject to the embargo. The other obvious supplier-indeed, the world market leader in cell-site-ports-is the previously mentioned Swedish-American firm, Pharmacia, which is also covered by the embargo.

Even when Cuba is able to find a third-country supplier of medical equipment, penalties under the embargo have proved to be a serious impediment. The CDA's extraterritorial provision barring entrance to U.S. ports of any ship docking in Cuba during the preceding 180 days has not only impeded normal commercial shipping to the island but cost Cuban importers up to 30 percent more in shipping charges over the World Seacrate. Within months of the CDA's passage, shipping problems caused major delays in deliveries of soap, fuel, powdered milk, cooking oil, wheat, beans, rice and medical supplies. Steeper rates require Cuba to spend more of a limited budget on shipping and less on purchases of food and medicines critical to the welfare of the Cuban population.

The 1996 Helms-Burton law seeks to discourage foreign investment in Cuba by threatening third-country investors with suits in U.S. courts and by applying sanctions against their executives. The law has had a chilling effect, further discouraging American suppliers in the health care industry from even contemplating trade with Cuba.

The Cuban government has responded to the challenges posed by the stiffened

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embargo by boosting its health care spending. During the years from **1989** to 1996—a period of general economic trauma—the national budget remained static, but public health outlays nevertheless increased by 30.4 percent, reaching **\$1 .18** billion pesos. This added investment in public health came at the expense of other sectors, such as public administration, defense, culture and the arts. While priority was also afforded to health in hard currency spending, the devaluation of the Cuban peso and general hard currency shortfall reduced dollars for the health sector by 30 percent from 1989 to 1993, the year after the Cuban Democracy Act went into effect. The slow climb to **\$104.2** million in hard currency expenditures in 1995 remained less than half the 1989 spending levels.

Both the embargo and the hard currency shortfalls have resulted in an acute shortage of medical products. Of the 1,297 medicines in the country in 1991, only 889 can be obtained today, many of them only intermittently. Lack of spare parts has slowed equipment repair and replacements are virtually unobtainable. The Ministry of Health reports, for example, that 13 per cent of Cuba's X-ray machines are out of commission, as are 21 per cent of their cobalt therapy units.

In addition, the nation's health care infrastructure has suffered from diminished access to electricity, oil, diesel and gasoline. Many ambulances and mobile mammography vehicles stand idle for lack of gasoline. Pharmaceutical plants are operating at one third their 1980's levels, and power outages risk spoilage of medications and vaccines in refrigerated warehouses and threaten the lives of patients in the midst of surgery.

Lack of spare parts for U.S.-outfitted water treatment plants, and shortages of chlorine, detergents and disinfectants have led to an increase in water-borne disease, with higher mortality rates among the elderly; outbreaks of scabies and other dermatological disorders are on the rise, as are incidents of hospital infections and sepsis.

Sharp declines in food imports and inputs for agriculture have resulted in significant signs of nutritional deficits, most notably in the 1993 neuropathy epidemic that temporarily blinded over 50,000 Cubans. Workplace and school dining halls serve fewer calories and less protein, while the daily liter of milk once assured to all children up to age 13 is now limited to children through age 6. The population over 65 no longer receives special dietary supplements.

Quite clearly, Cuba's health care delivery system has been severely weakened, particularly at the secondary and tertiary levels of care. Only the pre-existing excellence of the system and the extraordinary dedication of the Cuban medical community have prevented infinitely greater loss of life and suffering.

The AAWH Investigation

This study was conducted over a year-long period of time by an interdisciplinary team of researchers. Visits were made to 28 patient-care facilities and 15 non-governmental and international organizations. More than 160 professionals were interviewed, as well as innumerable patients and families. Data was obtained from the Cuban Ministry of Health, international agencies and U.S. government sources. Several lawyers in the United States contributed to the sections of the report dealing with the history and legal aspects of the embargo, the impact on the pharmaceutical industry and the human rights implications of including food and medicine in the embargo.

The study examined Cuba's public health system sector by sector, including such critical areas as: Food Security and Nutrition, Water Resources, Women's Health, Children's Health, Family Relations, National Health Emergencies, Hospital Care, Humanitarian Donations and International Cooperation, Oncology, Cardiology, the HIV/AIDS Program, Nephrology, Endocrinology, Ophthalmology, Diagnostic Testing and Protection of the Blood Supply, Scientific Information and Medical Education.

While signs of deterioration abound, a herculean effort is underway to try to maintain the previous high standard of the health care. The public health system has adapted its resources to address specific problems: Community clinics, for instance, have expanded their facilities to include emergency services. The study concludes, however, that the embargo is driving the system towards crisis and causing significant suffering and death.

The AAWH finds that while present law, as set forth in the Cuban Democracy Act, has been construed as a loosening of the embargo on medicine, in practice, new and almost insurmountable obstacles to free trade have been created. The embargo has been extended to include U.S. subsidiaries and any products from third-country companies which contain U.S. components. The result has been to tighten — not loosen — the embargo on medicines and medical supplies.

The Cuban Democracy Act of 1992 (CDA) permits U.S. firms and their subsidiaries to apply for licenses to sell medicines or medical equipment to the island, provided they meet a number of prerequisites. These include the following: that there is no reasonable likelihood the item will be used for torture or human rights abuses; that it will not be re-exported; that it will not be used to treat any of the several thousand foreign patients who come to Cuba each year and pay for medical care; and that it not be used in the production of any biotechnology product. The law also requires end-use certification, which in practice means companies must supply detailed information on distribution in Cuba, and the Cubans must be willing to accept the possibility of independent on-site verification to prove the end use is what is claimed. The U.S. government further constricts the trade by interpreting "medical exports" to mean only finished products, thereby denying any license for inputs or equipment for Cuba's pharmaceutical industry, which are banned from sale. Embargo regulations prohibit third-country company sales to Cuba of any medical products containing over 20 percent U.S. components and require individual licenses for goods containing over 10 percent U.S. components.

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Drugs and Medical Equipment

Obtaining licenses from the departments of Commerce and Treasury to sell medical goods to Cuba on a contract-by-contract basis is a laborious process.

Obtaining licenses from the departments of Commerce and Treasury to sell medical goods to Cuba on a contract-by-contract basis is a laborious process. The severe restrictions impose such a disincentive that only four foreign subsidiaries of U.S. companies sought and obtained such licenses from October 1992 through May, 1995. There is no record of government licenses approved for direct sales to Cuba from parent companies in the United States. AAWH surveyed 12 top U.S. pharmaceutical and medical supply companies: Baxter Health Care Corporation, Bristol-Myers Squibb, Eli Lilly and Company, Johnson and Johnson, Merck and Co., Ohmeda Pharmaceutical Products, Schering-Plough Corporation, Searle, Siemens USA, Smith Kline Beecham Pharmaceuticals, TPLC Pacemakers and Wyeth Ayerst Laboratories. Ten companies stated that the embargo prevented or discouraged them from selling products to Cuba, citing licensing red tape, additional financial burdens and shipping difficulties created by CDA. The executive of one pharmaceutical company told AAWH that so few apply primarily because they are discouraged by the CDA provision requiring certification of end use. Some feared U.S. government reprisals against them in other areas if they traded with Cuba.

Six of the 12 mistakenly believed that the embargo completely bans sales to Cuba. Two of the companies cited political reasons for not selling to Cuba. And the four that had made verbal inquiries regarding export found government licensing officials dampened such initiatives with inaccurate, confusing and misleading information on the law itself.

In the rare instances where licenses have been granted, the process itself creates delays of weeks to months or even years. For example, from initial inquiry, to purchase, documentation, licensing and finally delivery, the sale of spare parts for over 300 Siemens-Elema (of Sweden) Servo-900-C respirators took over two years and involved seven agencies in four countries. Since 1992 the U.S. government has required Johnson and Johnson's Belgian subsidiary to apply for a separate license for each sale of the anesthesia Thalamonal. An average period of six months elapses between each contract closure and delivery.

Examples of the Embargo's Impact

1) **NEW DRUGS INACCESSIBLE:** Due to U.S. embargo law, Cuban patients are deprived of any drug internationally patented by a U.S. manufacturer since 1980. Since the United States boasts the world's leading pharmaceutical research and production capability, the embargo effectively bans Cuba from purchasing nearly one half of the new world class drugs on the market. Of 265 "Major Global Drugs" developed between 1972 and 1992, nearly 50% were of US origin.

2) **MEDICAL EQUIPMENT BLOCKED:** The embargo virtually proscribes Cuban purchases of U.S. medical equipment, parts and accessories. U.S. firms, such as the hospital supplier Thomas Compressors, commonly refuse even price information to Cuban importers, citing the U.S. embargo. Foreign companies have refused sale of X-ray equipment, operating tables, respirators, and other medical supplies containing over 20 percent U.S. components, since such sales are prohibited under the embargo.

For example, in December, 1994, the Commerce Department denied a license for a CAN\$705.30 contract for 110 x-ray parts to the Canadian subsidiary of the Cleveland-based Picker International. The parts contained 27 percent U.S. components, valued at CAN\$193.10. Though Picker had received a previous

license in August 1992 authorizing replacement parts for the same equipment, in July, 1994, Dr. Eugene W. Lewis, Chief of Capital Goods and Production Material Branch of the Department of Commerce Office of Export Licensing, wrote Picker that the new exports would be "detrimental to United States foreign policy" and that "it is the policy of the United States not to approved (sic) license applications to Cuba, except for shipments to meet basic human needs." The parts were designated for 20-year-old x-ray machines in maternity, pediatric, and rural hospitals.

In another instance, a program at the National Oncology Institute that evaluates 360 patients per month for blood and coagulation information uses an Italian platelet aggregometer known as the Omniscribe Series D-500. But the metallic tape used to inscribe the test results is produced in Texas. Cuba has been unable to purchase the tape. Without it, the Omniscribe can read only one half of the information from each patient's tests.

Equipment donated on a humanitarian basis faces the same repair problem: Cuba has been unable to purchase parts or accessories for equipment ranging from 30 Cobe dialysis units to Preemicare respirators for newborns.

3) PHARMACEUTICAL AND BIOTECHNOLOGY INPUTS BANNED: The U.S. government refuses to license export of raw materials for Cuba's pharmaceutical industry. That industry has the capability of producing some 464 drugs at approximately 1/3 the price of importing comparable medications. As a direct result, Cuba is now producing only 119 drugs for its domestic market. The Cuban Democracy Act also explicitly bans exports for Cuba's biotechnology research and production. Cuban biotech research has not only added several vaccines to the national, immunization program but is also responsible for drugs such as recombinant streptokinase, the "clot-buster" for heart attack victims produced at a fraction of the cost of imports and thus now stocked in all Cuban hospitals.

4) FINANCIAL CONSTRAINTS: Effectively barred from the U.S. medical market, Cuba now pays higher prices for comparable European and Asian goods. Purchasing refurbished dialysis units directly from the United States, for instance, would save Cuba as much as 75 percent, multiplying by three or even four the number of units procured. The embargo also prohibits Cuba from using the U.S. dollar for international transactions. Thus, even when Cuba buys medical supplies from wholly-owned foreign companies, converting currencies increases costs.

5) DELIVERY DELAYS: The Cuban Democracy Act discourages even foreign companies from allowing their vessels to dock in Cuba. For example, just after the law took effect in October 1992, delivery to Cuba of 1500 metric tons of tallow for hospital soap was delayed by several months because the Argentine supplier refused to send its ship to Cuban ports. During an epidemic in 1981 of hemorrhagic dengue, the inability to acquire U.S. fumigation equipment on a timely basis resulted in a long delay in controlling the mosquito vector and a significant increase in the number of cases and unnecessary deaths.

Equipment donated on a humanitarian basis faces the same repair problem: Cuba has been unable to purchase parts or accessories for equipment ranging from 30 Cobe dialysis units to Preemicare respirators for newborns.

Food Security

The AAWH finds that the U.S. embargo directly threatens the food security of the Cuban population. U.S. sanctions reduce the island's import capacity for basic foodstuffs, agriculture and the food industry. Moreover, shipping regulations and the ban on direct and subsidiary trade in food close Cuba off from an otherwise natural market.

Subsidiary Trade-Ban With the post-1989 decline in East-bloc trade, Cuba's purchases from U.S. subsidiaries abroad increased, with grain, wheat and other consumables reaching 71 percent (or \$500 million) of Cuba's total imports from the United States by 1990. There was no prohibition on such sales prior to the passage of CDA in 1992.

By FY1992 (the last year before the CDA eliminated subsidiary trade) soybean products, wheat, sunflower oil, corn, rice and palm oil constituted 89% of total Cuban imports from U.S. foreign subsidiaries, such as Cargill, Central Soya, Continental Grain, Del Monte, Dow Chemical, H.J. Heinz, Hoechst Celanese, and International Multifoods. The AAWH found that, after the CDA took effect, suppliers were forced to cancel contracts with Cuba, including purchases of baby food from H.J. Heinz of Canada and of \$100 million in wheat, soy, beans, peas and lentils from the Argentine subsidiary of Continental Grain (New York) and Cargill (Minneapolis).

Shipping Costs The embargo's prohibition on vessels docking in U.S. ports if they have been in Cuba during the previous six months has deterred shippers, causing long delays in the importation of basic foodstuffs and dramatic increases in cost. The AAWH found that by 1993 Cuba was paying as much as 43 percent over pre-CDA shipping rates. Indeed, high fuel costs were partially responsible for many shut-downs in the food industry during the worst years of the crisis. A New Zealand milk producer canceled a long-standing contract to sell Cuba 1500 metric tons of powdered milk when its regular shipper refused to carry cargo bound for Cuba. Several months later Cuba found a new, more expensive source of powdered milk in Europe. Cuba was similarly forced to pay a high-cost shipper to bring in 9,000 metric tons of soy cooking oil from an Italian supplier unable to find a tanker willing to take the risk of docking in Cuba. Likewise, the CDA's shipping ban forced Cuba to send one of its freighters to China to pick up 20,000 metric tons of beans held up for seven months. If goods could be sent to Cuba from the United States, Cuba would save \$215,800 for each ship replacing a European freighter and \$516,700 for each replacing an Asian freighter.

Food Imports Cuban domestic agriculture- meats, grains, fruits, vegetables, rice, tubers-supplied, in 1985, 22.7 percent of the calorie intake per capita and 53.1 percent of the protein. But the economic crisis of the 1990's has taken its toll on harvests and on meat and dairy yields, obliging Cuba to continue relying on imports. The embargo explicitly bans the sale of foods either directly by U. S. companies or by their subsidiaries abroad. There is no licensing provision even though such an absolute ban directly violates international human rights conventions. The ban includes the sale of fertilizers, pesticides, animal feed, and fuel for domestic food production. In the absence of the embargo Cuba could buy grain from U.S. suppliers and ship it from a U.S. port at approximately \$13 per ton. The embargo obliges Cuba to buy wheat from Europe at \$25-28 per ton, including freight, a difference in 1994 of \$9,441,000. In 1994 alone, Cuba paid an additional \$35,881,896 to non-U.S. suppliers and shippers for deliveries of wheat flour, wheat, soy flour, corn, soy beans, chicken and milk. The same year, an extra \$8.3

million was paid for agricultural chemical imports, bringing embargo-related costs to a total of \$204.6 million through 1994, or 47 percent of the previous year's entire food import budget.

Baking and distribution of bread, a ration card staple, illustrates the toll the embargo has taken on basic foodstuffs in Cuba. Up until October 1992, Cuba bought wheat and other grains from U.S. subsidiaries. Since then, we estimate Cuba has paid about \$7.8 million more each year for wheat flour.

Agriculture The study found that the U.S. embargo's ban on exports of fertilizers, pesticides, animal feed and fuel has seriously damaged production and crop yields.

For example, in September, 1992, Bayer AG of Germany halted sales of the pesticide "Sencor" because the company transferred production of the pesticides' active ingredient to a plant in Kansas City. Bayer sought, but was flatly denied, a U.S. license for continued export. Eventually, Cuba replaced "Sencor" with more expensive potato pesticide. The switch cost money and delayed planting of the staple crop. Major fertilizer shipments have been canceled or delayed for similar reasons.

Nutritional Deficit Such embargo-imposed expenses have compounded food shortages and contributed to the deterioration of the Cuban population's nutritional intake. Between 1985 and 1989, calorie intake in Cuba exceeded **2800** per day, with protein levels at 76 grams per day.⁷ By 1993, daily caloric intake had dropped by 33 percent to 1863 and protein levels had dropped by 39 percent to 46 grams per day. By 1993, nutritional deficiencies began to emerge in the general population: The median weight of males and females in 1993 dropped, with adolescents registering weight loss of at least 2 kilograms compared to 1982 figures; children born in 1990 or after were notably smaller than those of the same age in 1982; and men and women age 20 to 60 registered a marked weight loss. Cuba also began to register deficient nutritional status in women at the beginning of their pregnancies, as well as an increase in the incidence of low-birth-weight babies.

Neuropathy Epidemic In 1992 and 1993, over 50,000 Cuban men and women between 25 and 64 years of age were afflicted with a widespread outbreak of neuropathy. After exhaustive research, Cuban and international specialists concluded that the nation's food shortages were a central cause of the epidemic, most likely complicated by the presence of an environmental toxin and heavy tobacco usage. They determined that the sudden decline in nutrition had left the Cubans particularly vulnerable to toxic factors.

Cuban researchers as well as those from the U.S. Centers for Disease Control and Prevention and the Pan American Health Organization also concluded that women, children and the elderly had been less affected by the epidemic because they received extra nutrients under the government's food distribution system. Investigators concluded that the U.S. embargo had significantly contributed to the appearance of this nutrition-related condition by leading to further cuts in foodstuffs and other key imports.

AAWH found that, after the CDA took effect suppliers were forced to cancel contracts with Cuba including purchases of baby food from H. J. Heinz of Canada and of \$100 million in wheat, soy, beans, peas and lentils from the Argentine subsidiary of Continental Grain (New York) and Carqill (Minneapolis).

⁷ *Cane cutters and other agricultural workers in Cuba consume a high-calorie diet to sustain long periods of intensive physical labor.*

Water Quality

The U.S. embargo has always posed serious obstacles to expanding water supplies and treatment in Cuba. The more stringent embargo restrictions of the 1990's deny Cuba competitively-priced water treatment chemicals and prevent ready purchase of spare parts and equipment for aqueducts, piping, meters, and other equipment upon which Cuba's clean water supply depends. The AAWH finds that the embargo contributes to serious cutbacks in supplies of safe drinking water and is a factor in the rising incidence in morbidity and mortality rates from water-borne disease.

Water Services and U.S. Parts Water services were progressively extended among both urban and rural settlements after 1959. In 1960, 65 percent of the urban population had ready access to water, while running water in rural areas was virtually unknown. By 1994, the figures reached 94.2 percent and 83 percent respectively. By 1993, budget cuts and embargo-related import obstacles resulted in deficient services for nearly one third of the population.

Cuba's water supply and sewerage systems generally mirror the U.S. construction model, which separates drainage from sewers, as distinct from the European model. Until 1959, all but two water pumping stations in Cuba were manufactured in the United States. Gradually, Cuba diversified its suppliers, and today the island relies on Russian, Chinese, Spanish and French suppliers. Nevertheless, the water supply program still requires U.S. parts, such as meters and couplings, and still uses the National Pipe Thread (N.P.T.) system, with all compatible fittings patented in the United States. All these items are fully embargoed.

The water treatment plants that use chlorine gas — treating 72 percent of Cuba's drinking water—are built with components from the U.S. firm Wallace and Tiernan and their subsidiaries. Since 1992 when the Cuban Democracy Act banned subsidiary sales to Cuba, Cuba can no longer purchase parts for the Wallace chlorination systems. That single embargo-related prohibition jeopardizes safe drinking water for every city in Cuba with over 100,000 inhabitants — a total of four million people. All reserve equipment has been exhausted, and in 1994, Habana (the semi-rural province outside the capital) shut down all 12 of its chlorination plants. Pinar del Rio province closed all 18 of its facilities.

By 1993, 40 percent of chlorination installations were shut down due to lack of parts and equipment breakdown, while 46 percent were shutdown because of chemical shortages. In 1994, for example, a shipment of Canadian chlorine was delayed by two months, leaving Havana at one point with only a one-day margin of supplies to keep the capital's water safe.

Disease The deterioration of Cuba's water supply has led to a rising incidence of water-borne diseases such as typhoid fever, dysenteries and viral hepatitis. Measured by the number of physician visits, the incidence of Acute Diarrhea1 Disease (ADD) in 1989 was 888,318. By 1993, the figure jumped to 1,115,616. Curbed slightly by 1995, the incidence of ADD was particularly higher in adults over the age of 65. Mortality rates from ADD increased from 2.7 per 100,000 inhabitants in 1989 to 6.7 per 100,000 inhabitants in 1994. Amebic and bacillary dysentery morbidity rates showed marked increases during the same period.

Such diseases as scabies and pediculosis— both related to inadequate water supply—are running to epidemic proportions in Cuba's boarding schools. Dirty water is also related to hospital infections which in 1995 alone accounted for 51 outbreaks involving 349 patients and 60 deaths.

AAWH found a strict correlation between cutbacks in water chlorination services and the outbreak of disease.

The AAWH found a strict correlation between cutbacks in water chlorination services and the outbreak of disease. Havana Province, the semi-urban and rural province just outside the capital city, is a case in point. In 1989, three-fourths of the 120.9 million cubic meters of water supplied was treated and safe to drink. By 1993, only 34.6% of Havana Province's 107.1 million cubic meters of water was safe to drink. The decline caused serious outbreaks of Hepatitis A, with 2,813 reported cases, or 22.1% of the national total. In 1994-95, the province showed viral hepatitis rates well above the national average.*

The AAWH finds that the U.S. embargo limits access to life-prolonging drugs for Cuban HIV and AIDS patients, and otherwise impairs prevention, diagnosis, treatment and research in this field. The families of AIDS patients have also been negatively affected by limitations on travel between the United States and Cuba.

From 1986, when the first HIV-positive cases were identified in Cuba, until January of 1996, the cumulative number of Cubans testing seropositive was 1200, including 440 AIDS patients, 292 of whom have died. The incubation time from HIV infection to full-blown AIDS is 11 years, and the average survival time from the onset of AIDS is 18 months. In 1987, Cuba introduced a broad screening program using domestically produced diagnostic kits. Until 1993, when an outpatient program was developed, all patients testing seropositive were hospitalized in 13 sanatoriums.

The U.S. embargo has jeopardized AIDS testing, diagnosis and protection of the blood supply. Mergers of European suppliers with U.S. companies have suddenly cut off parts and equipment, supplies of reagents and plastic modules for lab work, increasing long-term costs. For example, the Pharmacia Upjohn merger eliminated supplies of reagents for bloodwork to follow the progress of patients, making it impossible to carry out Cd4, Cd8, Cd22, Cd38 and Cd25 tests for specific T-lymphocytes until substitutes could be found.

Limiting the access of Cuban AIDS patients to medicines is the most damaging result of the U.S. embargo that we observed. Cuba does not have ready access to FDA-approved medications manufactured by U.S. firms that have been internationally patented in the last 17 years. As one AIDS professional told the AAWH, "The problem is that our patients don't have the time to wait." Cuba makes illegal purchases of some of these drugs through third parties, although at steeper rates, which in turn limit quantities procured.

U.S. manufacturers are an important source of AIDS medications for Cuba. A recent study reveals that for 22 years (between 1970 and May of 1992), the United States was the world's number one source for new immunology drugs. By 1995, the number of U.S.-developed and FDA-approved medications for AIDS and AIDS-related conditions had reached 30.

The following AIDS medications have been unavailable to Cuba:

- *Azithromycin* ("Zithromax" by Pfizer, FDA approved Nov. 1, 1991): This drug is used against toxoplasmosis (a parasitic infection that can affect muscle tissue, heart, liver, brain and the central nervous system; in AIDS, tumors may form within the brain).

HIV Infection and AIDS

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² National Epidemiology Division, Ministry of Public Health, Feb. 7 5, 1996.

AAWH found that the embargo was directly responsible for up to six month delays in AZT treatment for a total of 176 HIV patients in Cuba.

- *Fluconazole* ("Diflucan" by Pfizer, patented in 1984): This drug has no specific substitute for use in treatment of cryptococcosis (produced by a fungus that attacks the central nervous system, and can cause meningitis and death).
- *Ganciclovir* ("Cytovene," Syntex and Roche Bioscience; patented in 1983): This drug is used against cytomegalovirus, which can produce suprarenal insufficiency, and coreoretinitis, which destroys the retina and leaves scar tissue, causing loss of vision.
- *Antiretroviral products*, including zidovudine (AZT) ("Retrovir," Burroughs-Wellcome; patented in 1989); didanosine (ddl) ("Videx", Bristol Myers Squibb; patented in 1989); and zalcitabine (ddC) ("Hivid", Roche; patented in 1989.) When these products first appeared on the market, they were not freely available to Cuban importers due to embargo restrictions. Since then, AZT has been purchased at well above market prices; and ddC and ddl have only been received through donations.

The case of AZT is illustrative: Approved by the FDA in early 1987, it took several months for Cuban importers to locate suppliers willing to sell them even small amounts at virtually prohibitive cost. The AAWH found that the embargo was directly responsible for up to six month delays in AZT treatment for a total of 176 HIV patients in Cuba.

The outlook is even more bleak for U.S. medications still under development, to which Cuban patients will not have ready access for 17 years following international patent. The 1995 Survey on AIDS medications in the pipeline, published by the Pharmaceutical Research and Manufacturers of America, indicates that 110 medicines have begun the FDA approval process—only three of them by manufacturers outside the United States. Cuban specialists are particularly interested in the protease inhibitors, a new class of AIDS drugs, which are being developed by at least four U.S. pharmaceutical corporations.

Approximately 70% of all Cuban AIDS patients receive interferon as part of their treatment. This drug is produced relatively cheaply in Cuba, but enjoys only limited use in the U.S. because of the prohibitive cost in this country. Studies carried out in Cuba indicate the beneficial effects of interferon: Approximately half the HIV patients treated with interferon showed a greater delay in the onset of AIDS, adding 5.5 to 6 years to the incubation period, and interferon also prolonged survival time. At the same time, the embargo's biotech ban has hampered research on a promising Cuban AIDS vaccine, one of 18 worldwide, 14 of which are being developed in the United States. Ironically, should the Cuban vaccine prove successful, the embargo's ban on imports from Cuba would deny U.S. citizens access to it.

Women's Health

The AAWH concludes that the U.S. embargo directly contributes to lapses in prevention, diagnosis, therapeutic and surgical treatments of breast cancer; diminished alternatives for contraception; gaps in availability of in-vitro genetic testing resources; reduced access to medications associated with pregnancy, labor and delivery, and deficient nutrition during pregnancy.

Breast Cancer. Breast cancer, a primary cause of death for women worldwide, is often preventable with early detection and treatment. Until 1990 all Cuban women over 35 received mammograms on a regular basis at no cost. Today mammograms are no longer employed as a routine preventive procedure and are used only for women considered to be at high risk.

Cuba has two mammogram units based at medical institutions in Havana and 15 mobile units. When functioning, each unit can carry out some 400 mammograms per week. Shut-downs in the entire screening program occurred in 1994 and 1995 for lack of x-ray film. The embargo prevents the Eastman Kodak company or any subsidiary from selling the U.S.-produced Kodak Mini-R film — a product specifically recommended by the World Health Organization because it exposes women to less radiation. Cuba has attempted to buy the film from third-party trading companies, but their markups priced the film out of Cuba's reach. Moreover, intermediaries were reluctant to purchase sufficient quantities that might have called U.S. attention to the illegal sale.

Treatment for breast cancer has also been severely compromised. During the 1980s an average of 15 surgical interventions were performed daily. Now due to lack of surgical supplies that number has dropped to two to three with up to 100 women on a two-month waiting list. Cuban oncologists normally apply a chemotherapy protocol that includes cyclophosphamides and 5-fluorouracil, combined with either methotrexate or adriamycin. These drugs are not always in sufficient stock, and supplies often arrive at erratic intervals. Further, the U.S. dominance of the cancer drug market, combined with the 17-year patent for drug manufacturers, make breast cancer therapies developed as far back as 1980 inaccessible to Cuban women. Some 48 percent of the 215 new medications in phase I-III FDA trials in 1995 are specifically for breast cancer. None will be fully accessible to Cuban women as long as the embargo remains in place.

To compound this tragedy, the embargo directly interferes with Cuba's own ability to produce some anti-cancer drugs. For example, in 1993 the U.S. Treasury Department denied a license to the German subsidiary of Pfizer to sell Cuba one pound of the active ingredient methotrexate for trials of the anticancer drug by the same name. The embargo also bars purchase of key U.S.-origin equipment necessary for domestic manufacture of chemotherapy drugs. For example, Cuba's Center for Medical Research and Development (CIDEM) has been unable even to obtain a quotation for a freeze dryer for dehydration of injectable chemotherapy compounds. The unit is sold by the British firm Edwards, but produced in the United States.

Access to contraception alternatives Until 1990 most Cuban women relied on birth control pills for contraception. Cuba's domestic pharmaceutical industry produced pills for most of the country's consumers. However, when in 1995 Swedish Pharmacia merged with Upjohn, Cuba was suddenly denied access to repair parts for lab equipment essential for quality control, delaying the release of millions of pills. The cut-off forced Cuban women to rely on donated pills that can change month-to-month — with uncomfortable fluctuations in hormone levels,

Genetic Testing In 1985 Cuba initiated a comprehensive testing program for detecting congenital malformations, with alpha fetoprotein (AFP) and corollary analysis, covering 95 percent of pregnant women. The tests determine the presence of congenital hypothyroidism, infant allergy predisposition, HIV 1 and 2 viruses, and hepatitis B and C. The program uses reagents and kits produced by the National Immunoassay Center, which is responsible for some 8 million laboratory diagnostic tests every year, and for supplying reagents, technology and equipment for over 100 Cuban laboratories.

When Pharmacia merged with Upjohn, and Nunc (Germany) with Sybron International of Milwaukee, Wisconsin, they were forced under CDA to cancel

To compound this tragedy, the embargo directly interferes with Cuba's own ability to produce some anti-cancer drugs.

Children's Health

their contracts with Cuba. This eliminated two key suppliers of components necessary for quality control in genetic testing laboratories. The mergers forced Cuba to find substitutes for these products at substantially higher cost. Delays of as much as six months have undermined Cuba's diagnostic testing regime, by decreasing the use of amniocentesis (by 80 per cent between 1989 and 1995), thereby limiting the diagnosis of congenital malformations, and other conditions.

Basic indicators for newborns, infants and children underscore their priority status in Cuban health care. For example, infant mortality has declined from 60-65 per 1,000 live births in 1960 to 9.4 per 1,000 live births in 1995, the lowest in Latin America. The AAWH finds, however, that the economic crisis, aggravated by embargo restrictions, is exacting a toll on children's health, particularly in neonatology, immunizations, pediatric hospital care, access to medicines, and treatment of acute illness.

Neonatology Since 1992, the CDA food embargo has caused an increase in maternal malnutrition leading to a significant rise in low birth-weight babies and premature births. This occurred despite Havana's efforts to provide supplemental feeding for pregnant women. The AAWH found under-equipped and under-stocked neonatology services, with neonatal sepsis becoming the third leading cause of infant mortality by 1995. Lack of hard currency and embargo restrictions impair purchases of essential equipment. For example, Cuba received 25 Preemicare Model 1 O5-4 Neonatal Respirators as a donation, but the embargo prohibits sale of spare parts, accessories and provision of services to train specialists in their use.

immunizations Cuba's immunization program covers 11 infectious diseases: polio, diphtheria, tetanus, whooping cough, measles, rubella, mumps, meningococcal meningitis, hepatitis B, Typhoid Fever and tuberculosis. Fuel shortages, power outages, refrigeration cuts, and transportation lags impede delivery of vaccines. Though Cuba produces all its own vaccines except polio, domestic production remains vulnerable to embargo-related shifts in suppliers. Since 1992, mergers of U.S. companies with third-country companies have resulted in sudden cancellation of contracts for vaccine production inputs.

Pediatric Hospital Care: Equipment Cuba's National Medical Supply company (EMSUME) prioritizes purchases for pediatric hospitals. Still, hard currency shortfalls oblige Cuba to depend upon donations of equipment that frequently require U.S. parts and accessories procured through intermediaries. But third-parties cannot always substitute for direct trade with the United States. For example, the AAWH found donated refurbished Eli Lilly-IVAC 560 infusion pumps out of commission in hospitals in both Pinar del Rio and Havana. Infusion pumps are critical for administration of anesthesia and for intensive care units. We also found Bird, Babylock, Siemens USA and Preemicare respirators in Cuban hospitals that are in and out of commission for want of spare parts. X-rays in Pinar del Rio's Pepe Portillo Pediatric hospital are down 70-80 percent because the United States denied licenses for the sale of Picker X-Ray unit parts describe above.

Medicines In the nine pediatric hospitals and neonatology units we visited, we found the following drugs in critical short supply:

- Fluconazole, or "Difulcan," an important systemic anti-mycotic, produced by Pfizer and patented in 1983. It is used in ICUs for pseudomonas; post-surgically, in immunodepressed patients (cytotoxic chemotherapy and radiation patients, bone marrow transplant patients) particularly susceptible to candidiasis

- Vancomycin, an important antibiotic without substitute, for patients with antibiotic resistance, gram positive supra-infections
- Third generation antibiotics, in general; cephalosporins: Often more effective drugs are not readily available in Cuba because they are still under U.S. patent,
- Ceftriaxonc (Rocephin): life-saving pediatric medication especially for meningitis in infants
- Bronchodilators: asthma medication (Note that pediatric deaths from asthma have risen.)
- Anti-convulsants: for epilepsies and other neuropediatric disorders
- Cancer medications. These critical medicines are always in short supply, particularly the combinations needed for typical protocols.
- Dobutami'ne and dopamine: lifesaving in shock and heart failure, particularly in ICUs
- Growth hormone (somatropin) for dwarfism
- Oral analgesics and anti-pyretics (we found no acetaminophen or ibuprofen anywhere): In Pinar del Rio we found acupuncturists on 24 hour duty in emergency rooms to help compensate the nearly complete absence of these medications. High fevers in children were generally brought down by injection, when available.
- Steroid medications
- Anesthetics: especially scarce in 1993-94 and cause for numerous surgery cancellations
- Erythropoietin and other medications needed by renal patients
- Heart medications, including Prostin V-R, an I.V.-administered substance produced by Upjohn and patented in **1981** to maintain patency of the ductus arteriosus in newborns [blue babies] who have cyanotic congenital heart disease.

Other medications denied to Cubans of all ages because of the embargo include third generation antibiotics, various cardiac and hypertensive drugs, chemotherapy agents, antimycotics, analgesics, anti-inflammatory and psychoactive drugs, and steroids. Cuban physicians specifically cite shortages or absence of the following:

- Aprotinin (Trasylol), Miles Laboratories. Antifibrinolytic used to reduce preoperative blood loss and for transfusion in select coronary patients
- Captopril, Bristol Myers Squibb. Treatment of left ventricular dysfunction following myocardial infarction
- Enalapril Maleate, Merck. Treatment of asymptomatic left ventricular dysfunction
- Doputrex (Dobutamina 259). Treatment of coronaries
- Megestrol Acetate (Megace), Bristol Myers Squibb. Progesterone derivative for treatment of anorexia or unexplained weight loss in patients with AIDS

Our researchers encountered numerous cases where individual children were suffering needlessly with terrible pain merely because some drugs are unavailable due to the embargo.

Rosabel Cano Guerra, a 35-day-old baby girl, was hospitalized in the Pinar del Rio with a serious fungal infection. Care providers searched for the U.S.-patented

Our researchers encountered numerous cases where individual children were suffering needlessly with terrible pain merely because some drugs are unavailable due to the embargo.

anti-mycotic, Fluconazole, which would allow the baby to recover for pending surgery. Though they obtained a small amount from donations, it was not enough for a full course of treatment. The operation had to be postponed, endangering the life of the baby. Eventually, the operation took place and the baby survived.

Cuban children with leukemia are denied access to new, life-prolonging drugs. For example, the FDA has already approved Oncaspar (pegaspargase), patented by the U.S. company Enzon for patients allergic to L-Spar (l-asparaginase). Both drugs produce longer remission when included in treatment for lymphoblastic leukemia (ALL). However, L-Spar has an allergy rate of 40 percent for first-time use and 70 percent for relapsed ALL patients. Further, Oncaspar is less traumatic to a child suffering from ALL, since it requires only one-sixth the number of injections of L-Spar. But the embargo deprives Cuban children of this innovation. Left untreated, this type of leukemia is fatal in two to three months.

Hospital Care

Cuba has 278 hospitals that provide general, pediatric, maternity and neonatology, ob-gyn, clinical, surgical and other specialized care. The AAWH study of 20 hospitals in the city of Havana and in the Province of Pinar del Rio suggests that the economic crisis and the U.S. embargo have seriously eroded surgery, radiology, clinical services and access to medications, hospital nutrition and hygiene.

Surgery The drop in surgeries from 885,790 in 1990 down to 536,547 in 1995 is a glaring indicator of the decline in hospital resources. Surgical services face shortages of most modern anesthetics and related equipment, specialized catheters, third generation antibiotics and other key drugs, sutures, instruments, fabric for surgical greens, air conditioning equipment and disposable supplies. The United States is a leading producer of state-of-the-art anesthesia and related equipment. In one of the rare instances in which the U.S. government has issued a license, Cuba has been able to import the anesthesia Thalamonal, produced by a Johnson and Johnson subsidiary. Even so, each shipment has taken six to nine months for delivery because Washington bureaucrats have quibbled over the specifics of the end use certification. When Thalamonal runs out, other anesthetics can be substituted, but are subject to considerably greater side effects.

Radiology Over the last 20 years, the Cuban health system has made major investments to outfit the country's hospitals and specialized institutes with x-ray units, CAT scans, ultrasounds, image enhancers and even MRIs. Since 1992, maintenance costs associated with this equipment have risen dramatically due to the embargo. For example, by the end of 1995, out of a total of ten hospitals with CAT scans, five reported their units out of order for lack of tubes or other components. European prices for parts tend to be higher than those produced in the United States. A tube produced by Siemens in Germany costs \$40,000, while Varian X-Ray Tube products of Salt Lake City, Utah, lists prices at \$16,000-\$33,000.

Oncology

On the basis of visits to diagnostic and treatment facilities, adult and pediatric wards, and interviews with specialists, the AAWH concludes that the U.S. embargo has significant direct and indirect impact on the quality of patient care and even on the chances for survival of Cuba's cancer victims. As we have noted in earlier portions of this report, the U.S. embargo bars Cuban access to state-of-the-art cancer treatment under U.S. patent, subjects all diagnosis and

treatment-related imports to delays due to the shipping ban, and hinders domestic research, development and production due to the embargo's ban on biotechnology-related exports.

Prevention and Diagnosis Since 1960 Cuba has developed nationwide programs for prevention and early detection of pediatric cancers and cancer of the lung, cervix, breast and mouth. The embargo constantly frustrates the ability of Cuban doctors to provide the quality of diagnosis and follow-up for cancer patients they would wish. For instance, their ability to treat patients with intra-ocular tumors was frustrated by the inability to purchase parts for the Oncology Institute's ophthalmological ultrasound equipment. In 1985, the Institute purchased 10 Cooper-Vision Model System IV ultrasound units through Mexico from a U.S. company located in Redding, California. The embargo has since prevented the acquisition of spare parts for the equipment, even from third parties.

Radiation Therapy Cuban oncologists regard U.S. cobalt radiation therapy equipment and accelerators as among the best on the market. Cut off from that market, Cuba pays higher prices for inferior quality from non-U.S. sources. As a result, there is one cobalt therapy unit working at the National Oncology Institute. The unit is in use from 6:00 am to 1:00 am the next day, with technicians rotating on round-the-clock duty. Such schedules cause untold hardship on sick patients and greater stress for medical staff. The equipment also suffers: In the last four years the unit has used up eight years of its normal 12-year lifespan.

Chemotherapy We have already seen in the section on Breast Cancer that Cuban cancer patients have limited if any access to U.S. medicines under patent. They miss out not only on leading U.S. state-of-the-art cancer therapies but also on medications that ameliorate side effects. Gaps in availability of these medications, such as hormones, antiemetics, analgesics or antibiotics, increase patient suffering and prolong hospital stays and can be life-threatening. For example, the AAWH visited a pediatric ward then on its 22nd day without metoclopramide HCl, a drug used in combination with others such as betamethasone for pediatric chemotherapy. Without these drugs' nausea-preventing effects, the 35 children in the ward were vomiting an average of 28-to-30 times a day.

Based on hospital visits and extensive interviews with cardiologists, the AAWH concludes that the U.S. embargo constitutes a direct threat to patient care, by denying Cuban heart patients access to lifesaving medications and equipment available only in the United States.

Cardiology

Heart disease is the number one cause of death in Cuba. Mortality rates for men and women have increased since 1989: with 189.3 deaths per 100,000 in 1989 and 199.8 deaths per 100,000 in 1995. One hospital, the Cardiology Institute in Havana, implants nearly two-thirds of all pacemakers nationwide. The Institute performed an average of 400 major operations per year through 1990 but by 1995 carried out only 174 surgeries. As of early 1996, nearly 300 patients were on a waiting list for surgery, increasing the risk of death by 10 percent.

Pacemakers and Implantable Defibrillators Lack of access to this specialized equipment poses a particular problem. In one instance Cuban cardiologists diagnosed a heart attack patient with a ventricular arrhythmia. He required an implantable defibrillator to survive. Though the U.S. firm CPI, which then held a virtual monopoly on the device, expressed a willingness to make the sale, the U.S. government denied a license for it. Two months later the patient died.

Cuba was able to purchase pacemakers from Siemens-Elema of Sweden and Telectronics Pacing Systems of Australia until 1993 when both parent companies transferred production and ownership to the United States and were required to cut off sale to Cuba. Replacing the long-time suppliers involved purchasing new lines of accessory equipment and re-training personnel to program the pacemakers. While no fatalities resulted from the change in supplier, the case illustrates the vulnerability of life-saving procedures to the unpredictable and sudden consequences of the U.S. embargo. In addition, Telectronics' move to South Florida left 19 patients with defibrillators that expired in 1996, some requiring hospitalization until replacements could be procured.

In this highly specialized field of medicine, devices are often needed for a handful of patients, or even just one. The U.S. embargo is particularly costly when Cuba must find reasonably priced quality equipment for immediate delivery. The purchase of an internal pacemaker for baby boy Julio Gómez in **1992** is a case in point. While hooked up to an external pacemaker, five months passed before Cuba could find and buy the U.S.-manufactured Medtronic device in Peru at an inflated price through intermediaries. Such delays and heroics cost time and money, when without the embargo finding the item would have required little more than a phone call and a trip to the airport.

Medicines U.S.-manufactured medications under patent remain for the most part inaccessible to Cuban physicians and their patients. Among these are Dobutrex, produced by Eli Lilly for shock; Capoten, produced by Squibb for left ventricular dysfunction and hypertension; Vasotec, produced by Merck for asymptomatic left ventricle dysfunction and hypertension; and Inocor, produced by Winthrop for shock.

Pediatric Cardiology Infants with cyanotic heart disease, including tetralogy of fallot and pulmonary atresia, need drugs such as Upjohn's Prostin V-R, patented in **1981**. These babies frequently die before surgery if the Prostin is not administered in time: There is no substitute. Cuba purchased the drug through third-country trading companies until 1995. But at the end of that year, the Havana Cardiocenter faced a sudden cutoff when Upjohn declared the medication "for hospital use only," requiring the name of the hospital for which it was destined. Disclosing that the product was for a hospital in Cuba prevented intermediaries from making any further purchases. On January 18, 1996, the Cardiocenter used its last vial of Prostin for a 1 4-day-old baby. Unless more Prostin V-R was rapidly acquired the next child with a similar condition would die.

Nor do Cuban children have access to U.S. cardiac equipment. The stent produced by Cordiss Corporation for Johnson and Johnson is a tubular device that props open damaged blood vessels, preventing deterioration that might otherwise require a heart transplant. Cuban cardiologists have never had access to the stent, nor to U.S.-produced specialized catheters and umbrella devices used for angioplasty.

Nephrology

On the basis of on-site visits to nephrology services and institutes and interviews with nephrologists, the AAWH finds that the U.S. embargo limits the chances for survival of Cuban patients with chronic renal failure; increases their suffering; and adds significant expense to already costly care.

Renal failure occurs when the kidneys cannot maintain normal biochemical balance. In the chronic form, the nephrons are progressively destroyed. If not

reversed, this leads to end-stage renal disease (ESRD) and death. **Thus; early** recognition and management are critical. Kidney failure affects the whole body, and patients often suffer from anemia, hypertension, central nervous system disturbances, skeletal affectations, biochemical and mineral imbalances, and increased susceptibility to infection. All require higher calorie and protein intake, and children need growth hormones to tackle retardation of bone development.

The incidence of renal failure in Cuba (including acute, chronic and end-stage) is 355 per one million. Each year, approximately **80** per million (or 840) are added to the group with end-stage renal disease: These patients require dialysis to survive while they await transplant. Between 160 and 200 transplants per year are conducted in Cuba, with a survival rate of 55 percent.

Dialysis By the end of 1995, 1,094 patients with end-stage renal disease were eligible for regular dialysis. However, only 712 were enrolled, and due entirely to the shortage of hemodialysis units in the country, not all of them were receiving the necessary number of dialysis sessions. In fact, the AAWH found that the shortage of equipment has led to a situation in which each new patient added to the program reduces the hours of dialysis available for all.

The embargo closes off the nearest, most technologically developed and often most competitively priced market for dialysis equipment, accessories and maintenance. Baxter Healthcare, a leader in dialysis sales to Latin America, refuses to sell equipment to any country embargoed by the United States. Drake Whillock is another U.S. firm that, for the same reason, does not send equipment to Cuba because of the embargo. Vitalmex Interamericana, S.A., a Mexican distributor for the U.S. dialysis manufacturer Cobe, also cited the embargo when it refused to quote prices to Cuban medical importers for 20 dialysis units in July 1995. That fall, even the Pan American Health Organization (PAHO) had trouble obtaining bids from some U.S. firms on 18 dialysis units requested by Cuba, until PAHO assured them it would handle all negotiations with the U.S. licensing bureaucracy and arrange for shipping.

like used equipment for other tertiary care, refurbished dialysis units are readily available from the United States, but inaccessible to Cuba. Prices of this equipment run one-third to one-fourth of new machines. Cuban importers who resorted to purchasing in Europe could have 54 U.S.-made refurbished units for the price of the 18 new ones they ended up buying. As a result, another 180 Cuban patients are not receiving the dialysis prescribed by their doctors.

There are currently **21** youngsters under **18** suffering from end-stage renal disease. They are receiving dialysis as they await possible transplant. The primary difficulty in treating these patients is the absence in Cuba of modern peritoneal dialysis methods, critical to survival for smaller patients. Some of these children may be as old as five years of age, and yet they weigh less than 30 pounds because of disease-induced growth retardation. They cannot undergo standard hemodialysis; and yet, the embargo has made the alternative treatment — continuous cycling peritoneal dialysis (CCPD) — extremely expensive. Because Cuban hospitals are barred from the more competitively-priced U.S. equipment in this field, there is little hope for these low-weight children; most will quickly progress to end-stage renal disease and die.

Kidney Transplants As in other nephrology technology, a U.S. company, One-Lambda, produces what Cuban physicians consider the most useful kits for HLA (histocompatibility lymphocyte antigen) blood analysis, essential for matching kidney transplant patients with potential donors. Cuba cannot purchase these

The embargo closes off the nearest, most technologically developed and often most competitively priced market for dialysis equipment, accessories and maintenance.

kits, which test for 70 specificities and require only 2-3 ml. of blood from the patient. The European alternative purchased by Cuba tests only 20-30 specificities, making matches less secure, and requires drawing 20 ml. of blood from already weak and anemic patients. In another case, when Cuba's main supplier of reagents and other chemicals, Pharmacia of Sweden, merged with Upjohn, Cuban specialists faced a gap of weeks to months in supplies of Ficoll-400 and Ficoll Paque, the key reagents to organ matching.

Cyclosporins, the first drugs known to inhibit organ rejection, are costly for Cuba to import, and therefore only guaranteed to pediatric patients and adults who have shown highly reactive immunologic responses. The Cuban biotechnology industry could provide an alternative to this dilemma, with a domestically produced monoclonal antibody known as "ior t-3." The antibody has shown promising results in inhibiting organ rejection and has been used so far in Cuba, Uruguay, Chile, Argentina, Russia and India. However, production of ior t-3 depends on the Biopilot unit at the Center for Molecular Immunology, sold to Cuba by Pharmacia of Sweden before its 1995 merger with Upjohn after which the sale of necessary components was banned.

Professional Advancement and Scientific Information

The United States generates more medical and scientific information than any country in the world. Access to its vast body of hard-copy and on-line information, ranging from findings in professional journals to indices and other bibliographic information, is fundamental to continuing education in any country. But despite recent openings in the exchange of information between the two countries, the AAWH finds that the U.S. embargo remains a formidable barrier to the free flow of ideas and scientific information between Cuban medical researchers and their colleagues in the United States.

In 1988, an amendment to the Foreign Trade Act introduced by Congressman Howard Berman (D-CA) legalized trade with Cuba in U.S. books, journals and other informational materials. Though the 1988 law did not include electronic materials such as news wire feeds or computer information, by 1994 the U.S. Congress adopted the Free Trade in Ideas Act, which stipulated that the President can no longer regulate or prohibit the import or export of "any information, including but not limited to publications, films, posters, phonograph records, photographs, microfilms, microfiche, tapes, compact discs, CD ROMs, art works and news wire feeds."

Cuba's 28 medical schools, four dental schools and numerous facilities for health technicians currently face severe shortages in textbooks and other teaching tools. The embargo's ban on subsidiary trade with Cuba is partly to blame. For example, in 1990 the Spanish firm Editorial Interamericana S.A. became a subsidiary of McGraw Hill. The U.S. firm advised Interamericana that the latter's personnel could neither attend an upcoming book fair in Havana nor conduct future sales to the island. McGraw Hill's decision reflects the embargo's "chill factor," wherein companies are discouraged from trading with Cuba despite U.S. laws — in this case the 1988 Berman Amendment — that legalize sales of Interamericana's medical textbooks. By 1992, of 73 titles Cuba wished to purchase in the field of oncology, only 19 were available.

The dearth of medical literature on computer disk or CD-ROM would seem to offer inexpensive alternatives to importing bulk texts and periodicals. Yet U.S.

companies remain under the impression that the embargo excludes their sale. **For** example, the Sciences Citation Index, a standard CD-ROM resource published by the institute for Scientific Information (ISI) in Pennsylvania, lists abstracts and bibliographic references. ISI was under the mistaken impression that selling the \$17,000 CD-ROM to Cuba would violate embargo laws and thus refused the sale. Likewise, despite the 1994 Free Trade in Ideas Act's expanded definition of "informational materials," DHL refused to ship to Cuba packages containing floppy disks.

Embargo regulations continue to limit the free flow of information. For example, the ban on bilateral banking activities prohibits direct subscription to and payment for U.S. journals or other informational materials; the virtual ban on export to Cuba of computer hardware limits options to support software programs, Internet connections and on-line services.

While the donation of professional services is legal, the related licensing process can act as a red flag. This occurred when the U.S. denied travel licenses to a group of ophthalmological surgeons to operate on dozens of Cuban patients in a professional exchange between Project Orbis and Cuban teams at the Pando Ferrer Ophthalmological Hospital in Havana. After significant lobbying, licenses were eventually granted. But the dispute delayed operations on nearly 50 patients.

The AAWH finds that donations from U.S. NGO's, international agencies and third countries do not compensate to any major degree for the hardships inflicted by the embargo on the health care system and the health of the Cuban people. Restrictions placed on charitable donations from the U.S. which are similar to those imposed on commercial trade have the same discouraging impact, severely limiting what might otherwise be contributed. In addition, contributions rarely match needs in terms of specific drugs, equipment or replacement parts. Delays in licensing, shipping and end-use certification requirements make charity an unacceptable alternative to free trade.

Humanitarian Donations

The U.S. embargo regulates various categories of humanitarian donations by U.S. nationals to Cuba; export and shipping licenses are required in the case of medicines, medical supplies and equipment, while food requires only a shipping license. Since March 1996, humanitarian goods require only shipping licenses as long as the donor is experienced in verifying that the donations reach their intended recipients. The American public has been generous in providing humanitarian donations, with Catholic Relief Services being in the forefront.

According to Treasury Department figures, between October 1992 and May 1995, 82 licenses for sales and donations valued at almost \$63 million were granted, while two licenses valued at just over \$23 million were denied. But in 1990 alone, prior to the enactment of CDA, Cuba imported from U.S. subsidiaries \$500 million in food and medicines. (The Treasury Department combines figures for sales and donations which obscures the minimal number of sales they have permitted.) Thus, licensed sales and donations during the 31 months after the October 1992 implementation of the Cuban Democracy Act reached just 12 percent of U.S. food and medical sales to Cuba in the 12 months before the law took effect.

Family visits have over the years become an exceptionally important source for medicines and medical equipment such as wheel chairs. From the late 1970s

until August 1994, the United States permitted persons visiting close relatives to travel to Cuba under a general license. In August, 1994, new presidential restrictions revoked this general license. Thereafter, the Treasury Department announced that "travel-related transactions by persons demonstrating a compelling need to travel to Cuba for humanitarian reasons involving extreme hardship...will be considered for a specific license on a case-by-case-basis." The case-by-case stipulation gave the Treasury Department's Office of Foreign Assets Control the jurisdiction to define "compelling need," "extreme hardship," or "extreme humanitarian need." It also created a backlog in license requests that reached into the thousands at one point in 1995.

Until 1994, the law permitted a U.S. resident to send a monthly \$200 gift parcel to individual Cubans or Cuban educational, charitable or religious organizations. But the August 1994 Presidential ruling limited gift parcels to food, vitamins, seeds, medicines in dosage form, medical supplies and devices, hospital supplies and equipment, equipment for the handicapped, clothing, personal hygiene items, veterinary medicines and supplies, fishing equipment and supplies, soap-making equipment, radio equipment capable only of receiving and batteries for the same. New U.S. Commerce Department regulations issued in March 1996 permit unlimited gift parcels of food. But sending gift parcels to Cuba became significantly more expensive with the end of direct charter flights between Miami and Havana in late February 1996.

The licensing process also kept Cuban families apart. For example, on March 7, 1995, the Treasury Department denied a travel license to Isabel and Angel G. Muñoz to visit their ill mother in Cuba. The Muñozes presented documents showing their mother had cancer, but OFAC found that her illness did not constitute "extreme humanitarian need." When the Treasury Department granted a license on appeal two months later, it acknowledged "that the applicant's relative is in a final state of cancer." But the license arrived just days before the Muñozes mother died, too late to make the trip.

On October 6, 1995, President Clinton announced changes governing Cuban-American travel to the island. The new regulations now permit travel once a year under a general license for "extreme humanitarian need."

Air Travel

Despite loosened regulations governing donations, U.S. NGO's must still procure licenses for donations of medicines and medical supplies. In addition, travel licenses are required from the Treasury Department, which can take anywhere from three weeks to six months. The Cuban Council of Churches, for instance, has experienced up to three-month delays in U.S. donations re-routed through Canada. The AAWH found that the Catholic Church's CARITAS-Cuba spent an additional \$30,000 to re-route through Canada U.S. donations of \$2.5 million in cephalosporins [broad-spectrum antibiotics] for Cuban intensive care unit. The additional shipping costs could have been spent for more medicine. (During the autumn of 1996, the Clinton administration did waive the travel restrictions to allow hurricane relief supplies to be flown directly to Cuba.)

Third-Countries and International Agencies Third countries donate a substantial portion of the \$20 million each year that Cuba receives in health care-related assistance. The extraterritorial reach of the embargo affects those donations in at least two ways. First, the Cuban Democracy Act's effective blacklisting on ships that have docked in Cuba, preventing them from stopping within 180 days

in U.S. ports, applies to purchases and donations. Second, like their U.S. counterparts, international donors must apply for licenses from U.S. government agencies if the material they will send to Cuba contains over **10** percent U.S.-origin components.

Delays and increased costs, according to one international NGO, the Spanish *Medicos Sin Fronteras* (Doctors Without Borders), reduce “the effectiveness of every dollar spent” to assist Cuba. *Medicos* could have purchased far more water supply and purification equipment with its \$1.8 million budget if it could buy calcium hypochlorite in Georgia, rather than in the United Kingdom.

In November, 1994, Tropical Storm Gordon displaced 2,570 families in the Eastern Cuban provinces, leaving some 11,967 refugees in its wake. The European Union contributed nearly \$500,000 in disaster relief assistance to the International Federation of the Red Cross Societies in Central America to purchase materials ranging from fumigation equipment, insecticides, electrical wiring, and housing repair supplies. Currency and shipping restrictions imposed by the embargo, however, delayed delivery of the storm relief assistance by a total of six months.

The inclusion of food and medicine in an international trade embargo is a violation of international human rights conventions which uphold the principle of a free flow of food and medicines, even in wartime, to serve the basic needs of civilian populations.

International Human Rights law and Conventions

The U.S. embargo's ban on food and de facto ban on medical exports to Cuba violates international and inter-American resolutions, charters and conventions governing human rights, among them the United Nations Charter, the charter of the Organization of American States, the American Declaration and American Convention, and Geneva Convention articles regarding the treatment of civilians during wartime. Moreover, the embargo's prohibition on food and its virtual prohibition on medicines is extremely rare among trade embargoes of the post-World War II era.

The United Nations

In four consecutive sessions the United Nations General Assembly has passed resolutions condemning the U.S. embargo against Cuba and calling on the nation to rescind those aspects of the statutes that violate principles of international law and the United Nations Charter. In November 1995, for instance, the U.N. General Assembly registered its concern with the embargo's extraterritorial reach and the manner in which measures related to the Cuban Democracy Act extended “the economic, commercial and financial embargo against Cuba...and the adverse effects of such measures on the Cuban people and on Cuban nationals living in other countries.” In 1994, the United Nations Commission on Human Rights characterized unilateral coercive measures such as trade embargoes as a “clear contradiction of international law,” and noted that “such unilateral coercive economic measures create obstacles to trade relations among states, adversely affect the socio-humanitarian activities of developing countries, and hinder the full realization of human rights by the people subject to those measures.”

Organization of American States

In 1975, the OAS resolved to permit each member state to decide independently whether to trade with Cuba. One month later, the United States lifted its own ban on subsidiary trade with Cuba. But the embargo-tightening measures of 1992

described in this report violate not only the intent of the 1975 OAS ruling but also U.S. obligations under the OAS charter, the American Declaration of the Rights and Duties of Man and the American Convention on Human Rights. Together with the OAS charter, the Declaration is among the "sources of international obligation" binding member states, the United States included.

Article 31 of the OAS charter, for example, notes that "...member states agree to dedicate every effort to...protection of man's potential through the extension and the application of modern medical science...[and] proper nutrition, especially through the acceleration of national efforts to increase the production and availability of food." As documented herein, U.S. restrictions on the sales of medicines and food to Cuba directly impair the ability of the Cuban population and their government to preserve health and welfare through adequate and proper medical care. As such, the punitive and extraterritorial reach of U.S. embargo laws are in violation of the regional system of inter-American rights set forth by the Organization of American States.

Geneva Conventions

The Geneva Conventions, to which some 165 countries including the United States are party, require free passage of all medical supplies and food intended for civilian use during war time. The United States and Cuba are not at war. Indeed, the two countries maintain Interest Sections in one another's capitals. Nevertheless, the AAWH findings suggest that the embargo's restrictions amount to the purposeful impeding of foods and medicines-in peacetime.

Twentieth Century Trade Embargoes and Humanitarian Exemptions

International practice in applying trade sanctions for political ends has come to include an exception for medicines, medical supplies and certain basic foodstuffs in order to prevent unnecessary suffering amongst civilian populations. The multilateral embargoes imposed against Southern Rhodesia, North Korea, Vietnam, South Africa, Chile, El Salvador, the Soviet Union, and Haiti featured humanitarian exceptions permitting the free flow of medicines and food. In the recent United Nations-supported embargoes against Iraq and the territories of the former Yugoslavia, the United Nations upheld the principle that food and medicines must be allowed to enter those areas in order to serve the basic needs of the civilian populations. In the case of Iraq, a special Sanctions Committee was established within the United Nations in order to ensure free passage.

The United States government itself has acknowledged that embargoes of food and medicines violate international humanitarian law. To note, during the 1992 siege of Sarajevo, the United States joined numerous other countries in proposing a resolution before the U.N. Security Council which:

"Condemns all violations of international humanitarian law, including... the deliberate impeding of the delivery of food and medical supplies to the civilian population of Bosnia and Herzegovina, and reaffirms that those that commit or order the commission of such acts will be held individually responsible in respect of such acts." [November 13, 1992]

It seems only reasonable that if international law requires a humanitarian exception to a blockade for food and medicines even in the midst of armed conflict, then it requires such an exception to the embargo against Cuba.

Appendix-A

Key Drugs Patented since 7 980 that Cuba Cannot Freely Purchase

- 1) Adenosine or "Adenocard", injection produced by Medco for supraventricular tachycardia patented in 1987
- 2) Atovaquone, or "Mepron" tablet produced by Burroughs Wellcome for parasites patented in 1991
- 3) Azithromycin "Zithromax", capsule produced by Pfizer antibacterial approved by the FDA in **1991**
- 4) Bepridil Hydrochloride or "Vascor," a calcium channel blocker produced by RW Johnson for heart patients and patented in 1981
- 5) Carboplatin, or "Paraplatin," an injection for malignant tumors produced by Bristol-Myers Squibb and patented in **1987**
- 6) Cisapride Monohydrate or "Propulsid," tablet developed by Janssen, a Johnson and Johnson subsidiary, a motility stimulant, patented in **1990**
- 7) Clozapine, or "Clozaril," an anti-psychotic tablet produced by Sandoz and patented in **1989**
- 8) Didanosine, "Videx," a chewable tablet produced by Bristol-Myers Squibb for retro viral infections associated with HIV patented in 1989
- 9) "Prostin V-R," an injection for pediatric heart patients known as "blue babies" produced by Upjohn and patented in 1981
- 10) Eflornithine Hydrochloride, "Ornidyl," an anti-protozoal injection produced by Merrell Dow and patented in 1983
- 11) Felbamate, or "Felbatol," a tablet for prevention and control of epileptic seizures produced by Carter-Wallace, Inc. and patented in 1990
- 12) Finasteride or "Proscar," a testosterone inhibitor used in cancer treatment produced by Merck Sharp & Dohme and patented in **1983**
- 13) Fluconazole, or "Diflucan," an antifungal tablet produced by Pfizer and patented in 1983
- 14) Fludarabine Phosphate or "Fludora" produced by Berlex an injection for an immunomodulator and patented in 1982
- 15) Ganciclovir or "Cytovene," a powder for injection produced by Syntex and patented in 1987, an antiviral used in HIV and AIDS
- 16) Levamisole Hydrochloride, or "Ergamisol," a tablet for cancer treatment produced by Janssen, Johnson and Johnson subsidiary, and patented in 1986
- 17) Levocabastine Hydrochloride or "Livostin," a suspension produced by Janssen, Johnson and Johnson subsidiary, an antihistamine, patented in 1983
- 18) Mivacurium Chloride, or "Mivacron," an injection for skeletal muscle relaxant during surgery produced by Burroughs Wellcome and patented in 1988
- 20) Risperidone, or "Risperdal," an antipsychotic tablet produced by Janssen (Johnson and Johnson subsidiary) and patented in 1989

- 21) Zalcitabine, or "HIVID" an anti-viral tablet used in AIDS prevention and treatment, produced by Hoffman La Roche of New Jersey and patented in 1989
- 22) Zidovudine, or "Retrovir," an anti-viral capsule used in AIDS prevention and treatment, produced by Burroughs Wellcome and patented in 1989

Appendix-B

American Association of World Health Delegation to Cuba, October 4-11, 1996

Alfred W. Brann, M.D., is Professor of Pediatrics, Emory University School of Medicine, specializing in neonatal and perinatal medicine and in child neurology. As the current Director of the World Health Organization (WHO) collaborating Center in Perinatal Health and Health Services Research in Maternal and Child Health, he evaluates the quality of perinatal/neonatal care and performance of the health systems that deliver that care. Dr. Brann has also worked with the Carter Center of Emory University, the Task Force of Child Survival, Project Hope, and the World Bank. He has consulted in Central and South America, Asia, Eastern Europe, India, Bangladesh and Pakistan.

Peter G. Bourne, M.D., is currently Chairman of the Board of the American Association for World Health. He is also Professor and chair of the Department of Psychiatry at St. George's Medical School in Grenada. He was an advisor to former President Jimmy Carter on health issues and served as Assistant Secretary General of the United Nations from 1979-1981. He has authored over 100 articles and several books on international health and political issues. He has traveled on numerous occasions to Cuba on behalf of the White House, the United Nations, and as a professional researcher.

C. William Keck, M.D., M.P.H., is currently Director, Akron Public Health Department, and Director, Division of Community Health Sciences, Northeastern Ohio University's College of Medicine. He has served in these positions since 1976. He was Field Professor of Community Medicine, University of Kentucky College of Medicine from 1972 through 1975. After earning his medical degree, Dr. Keck served as a Peace Corps physician for three years. He has held the title President in the following organizations: Summit County Medical Society, American Public Health Association, Association of Ohio Health Commissioners, and the Ohio Public Health Association.

Thomas M. Kerkering, M.D., is Professor of Medicine at the Medical College of Virginia in Richmond, Virginia. He directs the Richmond AIDS Consortium, an NIH-funded clinical research program on HIV/AIDS, and heads the Child Survival Program for Guatemala, recently funded by USAID. He is an author on 57 publications in peer-reviewed journals, 60 abstracts at national international meetings, and 10 book chapters dealing with the subjects of mycology, HIV/AIDS and international health. He has assessed health programs and health status in Russia, the Baltic states, Poland, Ethiopia, Kenya, Uganda, Zambia, Angola, Sierra Leone, the Gambia, Senegal, Bolivia, Guatemala, India, Sri Lanka, and Cuba.

Karen Olness, M.D., is Professor of Pediatrics, Family Medicine, and International Health at Case Western Reserve University. She is also Director, International Child Health at Rainbow Babies and Children's Hospital, where she coordinates international child health training for pediatric residents. She has served on the faculties of George Washington University, University of Minnesota, and Case Western University. For the past nine years, she has directed research on pediatric AIDS in Uganda and faculty development project in Laos. In 1995, she was a WHO consultant, working to develop a Community and Social Pediatrics curriculum for Laos.

Elisabeth A. Squeglia, J.D., is a practicing attorney specializing in government affairs, health care and insurance, serving as a partner in the law firm of Bricker &

Eckler in Columbus, Ohio. In addition to serving on the Board of Directors of the American Association for World Health, Ms. Squeglia is a member of the Health Care Forum of the American Bar Association, the National Health Lawyers Association, and the American Academy of Hospital Attorneys. Formerly, she served as the Chief of Staff and Assistant to the Minority Leader of the Ohio Senate.

Robert I. White, M.D., Ph.D., is currently Professor of Neurosurgery at Case Western Reserve University School of Medicine and Director of the Division of Neurosurgery and the Brain Research Laboratory at the MetroHealth Medical Center. He is a consultant to the Burdenko Institute of Neurosurgery in Moscow, the Polenov Neurological Institute in Saint Petersburg, Russia, and the Ukrainian Research Institute in Kiev. He has served as the Editor or on the Editorial Board of several journals and has authored almost seven hundred publications on clinical neurosurgery, brain research, medical ethics, and health care delivery.

Robin Williams, M.D., is the Medical Officer of Health for the Regional Municipality of Niagara, Ontario, Canada.

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Appendix C

Executive Summary Editors

Julia Sweig, Kai Bird

Researchers and Authors of the Full Study

Michele Frank, M.D., is Health Editor of Cuba Update, the journal of the Center for Cuban Studies, and is pursuing a residency in child psychiatry.

Gail Reed is a journalist and development consultant, who has written for the U.S. press on Cuban economic policy and social conditions for the last ten years. She is currently associated with the World Policy Institute, New York. She has also conducted research in Cuba for UNICEF, the Christian Children's Fund, and For Children, evaluating potential NGO cooperation in the Cuban social sector. Before making Havana her professional base, Ms. Reed served on the executive staff of Church World Service, New York. She is a graduate of the Columbia School of Journalism.

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