

CHAPTER THREE

MEDICAL EXPORTS TO CUBA

Relevance to Cuba of U.S. Research, Development and Production

We have singled out medical imports for special consideration, since this is an arena where our findings indicate that the embargo has had significant health-specific impact, with implications for the medical system as a whole and patient care in particular.

In recent years, United States pharmaceutical and medical supply and equipment manufacturers have consolidated their dominant position in the international market. In the pharmaceutical industry, no other country compares to the United States in terms of the sheer variety, quantities and marketing of medications, with PhRMA member sales up to \$56.6 billion in the United States and \$30.5 billion abroad in 1995.¹ U.S. pharmaceutical manufacturers are also the world's number one in research and development: company-financed RandD expenditures by PhRMA members were projected at \$14.9 billion in 1995, up 7.9 percent from 1994.²

U.S. giants hold a strong 25-year lead over European and Japanese competitors in medical product breakthroughs, for the introduction of new world-class drugs marketed internationally. A recent study published in Britain concludes:

The American pharmaceutical industry has a clear and outstanding lead in discovering and developing major, medically innovative, globally competitive, and therapeutically accepted new drugs.

The American lead in origination has been continuous, with an average score of 43% of all "Major Global Drugs" during the 22-year-period (the 265 major global drugs developed from 1970 through May, 1992). This compares with average scores of 31% for the European Community, 13% for "Other West Europe," 11% for Japan, and 2% for East Europe.

The most recent period (1990-May 1992) shows the American share of "Major Global Drugs" at its highest (47%), with a surge from Japan to 21%, and a serious decline of the European Community to 19%.³

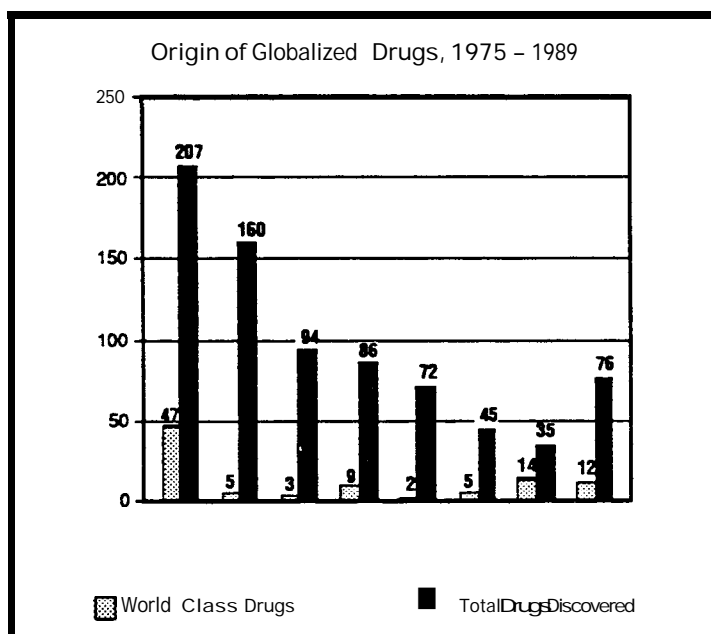
Due to U.S. and international patent law and practice, this means that a host of newly discovered medications are only available from U.S. pharmaceutical manufacturers, during the life of their 17-year patent. Since drugs are patented before they begin the FDA approval process, this means that a U.S. developer is guaranteed exclusive production and sales in the USA for an average of 8 to 10 years, once the new drug emerges onto the market with FDA authorization. International patent practice will guarantee these firms similar rights in other countries. Therefore, all medicines internationally patented by U.S. pharmaceutical companies since 1979 are still exclusively produced by these manufacturers, and thus only available from them directly or under licensed production agreements.⁴ The U.S. embargo's virtual ban on such sales to Cuba, as we will see throughout this study, has had a serious impact on the Cuban population's access to new cures for illnesses, more effective treatments, and alternative therapies.

In Cuba's case, access to the results of U.S. research, development and production takes on additional importance for several reasons:

1. United States suppliers not only occupy the largest share of the international market, but are also the closest to the island, making Cuban importers a "natural" for U.S. firms. Indeed, this was the case prior to the embargo, when most medications were imported from the United States, even to the detriment of developing a domestic pharmaceutical production capability. According to the Cuban Ministry of Public Health, 40,000 medical products were registered in Cuba in 1959 (including medicines, reagents, instruments, accessories, etc.), of which 80% came from foreign firms, mainly those of the United States.⁵ Access to close-at-hand U.S.

suppliers would translate into reduced freight, immediate delivery, less moneys tied up in bulk purchases for the long term, and reduced inventories and warehouse needs.

2. Since the United States manufacturers are often among the strongest in their respective lines of production, they are able to offer more competitive prices, underbidding suppliers elsewhere. This is especially true in terms of their efforts to guarantee maintenance of a major presence in the Latin American and Caribbean markets.
3. New U.S. "state of the art" equipment, supplies and pharmaceuticals are well assimilated by the Cuban health system, both because of its internationally recognized level of development, and because the tradition of Cuban medicine has followed closely in the path of United States medical practice. Thus, many Cuban physicians and specialists told us they often prefer to work with U.S. products because they trust the credibility of FDA and manufacturing standards.



Orlando Romero is General Manager of MEDICUBA, Cuba's government-owned import-export firm for medicines, pharmaceutical raw materials and reagents, medical equipment, supplies, parts and accessories. The company is primarily funded by the government, but derives some of its operating budget from exports. According to Romero, all profits from exports are reinvested in the company or go directly to purchasing medical imports.

During the economic crisis of the past five years, exacerbated by the embargo as noted earlier in this report, the purchasing power of MEDICUBA has plummeted. Despite attempts at import substitution by domestic production (see chapter on the Pharmaceutical Industry) and the adoption of complementary alternative medicine approaches, hard currency budget reductions have drastically diminished supplies of medications and equipment. MEDICUBA is the supplier of 95% of the medical imports for the country's health system, but Romero calculates that the firm's current import budget only covers 40% of the country's needs.⁶

At the height of purchases in the 1980s, he estimates, the company annually spent some \$200 million. But by 1992-the most serious year of MEDICUBA's budget crisis-the firm's import capabilities constituted only a fraction of this figure.

CUBAN MEDICAL IMPORTS .	
Years	Reduction in Imports
1989 to 1990	12 %
1990 to 1991	18 %
1991 to 1992	38 %
1992 to 1993	5 %
1993 to 1994	8 %

'Includes medicines, reagents, raw materials for pharmaceuticals equipment, accessories and parts.

Source: MEDICUBA, November 24, 1995

However, by 1995 the hard currency budget slide had been halted, and Romero predicted an increase in medical imports for 1996, the first time in the last seven years. Even in such depressed times, the MEDICUBA manager calculates that his company would spend \$50-\$60 million annually in the U.S. marketplace if the embargo were lifted on medicines and medical supplies, and he estimates that amount would reach \$150 million under conditions of relative economic recovery.⁷

Application of U.S. Embargo Restrictions on Medical Exports to Cuba

As noted in previous chapters, the U.S. government has levied a series of restrictions on medical exports to Cuba. These apply to all products from U.S. pharmaceutical and medical supply houses, subsidiaries of these firms in third countries, and third-country firms **with** a substantial percentage of U.S. ownership. They also apply to the goods themselves, regardless of nationality or ownership of the manufacturer, when U.S.-origin components, U.S. patents or technology are implicated in the manufacturing process. And finally, these suppliers are subject to U.S. government requirements to certify specific end-use of pharmaceuticals and medical equipment in Cuba, requiring detailed distribution information and the possibility of on-site verification of the information provided.

The regulations governing export of medications and medical supplies to Cuba have changed a number of times since the full U.S. embargo was imposed in 1962. Although we make a general chronological review of U.S. embargo legislation in an earlier chapter, it is useful to look at modifications which have specific relevance to sales for medical purposes.

Until 1964, medicines were exempted from the embargo altogether, and their export to Cuba was permitted. However, on May 14, 1964, the Commerce Department revoked the general license for foods and medicines and indicated that henceforth policy would be to deny such sales, and permit only limited humanitarian donations.* From 1964 until October 1975, no sales to Cuba of medications, medical equipment or supplies containing any U.S. components or technology were permitted, including those by companies in third countries.

In 1975, U.S. Treasury Department regulations *were* liberalized, to permit case-by-case licensing to foreign firms owned or controlled by U.S. nationals, yet limited to those which did not share a substantial number of officers or directors with the parent firm in the United States. This change affected all exports to Cuba, not only those in the health field. The Commerce Department also relaxed its regulations to allow for exports by third countries of foreign-made products containing "an insubstantial proportion of U.S.-origin materials, parts or components." Special licenses could be granted where the U.S. parts or components amounted to 20 percent or less of the value of the product; licenses were less likely to be granted for larger proportions. The government also

took the first steps to eliminate the so-called blacklist of foreign ships, which had prohibited foreign assistance to third countries that permitted their vessels to carry goods to or from Cuba.⁹

From 1977 to 1982, travel restrictions were lifted for the first time, allowing representatives of U.S. firms to explore the Cuban market. However, the prohibition on such trips was reinstated on April 20, 1982. (And it was not until November, 1994, that efficient telephone communication was resumed between the United States and Cuba.)

In 1988, the Treasury Department's Office of Foreign Assets Control (OFAC) embarked on a stepped-up drive to more closely monitor Cuba's international trading ties and "bear most effectively on the key vulnerabilities of the Cuban economy and its embargo circumvention attempts." As a result, by August 2, 1989, OFAC had compiled a list of 258 names of third-country companies or persons considered "Cuban nationals" by the U.S. government, and thus barred from entering into any commercial transactions with the United States.

Finally, on October 28, 1992, the Cuban Democracy Act (CDA) was signed into law, reversing the 1975 decision to allow third-country companies owned or controlled by U.S. firms to engage in licensed trade with Cuba. An exception allowed special licenses to be granted for the sale of medicines or medical equipment by these firms or their parent companies in the USA provided that a number of prerequisites were met to the satisfaction of the U.S. government." These include: that there is no reasonable likelihood that the item exported will be used for the purposes of torture or human rights abuses, that it will be reexported, or that it could be used in the production of any biotechnology product. The law also provides that medical exports can only be authorized if the President determines that the U.S. government is able to verify, by on-site inspection and other appropriate means, that the exported item is to be used for the purposes for which it was intended and only for the use and benefit of the Cuban people.**

In addition, the CDA prohibits foreign ships which have docked in Cuba from entering U.S. ports for the next 180 days, partially reinstating the blacklist.

Also in October 1992, the U.S. Congress increased criminal penalties for those who knowingly violate the embargo. The new regulations allow for a maximum of \$1 million in fines to be levied on corporations and \$100,000 for individuals, ten years in prison and forfeiture of properties involved in the violation.¹² The Helms-Burton Act, enacted on March 12, 1998, mandates full enforcement of these penalties and permits administrative fines to be levied without going to court.

U.S. Exporters and Embargo Laws

Despite the fact that sales to Cuba of medicines and medical equipment may be authorized by the U.S. government, we find that major medical manufacturers in the USA do not in fact export their products to Cuba. Indeed, they report various "chill factors" that keep them from taking advantage of this possibility. Among these are the labyrinth of changing U.S. regulations and their interpretation, licensing requirements and the complex application process, time lags, the uncertainty of final authorization, often based on active discouragement by government offices, and stiffened penalties for embargo violations. We also observed considerable confusion among United States manufacturers in the medical supply field about current U.S. legislation, and a unanimous reluctance to engage Cuban import firms in conversation, much less contracts.

In a survey conducted for this study among 12 pharmaceutical and medical equipment manufacturers in the United States, we found that none sells or had recently sold products directly to Cuba and that none had ever applied for a license to do so. In the vast majority of cases respondents stated that it was their understanding that the U.S. embargo either prevented or

discouraged sale to Cuba. In fact, representatives of six of these companies had the mistaken understanding that the U.S. embargo prohibits all medical sales to Cuba.

The results of our interviews:13

My company sells or has recently sold its products directly to Cuba...

<i>Baxter Healthcare Corporation</i>	NO
<i>Bristol-Myers Squibb</i>	NO
<i>Eli Lilly and Company</i>	NO
<i>Johnson and Johnson</i>	NO
<i>Merck and Company</i>	NO
<i>Ohmeda Pharmaceutical Products</i>	NO
<i>Schering-Plough Corporation</i>	NO
<i>Searle</i>	NO
<i>Siemens, USA</i>	NO
<i>SmithKline Beecham Pharmaceuticals</i>	NO
<i>TPLC Pacemakers</i>	NO
<i>Wyeth-Ayerst Laboratories</i>	NO

My company has applied for a US. government license to sell directly to Cuba

<i>Baxter Healthcare Corporation</i>	NO
<i>Bristol-Myers Squibb</i>	NO
<i>Eli Lilly and Company</i>	NO
<i>Johnson and Johnson</i>	NO
<i>Merck and Company</i>	NO
<i>Ohmeda Pharmaceutical Products</i>	NO
<i>Schering-Plough Corporation</i>	NO
<i>Searle</i>	NO
<i>Siemens, USA</i>	NO
<i>SmithKline Beecham Pharmaceuticals</i>	NO
<i>TPLC Pacemakers</i>	NO
<i>Wyeth-Ayerst Laboratories</i>	NO

The barriers to direct sale are...

- The U.S. embargo prevents sales (they are illegal).
- The U.S. embargo discourages sales.
- The company does not sell to Cuba for political reasons.
- The company has not received a request from Cuban purchasing agents.
- The company's organizational structure does not permit direct sales to the Caribbean.
- Indicates uncertain response.

<i>Baxter Healthcare Corporation</i>	<i>A and C</i>
<i>Bristol-Myers Squibb</i>	<i>E and F</i>
<i>Eli Lilly and Company</i>	<i>B</i>
<i>Johnson and Johnson</i>	<i>A</i>
<i>Merck and Company</i>	<i>A</i>
<i>Ohmeda Pharmaceutical Products</i>	<i>A and B</i>
<i>Schering-Plough Corporation</i>	<i>B</i>

<i>Searle</i>	<i>A and B</i>
<i>Siemens, USA</i>	<i>E</i>
<i>SmithKline Beecham Pharmaceuticals</i>	<i>B and D</i>
<i>TPLC Pacemakers</i>	<i>A and C</i>
<i>Wyeth-Ayerst Laboratories</i>	<i>B</i>

Several companies had two responses, either because one person offered two reasons or because two representatives were contacted, and offered different--even somewhat contradictory--reasons. For example, in the case of Ohmeda Pharmaceutical Products, Judy Klon in International Sales said she thought, "the U.S. embargo makes sales to Cuba illegal." Yet, in-house Counsel Donna Boehme was aware of the licensing options for sales to Cuba, but said she nevertheless had advised the company not to take any action with regard to Cuba which might "incur any risk of government action" (a statement which implies that the embargo discourages, but does not prevent, sales to Cuba). 14

In the case of Searle, Export Manager Diana Smith did not wish to be directly quoted, but her answers indicate that, while she was aware that licensing procedures were in place, it was her understanding that it is not possible to sell to Cuba at the present time-15

In Summary- All ten of the U.S. manufacturers whose organizational structure would normally permit them to export directly to Cuba cited the U.S. embargo as either preventing or discouraging such sales. (Siemens, USA and Bristol-Myers Squibb said their U.S.-based operations would not be the ones to export to Cuba, and hence, regulations pursuant to such direct exports do not affect them.)

Six of the ten companies citing the embargo mistakenly perceive that it prevents sales to Cuba, and there is obviously confusion among them about the regulations now in place. Nelson Baker, General Counsel for Johnson and Johnson, despite his considerable knowledge and experience in applying for licenses for subsidiary sales and donations to Cuba, stated that it was his understanding that the Cuban Democracy Act permitted donations but not direct sales to the island.16 However, in retrospect, this may not be surprising: Tracy O'Donald at the Cuba Exports Desk of the Department of Commerce first told us that only donations were permitted, and only later corrected this statement to include the possibility of sales.17

Other firms' representatives simply stated, as did Robert Lively, Director of Legislative Affairs for Schering-Plough, that the U.S. embargo has a "discouraging effect on any thought of seeking such business sales to Cuba."18

Two companies contacted cited political reasons for not selling to Cuba: Michele Lockwood in International Sales at Baxter Healthcare Corporation (major distributors of dialysis and blood supply equipment and accessories) told us the company "respects the boycott of Cuba for political reasons".19 And Bill Nealon, Counsel for TPLC Pacemakers, said he had advised against using the Teletronics pacemaker trademark, licensed by TPLC, for sales to Cuba to avoid legal liabilities. He said top corporate executives at the Hialeah, Florida, offices had followed his recommendation, in order to stay within the law, and with an eye to the sensibilities of the largely Cuban-American workforce at the Hialeah plant20.

Additional survey item included the following:

My company has made verbal inquiries to be U.S. government about applying for licenses to permit direct sales to Cuba..

<i>Baxter Healthcare Corporation</i>	<i>nla</i>
<i>Bristol-Myers Squibb</i>	<i>nla</i>

<i>Eli Lilly and Company</i>	<i>YES. UTo my recollection, we have never received order for Cuba where we have received a license fo sale."</i>
<i>Johnson and Johnson</i>	<i>NO</i>
<i>Merck and Company</i>	<i>YES; not a positive experience</i>
<i>Ohmeda Pharmaceutical Products</i>	<i>Did not want to say</i>
<i>S&ring-Plough Corporation</i>	<i>Did not want to say</i>
<i>Searle</i>	<i>YES, a long time ago; the govenament was helpful, is not possible to sell to Cuba</i>
<i>Siemens, USA</i>	<i>nla</i>
<i>SmithKline Beecham</i>	<i>NO</i>
<i>Pharmaceuticals</i>	
<i>TPLC Pacemakers</i>	<i>nla</i>
<i>Wyeth-Ayerst Laboratories</i>	<i>YES; told not possible to sell</i>

Jaime Esteves, Director of Distribution for Wyeth-Ayerst Laboratories, reports that he received a hand-delivered request from Cuban importers to purchase \$6 million in antibiotics, but that the company's legal department advised him, based on their experience, that it would be "futile" to pursue licensing for the sale. Esteves said he is well aware that Cuba is interested in many Wyeth-Ayerst products, including antibiotics and cardiology medications, which the country has difficulty obtaining elsewhere.²¹

Experience with Subsidiary trade

<i>Baxter Heal thcare Corpomtion</i>	<i>Has a policy that subsidiaries do not sell to Cuba.</i>
<i>Bristol-Myers Squibb</i>	<i>Not mentioned.</i>
<i>Eli Lilly and Company</i>	<i>States CDA prohibits subsidiary trade..</i>
<i>Johnson and Johnson</i>	<i>Received licenses, but refers to process as discouraging.</i>
<i>Merck and Company</i>	<i>Not mentioned</i>
<i>Ohmeda Pharmaceutical Products</i>	<i>Not mentioned</i>
<i>Schering-Plough Corporation</i>	<i>Not mentioned</i>
<i>Searle</i>	<i>Not mentioned.</i>
<i>Siemens, USA</i>	<i>(see quotes below)</i>
<i>SmithKline Beecham</i>	<i>Not mentioned</i>
<i>TPLC Pacemakers</i>	<i>Not mentioned</i>
<i>Wyeth-Ayerst Laboratories</i>	<i>Law discourages such a process</i>

Keven *Krambeer*, in charge of Eli Lilly's International Corporate Affairs for Latin America, states that his company, a major supplier of insulin, sold to Cuba through subsidiaries before 1992 (when the CDA went into effect). But, he says, "Now, the Office of Foreign Assets Control (OFAC) and further restrictions forbid this." ¶In actual fact, the CDA opens the door to subsidiary sales, based on prior approval of individual licenses for each sale.

Nelson Baker of Johnson and Johnson said the CDA has virtually cut off the flow of medicines from U.S. companies to Cuba. He calls the licensing requirements for their subsidiaries a "major deterrent" to companies wanting to sell to Cuba. "You make the calls to OFAC to inquire about a license, and when you finally get someone to talk with you about filing a new application for something, they strongly discourage you, emphasizing how difficult the on-site inspection requirement is to meet."

His words coincide with comments from Clara David, Licensing Officer for OFAC, who said that since passage of the CDA, only a handful of licenses have been approved for subsidiary sales, and

no denials have been issued. She stated that the reason for no denials is that many companies phone to inquire about the application procedures, and when they learn how difficult it is to meet the on-site inspection requirement, they don't apply, as "companies don't like to receive a negative determination from the federal government on anything."²³

Baker reports that Johnson and Johnson has applied for licenses for the anesthesia *thalamonal*, and does so mainly for humanitarian reasons, since the company does not make serious financial gains on the sales and the licensing procedures "are not worth all the trouble." He said he has made many inquiries to OFAC about possible license-applications for other products, but was told before applying that these would be denied.

Siemens, USA states that it has no manufacturing plants in the United States and sales to Cuba are made through their parent company in Germany, where the plants are located. However, R. John Larson of Siemens' Licensing Department notes that a U.S. (Commerce Department) license is required, when the equipment exported to Cuba from Germany contains a part shipped from the United States (that is, when the German warehouse is out of stock and must reclaim a part from warehouses in the USA). He notes that this has made a license necessary to re-export a filter for a Servo lung ventilator, even when that filter was originally manufactured in Germany and is to be shipped from Germany to Cuba. He says this process usually has a turnaround time of three to six months. He speculated that Siemens, USA would have great difficulty in obtaining licenses to sell directly to Cuba, should it attempt to do so.²⁴

Finally, Wyeth-Ayerst Laboratories (which also owns Lederle Laboratories) reports that they have made repeated inquiries to OFAC to attempt to obtain licenses to sell various pharmaceuticals to Cuba. Each time, they have been told "not to bother" making a formal application, since they could expect the licenses to be denied, according to Jaime Esteves, Director of Distribution. He said the company has been repeatedly discouraged (by OFAC) from pursuing subsidiary sales to Cuba.²⁵

Experience with donations

<i>Baxter Healthcare Corporation</i>	<i>Not mentioned</i>
<i>Bristol-Myers Squibb</i>	<i>Not mentioned</i>
<i>Eli Lilly and Company</i>	<i>Yes, understands companies can donate, and has done so.</i>
<i>Johnson and Johnson</i>	<i>Yes, understands companies can donate and has done so.</i>
<i>Merck and Company</i>	<i>Yes, but understands even donations to be impossible for Merck now.</i>
<i>Ohmeda Pharmaceutical Products</i>	<i>Not mentioned.</i>
<i>Schering-Plough Corporation</i>	<i>Not mentioned.</i>
<i>Searle</i>	<i>Not mentioned.</i>
<i>Siemens, USA</i>	<i>Not mentioned</i>
<i>SmithKline Beecham Pharmaceuticals</i>	<i>Not mentioned</i>
<i>TPLC Pacemakers</i>	<i>Not mentioned</i>
<i>Wyeth-Ayerst Laboratories</i>	<i>Not mentioned</i>

Susan Crowley, Director of International Relations for Merck, discussed the U.S. government fine levied on the pharmaceutical giant for violating the embargo. "We wanted an information exchange and to do donations, and even this is apparently not allowed," she told us. "Basically we have been fined for indicating an interest in building a health bridge to Cuba. And just exploring the possibilities and talking about doing something within the law is criticized.*"

Her comments leave no doubt that hefty fines (Merck was charged \$127,500) are another deterrent to companies already hesitant to make their way through the legal labyrinth of licensing

procedures. Merck was fined in October 1995, accused of hiring a Cuban laboratory for testing services, sending company officials to the island, and bringing Cuban products into the United States. The company said at the time that the embargo violation arose out of a trip to Cuba by Merck scientists at the request of the Pan American Health Organization in 1993.²⁷ A Treasury Department statement said the fine was not higher because of the "high level of cooperation" provided by Merck. Merck believed that the scientists' activities were permitted by a general license under the U.S. Cuban Assets Control Regulations," noted a release from Merck itself. It said the violations were "inadvertent and technical" and "resulted in no payment of any kind to Cuba".²⁸

Merck and Eli Lilly were later also threatened with Congressional investigations, apparently as a result of publicity surrounding major donations they made to Cuban nongovernmental organizations. There is no doubt that ~~the~~ subject has become highly charged in political terms for some sectors in the United States, beyond the legal questions involved. Companies like Merck perceive this as an additional obstacle to both donations and sales.

Cuban Importers and The U.S. Embargo

Cuban importers in the medical field also report that the embargo has discouraged them from exploring purchases from U.S. firms, even during the years of liberalized legislation. MEDICUBA's Orlando Romero cited the absolute prohibition on medical sales for over a decade (including from U.S. subsidiaries abroad), the ban on sales by U.S.-based firms for 28 years, subsequent ups and downs in U.S. policy, and other embargo regulations that "tend to hinder transactions." These, he said, are the reasons why "we have spent over 30 years looking for products to substitute those from the United States, manufacturers to substitute U.S. producers".²⁹

Yet, even when inquiries have been made by MEDICUBA to U.S. firms (not an easy initiative in itself, given the communications difficulties between the two countries for nearly three decades), they have been largely "unwelcome," according to Nancy Blanco, Deputy Manager for Pharmaceuticals at MEDICUBA. She contends that requests for catalogs, price quotations and other basic information "are met with no reply at all, or with a negative response." She says she does not remember a single case where a U.S. firm was contacted and decided to pursue a license application to the U.S. government.⁹⁰ Rolando Díaz, Deputy Manager for Medical Equipment, concurs.³¹ They cite several of the most recent examples in which companies have denied information or sale on the basis of the notion that the embargo prohibits transactions with Cuba. Among these:

Thomas Compressors and Vacuum Pumps (Sheboygan, WI): A July 20, 1995, letter from MEDICUBA requesting catalogs, brochures and price lists was answered by Diana Popp, Latin American Marketing Specialist for Thomas, on July 28, 1995. "Due to the embargo between the United States and Cuba, we are unable to conduct any commercial transactions with your company."

Vitalmex Interamericana, S.A. de C.V., Latin American distributors for the U.S.-manufactured Cobe dialysis equipment, (Mexico, D.F.): A June 21 fax from MEDICUBA requested prices for purchase of 20 Cobe dialysis machines. This communication was answered by Jaime A. Cervantes of Vitalmex on July 11, 1995, asserting that since Vitalmex is "associated with" a U.S. company, "we cannot supply the Cobe equipment . . . since I am not authorized lby Cobe in the USA1 to sell equipment or supplies to your country."

DuPont Merck, Manufacturing Division (Wilmington, DE): A fax from Gemex GmbH of Frankfurt, Germany (which represents MEDICUBA) dated 29 March, 1995, requested purchase of warfarin sodium, a pharmaceutical component for an anti-coagulant medication, that had

formerly been supplied to Cuba by the Swedish firm Chemoswed. Dr. John C. Budxinski, Warfarin Sodium Business Manager for DuPont-Merck replied on April 24, 1995, that DuPont-Merck "has acquired the rights to the warfarin sodium technology from Chemoswed . . . I regret to inform you that we will not be able to provide warfarin sodium."

Telectronics (Denver, CO and Hialeah, FL) and St. Jude Medical (St. Paul, MN): Both of these enterprises are manufacturers of pacemakers. In 1993, Telectronics of Australia, a major supplier of pacemakers to Cuba, shut down its pacemaker manufacturing, and transferred both sales and production to the United States. As we noted earlier, legal counsel advised TPLC of Florida (which produces Telectronics pacemakers under patent license) not to pursue sales to Cuba, in order to "stay within the law" and 'with an eye to the sensibilities of the largely Cuban-American workforce" at the Hialeah plant, where executives agreed with his recommendation. It should be noted that in May, 1993, the Florida state legislature passed a law sanctioning companies in the state that maintain economic or trade ties to Cuba.³²

On June 27, 1994, Siemens-Elema of Sweden, another major supplier of pacemakers to Cuba, sold its pacemaker division to St. Jude Medical, and informed MEDICUBA of the sale.³³ According to a telephone interview by Dr. Anthony Kirkpatrick, St. Jude's legal director Kevin O'Malley, told him that he twice attempted to convince the U.S. government to allow export to Cuba of the pacemakers for humanitarian reasons, but was "decidedly rejected." (Refer to the section on Cardiology in 'Selected Aspects of Health & Welfare.')

According to Rolando Díaz, Drake-Whillock, manufacturer of dialysis equipment, has told MEDICUBA that U.S. embargo laws have made it unable to send equipment to Cuba for trials, to allow company technicians to travel to Cuba, or to sell to the island."

Blanco reports what she terms a new phenomenon: approaches and visits to MEDICUBA by numerous persons representing themselves as sales agents for U.S. firms. But, she says she seriously questions their credibility because, among other reasons, "the prices they quote are off the charts, often 200% or more than current market prices."³⁶

Firms Abroad Reluctant to do Business with Cuba

Our research shows that the U.S. embargo also discourages companies in third countries from attempting to sell medical supplies to Cuba. Such companies share many of the misconceptions voiced by U.S.-headquartered firms. Among the problems:

A number of foreign medical firms have apparently assumed that U.S.-origin components or technology makes their equipment automatically out-of-bounds for sale to Cuba, when, in fact, a license could be sought from the U.S. Commerce Department.

Some U.S. subsidiaries abroad have received word from their U.S. headquarters that sales to Cuba are not permitted, when, in fact, licenses could be requested from the U.S. Treasury Department.

And finally, foreign firms that have merged or been purchased by U.S. companies have interrupted sales to Cuba, because they also mistakenly understand that they are no longer permitted under any circumstances.

Examples of these three cases include:

Jena (Germany): A May 1995 inquiry from MEDICUBA for the purchase of an autorefractometer was answered by a June 6, 1995 fax from VL Munkelt advising that "according to embargo (law) an autorefractometer cannot be ordered for MEDICUBA"

Gummi: This company informed Gemex (MEDICUBA's representative in Germany) that it cannot sell aluminum seals to Cuba for domestically-produced medications, since it has been purchased by a United States firm.³⁷

Jbhnsn & Johnson Iudustria e Comercio Ltda. (Brazil), a subsidiary of Johnson & Johnson, USA: Cuban importers Consumimport attempted to purchase toothbrushes, on the basis of price offers from the Brazilian company in June, 1993, but was informed that the company's headquarters had advised against the sale.⁹⁸

Latin American subsidiaries of Barter Healthcare Corporation USA: This company is a leader in the Latin American market in dialysis accessories, blood collection bags, and related equipment and supplies. Rolando Díaz of MEDICUBA reports that a number of Baxter's regional subsidiaries have been contacted, and the reply in each case is that they are "not permitted to sell to Cuba." According to Díaz, MEDICUBA has also been rebuffed by wholesalers carrying Baxter products.³⁹ This coincides with the information provided to us by the parent company in the United States.

Eli Lilly (Canada): In 1993, executives of the company informed Cuba that as a result of the prohibition on subsidiary trade with Cuba (the CDA), they would not be able to export medicines to the island. Lilly is the world's number one producer of insulin, among other products." Again, this coincides with the parent company's understanding of U.S. law, as noted in our survey.

Pharmacia (Sweden): Beginning in 1970, this company sold Cuba sophisticated protein purifying and other equipment and reagents for clinical laboratories and production plants, as well as chemotherapy drugs, growth hormone and other medicines. It is the number one supplier of reagents for vaccines and certain blood tests. In 1989, Pharmacia opened an office in Cuba and in 1991-92 sold over \$3 million to the island. In August, 1995, the Havana offices informed MEDICUBA that Pharmacia had merged with the U.S. giant Upjohn, and that this "might lead to a suspension of sales to Cuba.*' The new company, Pharmacia. and Upjohn, Inc., ranks ninth in world drug sales. Because of the U.S. embargo, it pulled up stakes in Cuba on November 2, 1995, leaving some merchandise undelivered and contracts canceled. In the case of equipment and reagents, this has caused major delays in research, production and laboratory analyses, as it takes four to six months to put a new line of reagents through quality control performance tests, assuming it can be identified as suitable for the existing Pharmacia equipment.⁴² (See sections on Vaccines and Biotechnology Research, Development and Production; Diagnostic Testing and Protection of the Blood Supply; the Pharmaceutical Industry; and Hospital Care for impact on the health system and patient care.)

Nunc (Denmark): Supplied plates for HIV-tests and diagnostic kits to screen for hepatitis B and C and congenital malformations, as well as to certify the purity of blood donations. The company was also in the blueprint stage for production of a Cuban-designed plate. However, on August 9, 1995, Nunc notified Cuba by fax: Much to our regret we have to inform you that unfortunately our cooperation of many years has to be terminated. The reason is that as of 1 August, 1995, BTR has sold Nunc A/5, Nunc GmbH and Nunc Inc. to Sybron International Corporation, USA In future, we therefore have to follow the directions laid down by the US Government in relation to Cuba. . . .We hope that the political situation will be normalized so that again we will be able to supply our loyal customers in Cuba with our products." (See chapters on AIDS, Women's Health, Children's Health, and Diagnostic Testing and the Blood Supply for implications of this cutoff.>

Wellcome Diagnostic Division (**formerly** of the UK): This division was taken over by Wellcome's U.S. branch, and Cuba was no longer offered Wellcome's products."

Editorial Interamericana, S. A (Spain): This is one of many cases in which products may not fall under the strict category of medical exports, but where refusal to sell to Cuba nevertheless directly impacts the health system. This firm supplied medical textbooks to Cuba until 1990, when it was purchased by McGraw-Hill of the USA "McGraw-Hill advised the Spanish company that since it now was the subsidiary of a United States corporation, its -personnel could not attend the Cuban book fair in Havana and the subsidiary could not make any future sales to Cuba. These instructions were not required by United States law: employees of third-country subsidiaries are permitted to travel to Cuba under Treasury Department regulations, . . . and Congress exempted the sale of books from the United States prohibitions against trade with Cuba (in 1988)."⁴⁴

Analysts advise that the rate of mergers and takeovers involving U.S. companies and manufacturers abroad is accelerating, especially in the pharmaceutical and medical equipment industries. "Mergers have reshaped the industry, and more may be on the way," comments Joseph Weber in a *Business Week* Industry Outlook early in 1996. He calculates that by mid-December 1995, the industry had chalked up \$41.2 billion in deals, up from the 1994 record of \$36.1 billion.⁴⁵ As it stands, this can only have a negative impact on Cuba's access to medical products.

The Recent Licensing Record

While there is ample evidence of reluctance to apply for authorization to export to Cuba, a number of firms-both U.S. subsidiaries and foreign companies manufacturing with U.S. components-have opted to request licenses under the conditions of the CDA of 1992, which provided for case-by-case decisions on medical sales.

However, the number of licenses approved for such transactions since enactment of the CDA has been impossible to ascertain from the U.S. Treasury and Commerce Departments. In summary information provided on June 14, 1995 to Rep. Charles Rangel by R Richard Newcomb, Director of the Office of Foreign Assets Control (OFAC), it is stated that 82 licenses have been issued (total value \$62,888,513) by the U.S. Commerce Department, and two denied (total value: \$23,031,580), between October 23, 1992 (when the CDA became effective) to May 3, 1995. However, Newcomb notes that the licenses do not distinguish between food, agricultural supplies, medicines and medical equipment, nor between purchases and donations. The dollar value of the licenses represents only the permission granted, and not the actual value of the shipments, which he notes was not readily available from the Commerce Department.

It should be clarified here that the Commerce Department is charged with licensing shipment of goods of U.S. origin or a percentage of U.S. composition, or those being re-exported from the United States to Cuba. The Treasury Department's OFAC is charged with licensing exports when they are made from U.S. foreign subsidiaries to Cuba.

Newcomb's letter reports that the OFAC itself has issued eight licenses authorizing the export of medicines and medical supplies from third countries by U.S. subsidiaries since the CDA became effective, the total value of which is US\$336,934. His information does not indicate the number of licenses denied. Licensing Officer Clara David reported to us that no licenses were denied in the same period.⁴⁶

The OFAC licenses issued are as follows, according to encloures provided by Newcomb:

The Johnson & Johnson subsidiary Janssen Pharmaceuticals of Belgium: For sale of 200 packs of the anesthesia thalamonal to MEDICUBA License C-15153, dated April 15, 1994, expired April 15, 1995. Subject to certification by the Belgian Embassy in Havana, "confirming that the exported item will be used for the purposes for which it was intended and only for the use and benefit of the Cuban people."

The Upjohn Company subsidiary N.V. Upjohn of Belgium: For sale of 2,000 vials of depo-provera to the United Nations Population Fund Office in Havana. License C-15071 dated February 7, 1994, expired July 31, 1994.

The Johnson & Johnson subsidiary Janssen Pharmaceuticals of Belgium: For sale of 200 packs of the anesthesia thalamonal to MEDICUBA License G14941, dated May 15, 1993, expired January 31, 1994. Subject to certification by the Belgian Embassy in Havana (see above).

The Upjohn Company subsidiary N.V. Upjohn of Belgium: For sale of 57,000 vials of depo-provera to the United Nations Population Fund in Havana. License C-16123, dated October 31, 1994, date of expiration missing on license.

The Becton Dickinson International, N.V., subsidiary of the same name in Belgium: For sale of 175 boxes of syringes to the United Nations Population Fund in Havana. License C-15153, dated April 15, 1994, expired April 15, 1995.

The Johnson & Johnson subsidiary Janssen Pharmaceuticals of Belgium: For sale of 438 packs of the anesthesia thalamonal, 2 ml., and 292 packs of thalamonal, 10 ml. to MEDICUBA. License C-15602, dated October 13, 1994, expired March 31, 1995. Subject to certification by the Belgian Embassy in Havana (see above).

The Johnson & Johnson subsidiary Janssen Pharmaceuticals of Belgium: For sale of 22,000 packs of Imap to MEDICUBA. License C-15154, dated January 31 1995, expired July 31, 1995. Subject to certification by the Belgian Embassy in Havana (see above).

The Johnson & Johnson subsidiary Ortho Diagnostics Systems Ltd. of England: For sale of an ortho cytron absolute flow cytometer system (including computer) to SERVICEX (a state-owned company in Cuba). License C-14942-a dated February 25, 1994, expired September 30, 1994. Notes that a separate license is required from the U.S. Commerce Department for re-export of the 15.9% U.S.-origin parts in the system. Subject to certification from the Pan American Health Organization, the Red Cross or "other appropriate internationally recognized multilateral relief or non-profit organization," that "The exported item is for the purposes for which it was intended and only for the use and benefit of the Cuban people."

U.S. Licenses Denied for Medical Export to Cuba

The following information was gleaned from documents issued by the companies involved, and from interviews with MEDICUBA importers. These are essentially licenses refused by the U.S. Commerce Department, denying authorization to export to Cuba items of U.S. composition or origin. However, in the Fluka, Schubert Seals and Heinrich Mach Nachf. cases, it seems that the U.S. Treasury Department was involved at some level.

Fluka Chemical Co., Ltd. (Switzerland) supplied Cuba with US\$300,000 annually in chemical reagents for laboratory testing. Fluka belongs to the U.S. group Sigma-Aldrich, based in St. Louis, MO. A fax from Fluka's Elisabeth Berger, dated Oct. 16, 1992, notes that the firm has been able to obtain U.S. Treasury licenses for sales to Cuba within 2-3 weeks when there are no U.S. components involved, but that "the big problem, nevertheless, are the products with U.S.-origin

(components).” She asks that MEDICUBA revise its list of purchases accordingly, apologizing for “this difficult situation, which makes life difficult for both of us.” On November 5, 1992, she informs MEDICUBA that five contracts have had to be canceled since Fluka did not receive the necessary U.S. licenses. On January 23, 1993, Berger telexes MEDICUBA that she has been informed that contracts signed before the CDA went into effect on October 23, 1992 are to be exempted from the CDA stipulation on ending U.S.-subsidiary trade with Cuba. She notes, however, “that in practice this is not the case. The U.S. Treasury Dept. does not answer our reclamations.” These contracts remained canceled, despite the fact that subsequent regulations issued under the CDA clarified that sales of medicines and medical supplies were exempted from the prohibition on subsidiary trade.

Schubert Seals (Denmark) sells rubber seals for domestically produced albumin. Schubert, a U.S. subsidiary, has informed MEDICUBA that it is having difficulties with U.S. licensing for a contract signed in 1994. Among other things, according to MEDICUBA’s Rosa Fuentes, this means that the funds transferred for this purchase will have to be recovered, involving a lengthy international process.” This refusal conforms with U.S. government practice not to authorize exports for Cuba’s domestic pharmaceutical industry (see also Heinrich Mack Nachf. case below.)

Siemens (Germany) applied for at least two licenses that were denied: for the sale of a U.S.-manufactured gamma camera (for diagnostic imaging in cancer patients and others) and computers of U.S. origin, for computer assisted tomography (CAT) scans sold by this company to MEDICUBA.⁴⁸

Heinrich Mack Nachf. (a Pfizer subsidiary in Germany) applied for a license to sell MEDICUBA 500 g. (about one pound) of methotrexate, the active ingredient needed to run trials for domestic production of a chemotherapy medication of the same name, as part of Cuba’s efforts at cost-effective import substitution. This drug is used, among other things, to treat childhood leukemia (MEDICUBA contract 30855 of 1993). A July 16, 1993 fax from Monika Biener of the Chemical Sales Division of Heinrich, indicated: “As informed before, we need prior to shipment an approval from American Authorities. Unfortunately, and unexpectedly, this authorisation has not been received from American Foreign Ministry. Therefore, we regret having to inform you that we cannot comply with your wishes to ship material.” (It is not clear whether the methotrexate was of U.S. origin.) > A September 5, 1995, telex from MEDICUBA’s German representative indicates that HMN no longer offers products to Cuba.

Enraf Nonios, Delft Instruments Physical Medicine (Netherlands) supplied Cuba for a decade with physical therapy equipment and parts, accounting for 80% of such equipment in the country. On July 16, 1991, a letter from the firm’s G. v.d. Schouw, Director of Physical Medicine, indicated that they were “restricted in supplying our products to Cuba” due to a “temporary changed policy from the United States government regarding reexportation of original or licensed (U.S.) components.” The company indicated it would proceed with “time-consuming” procedures in an attempt to procure the necessary licenses, but these were apparently never received. The same letter indicated that the firm would be able to supply sports trauma equipment for the July 1991 Pan American Games in Cuba, but only on consignment to an international organization, for their return upon conclusion of the games.

We have found that when a firm is denied a U.S. license to export to Cuba, the decision sometimes appears arbitrary, especially when the products for which licenses are denied are compared to those for which licenses have been granted. This is the situation with a license request pursued by Picker International, Inc. of Canada, a subsidiary of the Cleveland, Ohio company of the same name, manufacturer of x-ray equipment sold to Cuba, primarily between 1975 and 1978.” During that period, according to Cuba’s Medical Supply Company (EMSUME), 101 Picker x-ray machines were purchased, fundamentally model GX-300.⁵⁰

Alfredo Rivero of EMSUME notes that less than one quarter of the original machines are currently functioning, all of these primarily with parts from other companies, except for those for which there are no adequate substitutes-such as parts for the timing device and other accessories unique to the Picker model. When these break, the machines must be placed out of commission.

In April of 1994, MEDICUBA requested a series of spare parts for this x-ray equipment. The total contract amounted to 110 parts, valued at CAN\$705.30. The U.S. content of the parts was CAN\$193.10 (or 27%), and therefore subject to license by the U.S. Commerce Department.

The following chronology describes the licensing process, as pursued by both Picker of Canada and Picker, USA, from April 29, 1994, when the application was first submitted, through December 23, 1994, when MEDICUBA received final notice from Picker, Canada, that all license applications and appeals had been denied.⁵¹

- April 29, 1994 Paula Iseman of Picker International, Inc., Cleveland, Ohio, submits original license application with supporting documentation.
- May 10, 1994 U.S. Dept. of Commerce notifies Iseman that the case must be resubmitted on another form, as it involves reexport from Canada
- The application is resubmitted, with a copy of a previous license granted to Picker for replacement parts for the same equipment (Export License Number D179606, validated August 14, 1992 and expiring August 31, 1994) The new request is given the Department's Application Control Number H015462.
- July 26, 1994 Dr. Eugene W. Lewis, Chief of Capital Goods and Production Materials Branch of the Dept. of Commerce's Office of Export Licensing, informs Iseman of "the intent to deny the referenced application" since such an export would be "detrimental to United States foreign policy." He notes 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.*" (Italics added.) Lewis informs Iseman that Picker has 45 days to submit rebuttals or comments
- October 26, 1994 Eileen Albanese, Chief of Processing Branch of the Dept. of Commerce Office of Export Licensing, informs Iseman that the license has been denied, noting that "we have reviewed your letter objecting to the rejection of this application, however, we maintain our denial recommendation" on the grounds that "this export would be detrimental to U.S. foreign policy interests."
- December 23, 1994 Bill Dix of Picker International Canada, Inc., relays fax to MEDICUBA, explaining that "we regret to inform that this order has been canceled due to the denial of export license by U.S. Government Agencies. Happy Holidays."

A footnote to this chronology: On August 12, 1994, Bill Dix quoted a series of prices for a new request for purchase received from MEDICUBA of spare parts for x-ray equipment, "subject to availability and receipt of (U.S.) Government Permits". Such licenses had not been received as of January, 1996.⁵²

Our research in Cuba indicates that the parts requested in this application were destined for 20-year-old x-ray equipment in maternity hospitals, pediatric hospitals, rural hospitals, community health clinics, and one general hospital.⁵³ (See section on Hospital Care for the implications for patients of this license denial.)

The U.S. government interpretation of the licensing regulation on the proportion of U.S. composition of goods offered to Cuba by third-country firms has been particularly problematic, and is an example of the extra-territorial nature of the U.S. regulations limiting sales by these firms to Cuba, and reducing the range of suppliers available to Cuban importers. Even though the original piece of equipment may have contained less than 10% U.S. components, any replacement parts which themselves contain more than 10% U.S.-origin components require licenses, since they are considered as separate from the original purchase. In other words, while licensing may not have been necessary for Cuba to import the original piece of equipment, it may still be necessary to obtain a license for replacement parts needed to keep the equipment running. As in the Picker case, this interpretation can have particularly negative effects when applied to parts for third-country equipment in which Cuba has already made a substantial investment.

In addition to the Picker x-ray parts, earlier cases indicate that such an interpretation has been used to deny replacement parts for equipment purchased from third-country firms. One such instance involves the Swedish firm Alfa-Laval, which was unable to obtain permission to export 100% U.S.-origin cartridges for a filtration system manufactured by Alfa-Laval, and used in Cuba's domestic production of medicines. This resulted in the May 1991 cancellation by Alfa-Laval of its 1990 contract 06'772 with MEDICUBA. "We did what we could, but there seems to be nothing we can do in order to obtain the license," noted the May 28 letter from Tina V. Kristensen.⁵⁴

Such was also the fate of a request from MEDICUBA to purchase replacement parts for operating tables originally bought from Amsco of Canada. According to a note dated April 13, 1992, Amsco's Paul Montador declared: "Please he advised that the product in question is of U.S. origin and therefore not acceptable to you.*"

Licenses Approved: Delays in the Process

Even when licenses are granted, we find that the process of application and approval can substantially delay delivery to health institutions and patients. These delays vary considerably—from several weeks, to months, to years. Cases in point are replacement parts for Siemens respirators, used extensively in surgery and intensive care units, and the anesthesia thalamonal, produced by Janssen of Belgium, the Johnson & Johnson subsidiary referred to earlier.

The Life Support Systems Division of Siemens-Elema (Sweden) has sold several models of respirators to Cuba over the years. There are currently 300-350 Servo 900-C units (for long-term ventilation of intensive care patients) and Servo 900-D (used in surgery to administer anesthesia). Licenses were not necessary for original purchases, since the U.S.-origin components constituted less than 10 percent of the respirator's value. Each Servo cost at least US\$15,000 at the time of purchase.⁵⁶ However, as previously noted, the process of purchasing spare parts for this equipment is handled differently.

In the case of Siemens respirator parts, the purchasing process for two contracts involving U.S.-origin components, complicated by the intricacies of licensing, took over two years.

In July, 1995, MEDICUBA received shipment of 49 parts for the Servo respirators (both models), which were on order by virtue of contracts initiated in 1992 and signed in 1993. Nineteen of these parts are crucial to operating the equipment, and without them, the respirators do not function. Most

of this shipment was destined for hospitals in outlying provinces. (Refer to section on Hospital Care for the implications of such a delivery delay.)

Tracing the inquiry, purchase, documentation, licensing and delivery process, we find that a total of seven agencies in four countries were involved: two agencies in Havana (MEDICUBA and EMSUME), one in Germany (Gemex, the MEDICUBA representative), one in Sweden (Siemens-Elema), and three in the United States (Siemens, the U.S. Commerce Department and the U.S. State Department): We had access to full documentation of the following "paper trail":

- June 1992 Siemens-Elema informs Medicuba (directly and via Gemex) that its order for oxygen sensor cells requires export authorization from the United States before it can be sold to Cuba.
- July 1992 Siemens faxes Gemex with request that MEDICUBA fill out attached "Statement of Ultimate Consignee and Purchaser" from U.S. Commerce Department for the oxygen fuel cell, which it notes is manufactured in the United States by Catalyst Research, Owings Mills, MD. Gemex signs contract 26626 on behalf of MEDICUBA, for purchase of 24 test lungs, 2 step motors, 24 oxygen cells, and 6 magnet valves. Siemens-Elema notes transshipments will be made to Cuba via Brussels, Madrid or Paris, and final carrier will be Cubana Airlines, to be delivered collect to Havana. Total value of contract: 63,550.08 Swedish kronas (SEK).
- August 1992 MEDICUBA cancels oxygen cells (after finding another supplier). Contract now stands at 33,179.52 SEK
- March 1993 MEDICUBA transfers full amount for contract 26626 to Gemex for purchase.
- June 1993 Gemex signs contract 36552 on behalf of MEDICUBA, for purchase of 6 screens, 20 bacteria filters, and one airway pressure meter. Total value of contract: SEK 32,556. Notes transshipment points to be Berlin, Madrid or Paris.
- February 1994 Siemens-Elema asks MEDICUBA for "Statement of Ultimate Consignee and Purchaser" for bacteria filters (30% of part is of U.S.-origin); and for magnet valves (part is 100% U.S.-origin), since these require U.S. export authorization.
- March 1994 Gemex telex to MEDICUBA refers to contracts 26626 and 36552, noting that Siemens has sent "statement" forms to MEDICUBA which should be filled out as soon as possible, since Siemens must then send them on to the U.S. government, which decides whether or not to authorize sale to Cuba. "[Siemens-Elema] tells us that there are cases where [this decision] has taken six months." Proposes that bank transfer for contract 36552 be issued after Siemens-Elema informs Gemex that export has been authorized by the United States. Telex same day from Gemex to MEDICUBA confirms that contract 36552 has been reduced to SEK 18,716 (10 bacteria filters were canceled).
- MEDICUBA and EMSUME return "Statement"; form notes that Sylvia Biglin, Siemens Medical Systems, Inc., USA, assisted in preparing statement, on behalf of Siemens-Elema, Sweden. (Note: this statement covers parts ordered in both contracts signed.)

July 1994	Siemens applied for license to U.S. Commerce Dept.
September 1994	<p>Siemens-Elema informs Gemex that the U.S. government has required further information on the parts before a decision can be made. Encloses fax from Siemens USA to Siemens-Elema referring to conversation with State Department, in which the officer requested the names and addresses of hospitals in Cuba where the items will be shipped; asked if any of the hospitals listed are military hospitals, and asked if any-of the hospitals listed are primarily set up for foreigners, where the majority of patients are foreigners and not Cuban citizens.</p> <p>MEDICUBA informs Siemens-Elema via Gemex of specific hospitals where the parts are destined, noting that they also may be sent to "others that eventually need some spare parts like this one." States that these are not military hospitals, and are for the use of Cuban citizens.</p> <p>Siemens-Elema forwards to Gemex fax from Siemens USA, (dated September 14) with additional information requested by the U.S. Commerce Department. This fax notes that the licensing officer stated that the license would not be approved unless all end-users were known beforehand.</p> <p>U.S. Commerce Department faxes Siemens-USA to advise acceptance of the following conditions is necessary for license approval: the medicines and medical supplies will not be used for purposes of torture or other human rights abuses; will not be re-exported; and will not be used in the production of any biotechnological product.</p>
October 1994	Gemex telexes MEDICUBA with faxed request from U.S. Commerce Department.
November 1994	License approved by U.S. Commerce Dept. for both contracts.
July 1995	Parts for contract 26626 and 36552 are received in EMSUME warehouse, for distribution to hospitals.

The Case of Anesthesia Thalamonal

Thalamonal, an anesthesia manufactured by Janssen of Belgium (a subsidiary of Johnson & Johnson in the USA), is widely used in Cuban hospitals, especially for longer operations. Since 1992, MEDICUBA has signed five contracts for thalamonal with Janssen. U.S. government export authorization requires a separate license for each of these orders (even though the product is the same) and each license is valid for only one shipment."

December 17,1992	Contract 21554 signed with Janssen by MEDICUBA for 10,000 10ml vials of thalamonal. Value: \$30,950.
September 19,1993	Shipment of thalamonal received as per contract 21554.
December 7,1993	Contract 31621 signed with Janssen by MEDICUBA for 4,000 10ml. vials and 16,000 2ml. vials of thalamonal. Value: \$21,900.
May 16,1994	Shipment of thalamonal received as per contract 31621.

May 4, 1994	Contract 40725 signed with Janssen by MEDICUBA for 6,000 10ml. vials and 9,000 2ml. vials of thalamonal. Value: \$23,220.
December 25, 1994	Shipment of thalamonal received as per contract 40725.
May 18, 1994	Contract 41421 signed with Janssen by MEDICUBA for 8,600 10ml. vials and 12,900 2ml. vials of thalamonal. Value: \$33,282.
June 15, 1994	MEDICUBA receives request for information from the Belgian Embassy in Cuba on final destination of thalamonal in contract 41421.
June 21, 1994	MEDICUBA supplies information to Belgian Embassy in Cuba on hospitals destined to receive thalamonal as per contract 41421.
December 25, 1994	Shipment of thalamonal received as per contract 41421.
February 25, 1995	Contract 50558 signed with Janssen by MEDICUBA for 2,600 10ml. Vials and 10,900 2ml. vials of thalamonal. Value: \$15,282.
June, 1995	MEDICUBA receives request for information from the Belgian Embassy in Cuba on final destination of thalamonal in contract 50558.
June 19, 1995	MEDICUBA supplies information to Belgian Embassy in Cuba on hospital destined to receive thalamonal as per contract 50558.
December 22, 1995	Janssen informs MEDICUBA that it still has no response from U.S. Treasury Dept. on license request for contract 56558. Meanwhile, Janssen notes, it is returning to MEDICUBA the international narcotics licenses for export of this drug, which have by now expired- because of delays, Cuban importers will have to begin that process again.

According to this data,⁵⁸ an average of over seven months elapses between contract signing and delivery. Nelson Baker, General Counsel for Johnson and Johnson, reports that three to six months of this period is spent waiting for licenses to be approved.⁵⁹

The On-Site Inspection Requirement

Under the CDA, the Government of the United States must be able to verify-by on-site inspection-the end-use of any medication or medical equipment exported to Cuba under U.S. license. This is perhaps the most broadly interpreted stipulation in the CDA regulations. Whatever may have been the original intent of Congress, our research indicates that the provision constitutes a deterrent to medical exports to Cuba for several reasons:

1. Reviewing the CDA, the Congressional Research Service concludes that the on-site inspection requirements "are unlikely to be accepted by Cuba".⁶⁰ Indeed, various representatives of the Cuban Public Health Ministry confirmed that the Cuban Government would not allow U.S. Government inspection of its health facilities, for the purpose of determining end-use of imported medications or equipment.⁶¹
2. However, in the limited experience available for review, Treasury and Commerce Departments' interpretation of on-site inspection has not included inspection by the U.S. Government. It has translated into a requirement that Cuban health authorities provide lists of patient care facilities where medications or equipment are to be used; and that a foreign embassy, international agency or other "suitable" entity certify end-use of the products in

question. (See the case of thalamonal, for example, where the Belgian Embassy provided the requisite certificate for each license granted.) Thus, designation of an appropriate inspector becomes a secondary issue, constituting a further obstacle when one is not available.

3. The requirement has also been used to deter pharmaceutical and medical supply companies in the United States from applying for export licenses, either for their own direct sales to Cuba or on behalf of their subsidiaries abroad pursuing such sales. This practice is amply reflected in comments from company representatives, and from the Treasury Department itself.
- 4 Changes have been made in Government's own interpretation of on-site inspection: the original wording in the CDA states that "the United States Government is able to verify, by on-site inspections and other means, that the exported item is to be used for the purposes for which it was intended and only for the use and benefit of the Cuban people." However, the regulation governing foreign subsidiaries of U.S. corporations is reformulated to state that they can obtain licenses to sell to Cuba "except where it is determined that the United States Government is **unable** to verify, by on-site inspection or other means..." (emphasis added). This same reformulation was applied to direct medical exports to Cuba from the United States, by virtue of new Commerce Department regulations, issued in March, 1996.

In our view, such diverse interpretations and subtle changes only add to the confusion already created around licensing procedures, erecting more obstacles along the export route. In addition, the vague nature of this restriction opens the door to arbitrary decisions.

Conclusions on Licensing

Our investigation leads us to conclude that the U.S. government's complex licensing restrictions and procedures present a serious obstacle to the willingness of U.S. medical firms, their subsidiaries abroad, and even foreign medical companies to attempt exports to Cuba.

Aside from mistaken perceptions that it is simply illegal to trade with Cuba, the process of license application itself confronts sales departments with significant additional red tape, requiring communications among several offices and other agencies in as many as four countries. Not only is this a time-consuming effort, but for a cost-conscious corporation, the volume of trade involved may not be worth the bureaucratic bother-especially when there is no guarantee when or if the licenses will receive final approval from Washington. Indeed, when the U.S. origin of spare parts is over 20% U.S. government practice has been to deny licenses in several instances, even after enactment of the CDA in 1992, which seemed to open the door to more positive consideration of such cases.

For MEDICUBA, the licensing requirements, procedure, and uncertain approval present a special dilemma, according to General Manager Orlando Romero. In addition to the reluctance of U.S. firms to deal with Cuba, he says that the embargo regulations keep the Cuban import firm from seriously exploring long-term purchases in the U.S. market, for fear that critical pharmaceuticals and equipment would be held hostage to the decisions of the U.S. Treasury and Commerce Departments, or to the inclinations of a given U.S. administration or Congress. On many occasions, and despite higher prices, he says they have purchased U.S.-manufactured products through intermediaries or comparable items from non-U.S. producers, simply to guarantee stable deliveries for patient use.⁶²

Embargo Restrictions: Financial Impact on Cuban Medical Importers

We have found that the U.S. embargo reduces the hard currency funds available for medical imports-both by aggravating the general contraction of the Cuban economy and its access to hard currency, and by measures which specifically reduce the medical import budget. Among the latter:

Shipping Costs: During the last three years alone, MEDICUBA calculates that the company has spent an additional \$8.7 million on shipping, due to the necessity of importing from Asian, European and other American markets (as opposed to directly from the USA). Delays in maritime shipping have forced them to use the more expensive air routes, when time is of the essence.

COMPARATIVE COSTS OF MEDICAL SHIPMENTS BY AIR									
	1993			1994			1995		
	Europe	Asia	The Americas	Europe	Asia	The Americas	Europe	Asia	The Americas
Weight (Kg)	868,215	106,677	276,108	658,527	114,578	193,955	374,726	38,029	110,245
Freight Paid (USD)	\$2,691,466	\$746,739	\$383,790	\$1,975,581	\$801,626	\$269,597	\$1,161,650	\$266,203	\$153,240
If Imported from USA (1995 rates)	\$1,007,129	\$123,745	\$320,285	\$763,891	\$132,910	\$224,988	\$434,682	\$44,114	\$127,884
Difference	\$1,684,337	\$622,994	\$63,505	\$1,211,690	\$668,716	\$44,609	\$726,968	\$222,089	\$25,356
Total Extra Paid for Year	\$2,370,836			\$1,925,015			\$974,356		
Extra Paid for three years	\$5,270,264								

COMPARATIVE COSTS OF MEDICAL SHIPMENTS BY SEA									
	1993			1994			1995		
	Europe	Asia	The Americas	Europe	Asia	The Americas	Europe	Asia	The Americas
Weight(T)	788.55	4,462.21	608.50	1,650.10	8,542.68	273.10	1,739.61	14,419.84	263.45
Freight Paid (USD)	\$102,511.50	\$763,037.91	\$35,493.80	\$214,513.00	\$1,460,798.20	\$15,929.92	\$226,149.30	\$2,465,792.60	\$15,367.04
If Imported from USA (1995 rates)	\$45,996.12	\$260,280.71	\$35,493.80	\$96,250.33	\$498,294.52	\$15,929.92	\$101,471.45	\$841,109.27	\$15,367.04
Difference	\$56,515.38	\$502,757.20	-	\$118,262.67	\$962,503.68	-	\$124,677.85	\$1,624,683.30	-
Total Extra Paid for Year	\$559,272.58			\$1,080,766.40			\$1,749,361.20		
Extra Paid for three years	\$3,389,400.21								

Shipping and the Cuban Democracy Act: Freight of medicines and medical supplies has also increased in cost due to the fact that the CDA prohibits vessels that deliver goods to Cuba from docking in U.S. ports for the next 180 days. This regulation effectively limits the number of ships willing to travel to Cuba and often makes it necessary for medical supplies to be dropped off at a nearby Caribbean port (adding docking and storage charges), and then picked up by a Cuban vessel (adding more docking costs). Contracts have also stipulated that Cuban importers must provide shipping.

Warehousing Needs: Since imports must come with some delay from far-away ports instead of immediate delivery from the United States-Cuban importers must order more supplies to last them longer. According to both MEDICUBA and EMSUME (the Medical Supply Company in charge of distribution of equipment and materials), this translates into building costs for construction of significant warehouse space over the years, major financial resources tied up in large warehouse inventories, and less efficient use of moneys (since they must be spent towards long-term calculated needs, which are never exact). EMSUME is now carrying \$12 million in inventories, representing 88,000 types of parts and equipment.⁶³ EMSUME's Rivero argues that these moneys could be put to use more rationally, if they could be freed up for shorter term purchases from U.S. suppliers.

U.S. Dollar Purchases: The embargo prohibits Cuba from engaging in international transactions using the U.S. dollar. Thus, even when medical supplies are purchased from wholly-owned foreign companies, this often involves changing currencies, with the consequent banking charges and losses in exchange rates, because of the relative strength of the U.S. dollar. Dr. Jose Luis Fernández Yero, Director of the Immunoassay Center for diagnostic testing, says that he must budget at least an additional 10% for currency changes. He and others interviewed also note that because there are no banking relations with the USA, even though technically Cuban entities can purchase medical literature, in practice they must do so through third countries, at higher prices and with long delivery delays@

U.S. Firms Not in the Bidding. As noted earlier in this section, United States manufacturers tend to be the strongest and often most competitive in pharmaceuticals and medical equipment. Once they are eliminated from the bidding, the remaining companies are not obligated to come down to meet their prices, and consequently Cuba as a rule pays higher prices for comparable European goods?

Intermediary Purchases: When Cuban importers decide to purchase U.S. products through intermediaries or wholesalers, whether because these products are unique or simply of the quality required, the prices paid are often higher, due to the profit margin of the wholesalers or what MEDICUBA's Orlando Romero calls the 'third party risk tax,' charged by intermediaries who maintain they are taking a risk in selling U.S. goods to Cuba. In any case, if these products could be imported directly from the United States, prices would be lower. (See sections on National Health Emergencies and Hospital Care.)

Resources Tied UP Longer: Scarce financial resources are tied up longer as contracts are often closed months before the process of license application is completed (see the cases of thalamonal licenses). This can also result in higher banking fees when letters of credit are issued.

Credits: Long-term or medium-term credits are almost impossible to obtain, according to MEDICUBA General Manager Orlando Romero. Not only does the CDA open the door to sanctions against those who would offer such credits or preferential terms to Cuban customers, but the embargo, which has put a higher price tag on medical imports for the reasons outlined here, has also contributed to the debt of companies like MEDICUBA, which now stands at \$140 million. This has made it necessary for the firm to negotiate new agreements with suppliers, agreeing to pay as much as 40% more for new orders to pay off past debts.⁶⁶

Refurbished Equipment Unavailable: Because of its technological development in the medical field, the United States is virtually the hemisphere's only source of refurbished medical equipment, available for export at a fraction of the cost of new equipment. However, Rivero of EMSUME indicates that the embargo prevents Cuba from accessing this source of reduced-cost equipment. He argues: "Even if we were to find a company who would sell to us, and at least one in Miami has outright refused, and it were to obtain the necessary licenses, we would have the problem of travel, since buying refurbished equipment is rather like buying a used car: you must see it and test it for yourself."⁶⁷

The end result of the embargo's further limitation of funds available for medical imports is that Cuban health authorities have been obligated to reduce their purchases to absolute essentials, often simply products that determine life and death—and then, there are not always enough resources. (See section on Oncology.) As noted, efforts at import substitution by domestic pharmaceutical production have also been hindered by the embargo, and in particular by the U.S. Government practice of refusing to issue export licenses for Cuba's pharmaceutical industry. (See section on the Pharmaceutical Industry.)

Embargo Restrictions: Impact on Quality of Health Care

Cuba is unable to introduce the newest equipment and drugs that are a result of U.S. research and development, which, as we noted, is the most advanced and prolific in the world. As we have seen, several factors are implicated here: some firms simply refuse to offer catalog information on drugs or equipment, let alone the newest generations, so physicians in Cuba are even unaware of the latest developments. If licenses were applied for, there is no guarantee that they would be approved. And finally, if Cuba attempts to purchase these U.S. products through intermediaries, the prices are often out-of-reach for a strapped Cuban economy, since wholesalers' profit margins and increased freight costs from faraway markets are piled on top of an already higher price for a patented drug (as compared to later generic versions).

As we noted earlier, under U.S. patent laws, a company has 17 years exclusive rights on a drug, which turns into 9 to 10 years of marketing opportunities, once FDA approval is granted. However, pharmaceutical companies have recently been successful in extending patents on a number of their top money-makers, effectively putting them out of reach for Cuban patients for at least a decade after they go on the market. In general, we can conclude that any drug patented in the United States since 1979 is unavailable to Cuban patients, except at inflated intermediary prices, and some medications patented before that date as well.

The implications for patient care are discussed in sections on The HIV/AIDS Program, Nephrology, Cardiology, Oncology, and others. Other problems include:

Range of Therapeutic Options: Physicians constantly explained to us that their "therapeutic arsenal" has been seriously affected by the embargo, both because of budget problems, and because of difficulties in accessing U.S. drugs and equipment. This problem has become more serious in recent years for several reasons, among them, the fact that the United States has clinched its lead in the international pharmaceutical industry just at a time when less funds are available for intermediary purchases of such drugs. There are cases in which a patient will respond to one drug but not another, or will be allergic to one drug and not another, or will need a specific combination of medications, some of which may be of U.S. origin and therefore difficult, if not impossible, to obtain.

purchase Through Intermediaries: There are a number of U.S.-manufactured drugs that are still under patent by U.S. firms, and cannot be sold legally to Cuba without a license. Cuba's Deputy

Minister of Public Health for Economics estimates that, even in times of serious economic crisis, Cuba must purchase at least 20 drugs of U.S. origin that have no substitutes.⁶⁸ There is also a range of drugs and equipment manufactured in the United States which Cuban specialists consider to be incomparable in quality to other sources. When these items are purchased through intermediaries-usually with difficulty, given the penalties prescribed by U.S. law-their higher prices automatically translate into smaller amounts contracted, or the contrary occurs, and the higher prices obligate Cuban importers to purchase an alternative of inferior quality.

Repairs of Equipment: As we have seen, in examples related to x-ray equipment, operating tables, pharmaceutical manufacturing equipment and respirators, the embargo has restricted effective repair of medical equipment for patient care. This is also the case with donated items: a humanitarian donation may be approved by the U.S. government, but it may be impossible later to obtain a license to purchase replacement parts. This is the case of a significant number of Cobe dialysis machines. (See section on Nephrology.)

Accessories for Equipment: This category has met with the same fate as equipment repair, since often the disposable accessories are unavailable due to the embargo. This is the case of diagnostic testing, Kodak film for the national breast cancer detection program (see section on Women's Health), and patient circuits for neonatal ventilators (see section on Children's Health).

Ingredients and Equipment for the Pharmaceutical Industry: Practice has indicated that only finished products have received U.S. export licenses, meaning that Cuba must import finished medications at a much higher price. This not only leaves factory space and workforce idle, but limits often to one fourth the amount of a given drug available to the population. In addition, the embargo has made it impossible for Cuba to purchase key equipment for manufacturing and quality control of certain pharmaceuticals, or has made it necessary to purchase these through intermediaries at much higher prices. (See section on the Pharmaceutical Industry.) The CDA also especially targets Cuba's biotechnology research and production, specifically prohibiting any exports for such use. (See section on Biotechnology and Vaccine Research for the implications of this provision.)

Sudden Cutoffs: By virtue of the embargo, Cuba has lost key third-country suppliers when they have been bought out by U.S. firms. The cases of Pharmacia and Nunc have been amply documented, and Cuba suddenly lost its two main sources of pacemakers for this reason as well. (See section on Cardiology).

Delays in Arrivals: Delays in deliveries of medications and equipment are often a result of distance shipping, as well as the CDA regulations, which tend to limit the number of ships willing to travel to Cuba (see above). One example of this problem occurred just after the CDA was enacted, and involved the importation of 1,5 mtm of tallow from Argentina, used to produce soap for hospitals and the general population. Due to the fact that the Cuban fleet has very few ships with the technical requirements for bulk-shipping this product, contracts were usually closed to include shipping by the supplier. However, it took several months to find a tanker willing to transport the tallow to Cuba, and thus, manufacture and distribution of the soap was likewise delayed.⁶⁹ In some cases, suppliers have insisted that Cuban ships be used, again representing delays.

Additionally, as has been noted, the licensing procedures themselves add to the time between contract closure and delivery. All of these embargo-related factors tend to create gaps in supplies of medicines, materials, parts, equipment and related items. In some medical emergencies, this can create life-and-death situations. (See sections on National Health Emergencies and Family Relations and Humanitarian Emergencies.)

No Patient Compensation: If U.S. products are purchased, whether licensed or through third parties, and they prove defective, Cuba has no way to recover monetary compensation for patients

or their families. Even if a case to this effect **were** to be admitted to a U.S. court, and the patient were awarded compensation, none would be forthcoming, since the embargo prohibits transfers of funds to Cuban nationals. The compensation would no doubt be deposited in a blocked U.S. account. (See section on Cardiology, for the situation regarding Telectronics pacemakers.)

Security of Supply vs. Quality: As we have seen, U.S. firms are reticent about attempting exports to Cuba; licensing is by no means guaranteed for direct, subsidiary or U.S.-origin component exports; and foreign firms may be taken over by U.S. companies. Such implications of the embargo mean that U.S. products are-not-a stable source for the Cuban medical system. This, contends Deputy Health Minister Ramón Díaz Vallina, forces Cuban importers to choose stable supply over product quality. "If there is U.S. medication that will cure a patient in seven days, and a European alternative that takes 14, we will choose the European alternative to guarantee availability of the drug," he says.⁷⁰ Cur research has shown that this leads to longer hospital stays, resulting in heavier case loads for doctors and greater hospitalization costs.

In the following chapters, we will explore the embargo's limitations on medical imports as they impact both preventive and curative care throughout the Cuban health system.

NOTES

*Pharmaceutical Research and Manufacturers of America, "U.S. Pharmaceutical RandD and Sales," January, 1995.

²**Ibid.**

³*Price Regulation and Pharmaceutical Research: The Limits of Co-Existence*, by Heinz Redwood, Oldwicks Press, Suffolk, GB,-1993,-p. 21.

'New regulations issued by the U.S. Department of Commerce in March 1996, may open up a loophole in the patent restrictions. According to legal experts, the regulations may allow Cuban buyers to import medications licensed to a foreign firm under a U.S. patent, only **if** the medication is entirely manufactured in the third country, and contains no U.S. ingredients. However, this has yet to be tested, and even if certain, it is not clear what possibilities this would actually open up, since we do not have information on what average percentage of U.S. components or materials such a licensed pharmaceutical might contain.

⁵"Consecuencias adversas que tiene para el disfrute de los derechos humanos del pueblo de Cuba el embargo economico de los Estados Unidos de Norteamerica," mayo 1993, Office of the First Deputy Minister of Public Health, Havana, p. 1.

'Interviews with Orlando Romero, General Manager of MEDICUBA, Havana, 19 Sept1995 and 24 Nov. 1995.

'Interview with O. Romero, MEDICUBA, 19 Sept. 1995.

⁸Michael Krinsky and David Golove, *United States Economic Measures Against Cuba*, Aletheia Press, Northampton, Mass., 1993, p. 114.

⁹Krinsky and Golove, p. 118.

¹⁰In fact, it was not until June 29, 1993, that OFAC amended its regulations to bring them into line with the CDA. As noted in Congressional testimony by Airline Brokers Co., Inc., presented in their outline of "Communications with U.S. Pharmaceutical Companies Concerning the Exportation of Medicine to Cuba and Legislative History of the Cuban Democracy Act," 'OFAC (apparently) had difficulty drafting the amendments and ascertaining the intent of Congress when it enacted the CDA. For example: On the one hand, the CDA prohibited OFAC from issuing licenses to foreign subsidiaries that are owned or controlled by U.S. Arms and that wish in export foreign manufactured goods to Cuba. On the other hand, the CDA permitted U.S. persons to export directly from the United States to Cuba donated or sold medicine, provided certain conditions are met." These provisions were reconciled in July 1993 CDA regulations, which allowed for licensed sale of medicines and medical supplies to Cuba by both U.S. companies and their subsidiaries abroad.

"CDA, Sec. 1705.

¹²Krinsky and Golove, p. 126.

¹³The following interviews were conducted for the survey of pharmaceutical and medical equipment firms in the United States: Michele Lockwood, International Sales, Baxter Healthcare Corporation; Kathy Daniels, International Division, Bristol-Myers Squibb, March 28, 1996; Nelson Baker, General Counsel, Johnson and Johnson, February 20, 1996; Keven Rrambeer, International Corporate Affairs for Latin America, Eli Lilly and Company, March 28, 1996; Susan Crowley, Director of International Relations, Merck and Company, March 29, 1996; Donna Boehme, Legal Department, Judy Klon, International Sales, Peter Flanagan, outside counsel, De Bauer, Distribution, and Judee Shuler, Public Relations, Ohmeda Pharmaceutical Products; Robert Lively, Director of Legislative Affairs, Schering-Plough Corporation, April 4, 1996; Diana Smith, Export Manager, Searle, March 28, 1996; R. John Larson, Licensing Department, Siemens USA, Malcolm Barlow, Public Affairs, SmithKline Beecham Pharmaceuticals; William C. Nealon, Attorney for TPLC Pacemakers, October 27, 1995; Jaime Esteves, Director of Marketing for the Americas, Wyeth-Ayerst Laboratories. (Wyeth-Ayerst also owns Lederle Laboratories).

"Interviews with Donna Boehme and Judy Klon, Ohmeda Pharmaceutical Products.

¹⁵Interview with Diana Smith, Export Manager, Searle, March 28, 1996.

"Interview with Nelson Baker, February 20, 1996.

¹⁷Interview with Tracy O'Donald, U.S. Department of Commerce, Cuba Exports Desk, by Wallie Mason, Feb. 20, 1996. O'Donald told Mason that the Dept. only licenses medical donations, not sales. After being asked to consult the guidelines, she rectified her first statement, and said that licenses for sales were indeed possible. On reading requirements for on-site inspection and that goods be for the benefit of the Cuban people, she said: "I doubt very seriously that a license to sell medicines to Cuba would be approved: it would be very difficult to satisfy these two criteria."

¹⁸Interview with Robert Lively, Director of Legislative Affairs, Schering-Plough Corporation, April 4, 1996.

¹⁹Interview with Michele Lockwood, International Sales, Baxter Healthcare Corporation.

²⁰Interview with William C. Nealon, Attorney, October 27, 1995.

²¹Interview with Jaime Esteves, Director of Distribution, Wyeth-Ayerst Laboratories.

²²Interview with Keven Krambeer, International Corporate Affairs for Latin America, March 28 1996.

²³Interview with Clara David, Licensing Officer, OFAC, February 20, 1996.

"Interview with R. John Larson, Licensing Department, Siemens, USA

²⁵Interview with Jaime Esteves, Director of Distribution, Wyeth-Aye& Laboratories.

²⁶Interview with Susan Crowley, Director of International Relations, Merck and Company, March 29, 1996.

²⁷Responding to an inquiry concerning this issue, Dr. A D. Brandling-Bennett, Deputy Director of the Pan American Health Organization said in a letter to Richard Wittenberg, President of the American Association for World Health: "The Government to Cuba has had a long-standing interest in developing biologicals and vaccines and marketing them internationally. At the request of Cuba and with the approval of U.S. authorities, a technical group from Merck, Inc. visited several biotechnology institutions in Cuba to make an evaluation of their facilities. This assessment did not create any legal difficulties for Merck, and they were not fined for any of the work conducted at PAHO's request. We do not have information about other activities which may have been conducted outside those approved by the U.S. authorities." Communication of February 20, 1996.

²⁸Merck Pays \$127,500 to Settle Cuba Allegations," Bergen Record, October 25, 1995, a story by Bloomberg Business News.

²⁹Interview with O. Romero, MEDICUBA, 19 Sept., 1995.

³⁰Interview with Nancy Blanco, Deputy Manager of MEDICUBA, Havana, 7 September, 1995.

³¹This does not include Picker International, Inc., The Upjohn Company, Johnson Johnson, and Becton and Dickinson, in cases where the licensing process was carried out by these U.S.-based companies on behalf of their foreign subsidiaries, requesting permission to sell to Cuba.

³²Interview by Stephen Kimmerling with William Teletronics legal counsel, October 27, 1995. Also note that according to Dunn and Bradstreet's *America's Corporate Families, the* Teletronics pacemaker manufacturer in Australia was owned by Pacific Dunlop Ltd. of Melbourne, which owns Pacific Dunlop Holdings of Wilmington, DE., whose subsidiary Teletronics Pacing Systems of Englewood, CO, owns TPLC, Inc. of Hialeah, FL, where the pacemakers are manufactured under patent authorization from Australia.

³³Fax from Siemens-Elema, dated June 29, 1994.

³⁴Interview by Dr. Anthony Kirkpatrick with Kevin O'Malley, March 19, 1995.

³⁵Interview with Rolando Díaz, MEDICUBA, November 23, 1995.

³⁶Interview with N. Blanco, MEDICUBA, Sept. 7, 1995.

³⁷Telex dated September 27, 1994.

³⁸*Afectaciones por el bloqueo y la puesta en vigor de la Ley Torricelli*, Ministry of Foreign Trade, Havana, June, 1994, p. 6.

³⁹Interview with R. Díaz, MEDICUBA, Sept. 6, 1995.

"Letter from Cuban Foreign Minister Roberto Robaina to UN Secretary General Boutros Boutros Ghali, June 25, 1993, p. 7.

⁴¹Fax to MEDICUBA and others, from Aldo Galano, representative of Pharmacia, dated August 25,

1995.

⁴²Interview with Leonel Zúñiga, Director, Empresa Nacional de Suministros Medicos, ENSUFARMA. February 7, 1996.

⁴³MEDICUBA report, June, 1994.

⁴⁴Case cited by Krinsky and Golove, p. 103.

⁴⁵Pharmaceuticals: Robust and Ready to Brawl," by Joseph Weber, *Business Week*, January 8, 1996.

⁴⁶Interview with Clara David, February 20, 1996.

⁴⁷Interview with Rosa Fuentes, MEDICUBA purchasing agent, Sept. 7, 1995.

⁴⁸Interview with R. Diaz, MEDICUBA, *Nov. 23, 1995*; and *Business Week* article cited by Krinsky and Golove, p. 103.

⁴⁹Picker "Checklist for License Application," contained in appendix to this chapter, and interview with Juan Suarez, Deputy Director, National Center for Electromedicine, December 8, 1995.

⁵⁰Interview with Alfredo Rivero, Deputy Director for Medical Equipment, EMSUME, 22 December 1995.

⁵¹Authors of this study had access to full documentation of this process. However, Joyce Simon of the U.S. Commerce Department's Bureau of Export Controls (BXA) informed Wallie Mason on Feb. 20, 1996 that information concerning the denial of these licenses to Picker International "is confidential and the government will not comment."

⁵²August 12, 1994 fax from Bill Dix of Picker in Canada to Galax, Inc., Montreal, and interview with R. Díaz, Deputy Director of MEDICUBA for Medical Equipment, January 5, 1996.

⁶³Interview with Juan Suarez, Deputy Director of the National Center for Electromedicine, December 8, 1995.

⁵⁴Letter of May 28, 1991, signed by ALFA LAVAL's Tina V. Kristensen, to MEDICUBA.

⁵⁵Letter of April 13, 1992, signed by AMSCO's Paul Montado.

⁵⁶Interview with R. Díaz, MEDICUBA Sept. 6, 1995.

⁵⁷U.S. Treasury documents conflict with MEDICUBA records and with statements from Janssen itself: Treasury records only three licenses issued for thalamonal, while MEDICUBA records four shipments; and Janssen confirms that it has never shipped without a license. We were unable to obtain further clarification on the thalamonal licenses from Clara David, Licensing Officer for OFAC.

⁵⁸MEDICUBA contracts reviewed by the authors, and summarized in MEDICUBA report, January 16, 1996.

⁵⁹Interview with Nelson Baker, General Counsel for Johnson and Johnson, February 20, 1996.

⁶⁰"Cuba Issues for Congress," Congressional Research Service Issue Brief, May 2, 1994, CRS-7.

*Interviews with Ramón Díaz Vallina, Vice Minister of Public Health; Enrique Comendeiro, Advisor to the Minister of Public Health; and Orlando Romero, Director, MEDICUBA

⁶²Interview with O. Romero, MEDICUBA, Sept. 19, 1995.

⁶³Interview with A Rivero, EMSUME, Dec. 22, 1995.

⁶⁴Interview with Dr. Jose Luis Fernández Yero, Oct. 17, 1995.

⁶⁵Interview with R Díaz, MEDICUBA, Sept. 6, 1995.

⁶⁶Interview with O. Romero, MEDICUBA, Sept. 19, 1995.

⁶⁷Interview with A Rivero, Dec. 22, 1995.

⁶⁸Interview with Ramón Díaz Vallina, August 25, 1995.

⁶⁸Afectaciones por el bloqueo y la puesta en vigor de la Ley Torricelli," Ministry of Foreign Trade, Havana, June, 1994, p. 22.

⁷⁰Interview with R. Diaz Vallina, August