

THE UNITED STATES EMBARGO AGAINST CUBA: LEGAL ASPECTS OF THE RESTRICTIONS ON SALES OF PHARMACEUTICAL PRODUCTS, AS SET FORTH IN THE CUBAN DEMOCRACY ACT OF 1992

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BRIEF OVERVIEW OF THE U.S. EMBARGO AGAINST CUBA

The Cuban Democracy Act of 1992² (hereinafter “the CDA”) is but one of several measures adopted over the last three decades that exert economic pressure to effect political change in Cuba. Economic sanctions against the island were adopted in 1962 and, other than the ebb and flow of their severity brought on by various gestures towards Castro by intervening administrations, the embargo has intensified in its severity and scope. The bulk of U.S. prohibitions against trade with Cuba are set forth in the U.S. Department of the Treasury’s Cuban Assets Control Regulations, 31 C.F.R. §§ 515.502-515.574, and the Commerce Department’s Export Administration Regulations (notably 15 C.F.R. § 746.2, governing exports to Cuba). Federal law provides that civil penalties may be imposed for any violation of these regulations and that knowing violations are also punishable as criminal offenses, incurring substantial fines and possible prison terms of up to ten years. Property involved in such violations of the U.S. embargo regulations is subject to forfeiture.³

Since its formalized institution in 1962, the U.S. embargo against Cuba has become ever more comprehensive. The key elements of the embargo, as it now stands, include the following general prohibitions:

- **Imports:** U.S. law prohibits any imports from Cuba into the United States.
- **Exports:** U.S. law prohibits any exports to Cuba from the United States.
- **Travel:** U.S. law severely restricts the freedom of U.S. citizens and residents from traveling to Cuba. This is achieved by regulations which prohibit U.S. persons from paying Cuba or Cuban nationals for travel-related expenses such as hotels. There are exceptions for certain persons such as those visiting close relatives in Cuba (permitted only in cases of extreme humanitarian need), journalists, academics, and persons traveling on official business for the U.S. government, foreign governments, or international organizations. Even those in these excepted categories are subject to severe restrictions including a \$100 per day limit on travel expenses in Cuba.

1. This is a revised and edited version of a report prepared in October 1996 by the International Human Rights Consulting Group for the American Association of World Health.

2. Cuban Democracy Act of 1992, Title XVII, Pub. L. No. 102-484, §§ 1701 et seq.; 106 Stat. 2575.

3. 50 U.S.C. app. § 16.

- **Transfer of money or property:** The United States prohibits any U.S. person from transferring money or property of any nature to Cuban nationals. There are exceptions for family remittances, but these are limited to \$300 every three months to the household of a close relative in Cuba.
- **Receiving property:** U.S. law prohibits any U.S. person from receiving property from Cuba or a Cuban national.
- **Technical data:** The prohibition on transfers of property also includes the transfer of technical data.
- **Aircraft:** U.S. law prohibits any aircraft, other than those with the necessary licensure, from departing from the U.S. for Cuba and any aircraft owned or controlled by U.S. persons from departing for Cuba, regardless of departure point, unless such travel is licensed by the federal government.
- **Vessels:** U.S. law prohibits any third-country vessel from entering a U.S. port for a 180-day period following the vessel's entry into Cuba. This provision was included in the CDA and has been one of the most objectionable aspects of the embargo to other nations as it dramatically impacts foreign nations' freedom of trade.⁴
- **Penalties against other nations:** The United States may cut off aid and credits to countries which give preferential treatment to Cuba. The United States also maintains veto power within several international financial institutions over loans and credits to Cuba and nations that trade with Cuba.

Following the collapse of the Soviet Union in 1989 and the resulting loss of Soviet subsidies, Cuban trade with U.S. corporate subsidiaries rose dramatically. In the year prior to the October 1992 passage of the CDA, subsidiary sales to Cuba totaled between \$400-700 million.⁵ With the CDA's tightening of the embargo to include subsidiary sales (which had been licensed on a liberal basis prior to 1992) this growing trade was cut off almost overnight.

Perhaps the most onerous of the CDA's provisions, and that which is the focus of this report, are those restricting the sale of medicines and medical equipment to Cuba. The CDA provides, in relevant part:

Section 1705 (c) Exports of Medicines and Medical Supplies. — Exports of medicines or medical supplies, instruments, or equipment to Cuba shall not be restricted —

- (1) except to the extent such restrictions would be permitted under section 5(m) of the Export Administration Act of 1979 or section 203(b)(2) of the International Emergency Economic Powers Act;
 - (2) except in a case in which there is a reasonable likelihood that the item to be exported will be used for purposes of torture or other human rights abuses;
 - (3) except in a case in which there is a reasonable likelihood that the item to be exported will be re-exported; and
 - (4) except in a case in which the item to be exported could be used in the production of any biotechnological product.
- (d) Requirements for Certain Exports. —
- (1) On Site Verifications. —
 - (A) Subject to subparagraph (B), an export may be made under subsection (C) only if the President determines that the United States

4. This provision also causes grave impact on the price of any goods imported into Cuba, as ships from as far away as Europe and Asia are prohibited from visiting the U.S., and thus, the increased shipping costs are passed on to Cuban consumers.

5. U.S. Government officials have cited various figures. In a Special Report, *An Analysis of Licensed Trade with Cuba by Foreign Subsidiaries of U.S. Companies*, July 1993, published by the Office of Foreign Assets Control, U.S. Dept. of the Treasury, the figure of \$407 million in subsidiary trade for 1992 is cited. Peter Tarnoff, Undersecretary for Political Affairs, has cited the amount as over \$700 million in 1992. See testimony before the Foreign Relations Committee, Western Hemisphere Subcommittee, U.S. Senate, May 22, 1995. Richard Newcomb, Director of the Office of Foreign Assets Control, Dept. of the Treasury, has put the 1992 figure at \$336 million. See testimony before the Committee on Foreign Affairs, U.S. House of Representatives, November 18, 1993.

Government is able to verify, by on site inspections 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.

(B) Subparagraph (A) does not apply to donations to non-governmental organizations in Cuba of medicines for humanitarian purposes.

(2) Licenses. – Exports permitted under subsection (C) shall be made pursuant to specific licenses issued by the United States Government.

THE CDA'S RESTRICTIONS ON THE SALE OF MEDICINES

On its face, the language of the CDA regarding exports of medicines and medical supplies to Cuba seems to create a liberal policy of granting licenses for such sales. The Cuban Democracy Act's literal wording grants exceptions for commercial and humanitarian exports of medically related goods and for donative (i.e., noncommercial) exports of food. Section 1705 of the CDA exempts "donations of food to nongovernmental organizations [NGOs] ... [and] individuals in Cuba." Section 1705 further exempts "exports of medicines or medical supplies, instruments, or equipment," except where "restrictions would be permitted" under the Export Administration Act of 1979 or the International Emergency Economic Powers Act. The Act restricts the export of medical materials, however, where there is a "reasonable likelihood" of the Cuban government's use of such aid for reexport, human rights violations, or biotechnology.

The restrictions the CDA imposes on the delivery of medicines, however, subvert the spirit of such excep-

tions by making Cuba's access to such materials nearly impossible. The result is a de facto ban on critical medical and other assistance. For example, the medical goods exemption does not seem so generous when one reads that commercial export of such goods is subject to the issuance of specific licenses. Such licenses must issue from either the Department of the Treasury or the Department of Commerce, depending on the provider of the goods and the nature of the goods to be exported.

A Treasury license is required when a foreign U.S. subsidiary seeks to export medically related goods that are not of U.S. origin or that do not contain U.S.-origin matter. A Commerce license, however, is required for all exports of medically related U.S.-origin goods and medically related goods containing "U.S.-origin materials, parts, or components"⁶ to be exported from a U.S. entity (whether in the United States or abroad), from a foreign U.S. subsidiary, or from an independent overseas entity.⁷ Where foreign firms seek to export foreign-made goods composed of some amount of U.S.-origin matter, the Commerce Department will favorably consider these firms' export license requests if the goods contain only "an insubstantial proportion"⁸ of such matter and if the goods are "nonstrategic"⁹ in nature. To qualify as insubstantial, U.S.-origin matter incorporated into a foreign-made product can amount to no more than "20 percent of the value of the product to be exported from the third country."¹⁰

Even when a license does issue, exported goods are subject to the CDA's burdensome verification and on-site inspection procedures.¹¹ Under the CDA, permission for commercial (i.e., nonhumanitarian)

6. 15 C.F.R. § 746.2 (b) (3) (1997).

7. It is not clear whether a Treasury license is *also* required for export of medically related, U.S.-origin goods and medically related, U.S.-origin materials, parts, or components by foreign U.S. subsidiaries and foreign non-U.S.-related entities. Caution would suggest forwarding Treasury a photocopy of the Commerce license application along with a letter requesting that both the photocopy and the letter be deemed a Treasury license request should a Treasury license be required.

8. 15 C.F.R., *supra* note 6, at § 746.2 (b) (3).

9. *Id.*

10. *Id.* at § 746.2 (b) (3) (ii).

11. Cuban Democracy Act of 1992, *supra* note 2, at § 1705 (d) (1) (A); 31 C.F.R. § 515.559 (a) (2) (v) (1993); *see also* 15 C.F.R., *supra* note 6, at § 746.2 (b) (1) (v).

export of medical materials hinges on the President's determination "that the United States Government is able to verify by on site inspections"¹² that the items will be put to their intended use to benefit Cuban citizens. Treasury and Commerce regulations reword this requirement by restricting export of medically related goods "where it is determined that the United States Government is *unable* to verify"¹³ the goods' end use. The result is that Cuban citizens must wait and languish while U.S. companies and/or their subsidiaries endure the lengthy (and often fruitless) license application process, await word as to whether the U.S. government can verify that the exported medical items will be put to their intended use, and then submit to on-site inspection procedures.

On-site verification provides the U.S. Treasury and Commerce Departments with an effective weapon in discouraging and denying requests for licenses. In fact, the departments involved both openly state that it is their general policy to deny all applications. For example, in its 1994-1995 Annual Report, the Bureau of Export Administration (BXA) states that "[A]pplications for validated licenses will generally be denied, except on a case-by-case basis for ... exports to Cuba of medicines and medical items that satisfy the requirements of the CDA."¹⁴

Like Commerce, the Treasury Department also uses the authority and discretion granted it by the CDA to discourage and deny foreign U.S. subsidiaries' requests for licenses to sell to Cuba. Testifying before Congress in 1993 on the one-year anniversary of the passage of the CDA, Richard Newcomb, Director of the Office of Foreign Assets Control, boasted as to how the CDA had virtually cut off all sales to Cuba and stated that it was the agency's intention to see the number of licenses issued fall to zero:

The CDA prohibits the issuance of licenses pursuant to section 559 of our regulations allowing offshore transactions by Cuba with foreign subsidiaries of U.S. firms. The prohibition against issuing licenses was softened slightly, however, in that the CDA provides that the provision shall not affect contracts entered into before the enactment of the CDA ... In 1993 ... [Cuban trade with U.S. subsidiaries] ... was down to \$1.6 million. The \$1.6 million is accounted for by approximately 15 or 16 licenses which were pre-CDA contracts. We go over these [license applications] very, very carefully and only grant those that absolutely qualify. Frankly, I anticipate the number next year to be even less, falling ultimately to zero.¹⁵

In his statement before Congress, Mr. Newcomb wrongly stated that the CDA prohibits the issuance of licenses and only allows for the completion of pre-CDA contracts. His statement that the number of licenses would ultimately fall to zero either indicated his mistaken belief that once pre-CDA contracts had been completed no further licenses could be issued, or his intention that, notwithstanding the CDA's provisions for the future licensing of medical sales, the agency would not approve any additional licenses. His confusing comments with regard to the CDA's provisions are echoed throughout his agency and in his counterpart agency within the Department of Commerce, the BXA.

A phone call to the Department of Commerce, Bureau of Export Administration, sums up the similar confusion encountered in trying to obtain a license from that agency to sell medicine to Cuba. In a telephone interview conducted by the authors of this report, we asked a BXA information officer to provide us with an overview of the licensing procedures for sales of medicine to Cuba. The officer responded, incorrectly, that the BXA does not license sales to Cu-

12. Cuban Democracy Act of 1992, *supra* note 2, at § 1705 (d) (1) (A).

13. 31 C.F.R., *supra* note 11, at § 515.559 (a) (2) (v) (emphasis added); 15 C.F.R., *supra* note 5, at § 746.2 (b) (1) (v) (emphasis added).

14. Bureau of Export Administration, U.S. Dep't Com., 1994 Export Administration Annual Report and 1995 Report on Foreign Policy Export Controls III-18.

15. Richard Newcomb, Director, Off. of Foreign Assets Control, U.S. Dep't of the Treasury, testimony of November 18, 1993, before a joint hearing of the Subcomm. on Econ. Pol'y, Trade and Env't, W. Hemisphere Aff. and Int'l Cooperation of the Comm. on Foreign Aff., U.S. House of Representatives, at 21, 37.

ba, only donations. We responded that the CDA provides for licensing procedures for sales. The officer then consulted an agency manual and responded that this was indeed correct, but that the requesting company must list on the application “how it will provide for on-site inspection, and also that the goods would be for the benefit of the Cuban people.” She then commented, after reading these requirements, “I doubt very seriously that a license to sell medicines to Cuba would be approved; it would be very difficult to satisfy those two criteria.”¹⁶ When asked what the term “on-site inspection” meant, she was unable to offer an explanation. In short, the reply we received appears quite typical of the responses pharmaceutical companies encounter in seeking to obtain licenses from BXA or OFAC.

In the course of preparing this report, the authors conducted an informal survey of U.S. pharmaceutical companies to inquire as to their efforts in obtaining licenses for the sale of medicines to Cuba. In addition, the authors contacted the Office of Foreign Assets Control (OFAC) within the Department of the Treasury and the Bureau of Export Administration (BXA) within the Commerce Department, the two offices responsible for the processing of applications for licenses to sell medicines to Cuba.

In our interviews with pharmaceutical company representatives, we were told the same thing over and over: all inquiries to the U.S. government regarding the possibility of obtaining licenses to sell medicine to Cuba are met with confusing, sometimes hostile replies, all designed to discourage the company from even initiating the licensing process. Of the seven companies who agreed to participate in our survey, only one stated that it had successfully obtained licenses to sell to Cuba since 1992 and then only for a few specific items. In short, this company indicated

that it continued to seek to sell medicines to Cuba due to humanitarian concerns, though applying for licenses “is more trouble than it is worth.”¹⁷

We also filed requests with both the BXA and OFAC under the Freedom of Information Act (FOIA) seeking “all applications submitted to and approved licenses from” each agency regarding “subsidiary trade and/or sales of medicines, pharmaceuticals and medical supplies to Cuba” during the period 1990-1995.¹⁸ The request for information from the Commerce Department was denied for “national security reasons.” The FOIA request to Treasury was also denied, but information was obtained from the Department through other channels.¹⁹

According to the information provided by the Treasury Department, in the period 1992-1995, only eight licenses were granted by their agency for sales of medicines to Cuba; two licenses were denied. Considering the high volume of such sales pre-CDA enactment, one wonders why these total figures are so low. Based solely on these figures, it would appear that only ten applications were filed with OFAC between 1992 and 1995. Pharmaceutical industry members explained to us the reason why so few companies actually file applications for licenses. As one drug company representative put it, when a company calls to informally discuss the possibility of a license with OFAC, they are given confusing information and are generally discouraged from filing a request. Similarly, a representative of OFAC confirmed the same, stating that “companies hate to get a denial from the government for any kind of license. When they phone and are told how difficult it is to comply with the licensing procedures, and are generally discouraged from applying, they usually don’t follow up with filing a written application.”²⁰

16. Telephone interview with Tracy O’Donald, Dept. of Commerce, Bureau of Export Admin., Feb. 20, 1996.

17. At the request of those interviewed, we are not providing names of individuals quoted.

18. The FOIA requests were filed by the National Security Archives, an independent nongovernmental institute and library located in Washington, D.C.

19. The department provided information regarding licenses it had granted for medical sales in the 1992-1995 period to the office of Rep. Charles Rangel (D-NY) upon his request.

20. Telephone interview with Clara David, Off. of Foreign Assets Control, Apr. 18, 1996.

Of the licensing requirements described to would-be applicants, perhaps the most discouraging is that of on-site verification. Several of the pharmaceutical representatives interviewed mentioned this as an “untenable” requirement. As the CDA states in § 1705 (d) (1) (A), sales of medical supplies to Cuba may be licensed only if “the President determines that the United States Government is able to verify, by on site inspections 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.” Besides being an unprecedented requirement in the history of trade embargoes, neither Treasury nor Commerce has published any regulations making it clear what the exact meaning of this requirement is or how it is to be carried out. As some authors have commented, “[t]hrough the plain language of the Act, the United States is taking upon itself the authority to monitor delivery of medical care [in Cuba]. Carried to its logical extreme, authorities could follow shipments of medicines and medical supplies into the offices of physicians, hospitals and clinics to observe their actual use.”²¹

Of the copies of the OFAC licenses that we obtained, three were able to satisfy the on-site verification requirements by making special arrangements with U.N. agencies, three with the Belgian embassy in Cuba and one with the assistance of the Red Cross. Pharmaceutical company representatives interviewed indicated that the U.S. licensing agencies offer no guidance to them in interpreting the on-site verification requirement. Further, the ad hoc arrangements with the above-listed bodies were made out of humanitarian concern but were not satisfactory to those involved since international agencies and foreign embassies do not want to get involved in carrying out actions on behalf of the U.S. government or to appear to approve of U.S. policies under the CDA.

Clearly, the lack of clarity in the term “on-site inspection,” its political offensiveness to the Cuban government and its undesirability to those bodies which may be able to assist in carrying out the inspection all serve as a strong deterrent to pharmaceutical companies interested in selling medicine to Cuba.

THE REAL INTENT OF THE CDA'S RESTRICTIONS ON MEDICINES

The inclusion of medicines in an economic embargo violates international law principles on numerous grounds, which are discussed below. In general, the international community has declared that the embargo of medicines is incompatible with fundamental human rights guarantees and can only serve to cause needless suffering among the civilian population of the target states. Nevertheless, despite international outcry, including four U.N. resolutions denouncing the embargo, the U.S. has continued to effectively prohibit sales of medicines to Cuba.

An examination of the intent of the key architects of the CDA reveals a desire to dismantle the Cuban health care system. While the creation of its world-class medical capabilities has been called the “prize of the revolution” and Cuba’s leaders have been noted as viewing “health indicators as measures of government efficacy,”²² Cuba’s advances in medical care have caused Castro’s critics to view the system as a political target which must be destroyed. During a speech in South Florida in 1995, Richard Nuccio,²³ then Special Advisor to the President on Cuba stated: “During the heyday of its \$6 billion annual subsidies from the Soviet Union, the Cuban regime was able to establish a completely government-run, command economy, and provide free, universal education and health care. The Government, then, was the only

21. Anthony F. Kirkpatrick, M.D., Ph.D., et al., *The Time Has Come to Lift the Economic Embargo Against Cuba*, 81 J. Fla. Med. Ass'n 681 (1994).

22. Julie Feinsilver, *Healing the Masses: Cuban Health Politics at Home and Abroad* 1 (1993).

23. During the same 1995 address, Nuccio, one of the drafters of the CDA, stated, “Immodestly, I believe that the most effective role for the United States in promoting a democratic transition in Cuba is outlined in the Cuban Democracy Act, legislation I helped draft as an advisor to Congressman Bob Torricelli in 1992 and which President Clinton endorsed when he was still a candidate for office.”

source of everything for the individual, from his job to his home to medicine for his family.”²⁴

The United States’ contempt for the accomplishments of the Castro government in creating a viable, universal health care system is clear. The inclusion of medicines in the embargo, which has had devastating effects in Cuba, has been coupled with an increase in support for humanitarian donations of medicine. In explaining how the CDA has cut off trade with Cuba, CDA supporters are usually quick to point out that the amount of donations to Cuba from groups within the U.S. has increased. Richard Nuccio has commented: “Since the enactment of the CDA three years ago, the U.S. government has licensed over \$90 million in private humanitarian aid to Cuba, mostly food and medicine from nongovernmental groups in the U.S. distributed through nongovernmental organizations on the island.”²⁵

No nation, however, can provide adequate medical care for its population through reliance on donations. The quantity of U.S.-donated medical supplies to Cuba falls far below the need of Cuba’s residents. Further, the instability and unpredictability of products donated make it impossible for doctors to properly manage the treatment of certain patients, such as diabetics whose treatment necessitates precise potencies of insulin or other medicine.

THE UNITED STATES’ ROLE AS LEADER IN WORLD PHARMACEUTICAL DEVELOPMENT AND ITS IMPACT ON CUBA

U.S. pharmaceutical corporations’ large-scale acquisitions of foreign drug companies, which are taking place at an unprecedented rate, are worsening Cuba’s inability to obtain critical pharmaceuticals and medi-

cal equipment. These acquisitions trigger a broadening of the reach of U.S. patent protection and the 1992 Cuban Democracy Act’s preemptive embargo provisions.

Cuba’s ongoing shortage of certain medical materials is linked to the much-heralded globalization of the world economy. Yet in terms of Cuba’s access to world-class drugs and high-end medical technology, such globalization is less a result of neighborly cooperation than it is a byproduct of U.S. pharmaceutical companies’ mergers and acquisitions and the resulting international reach of U.S. patent and trade law.

For Cuba, pharmaceutical megamergers and the correspondingly broadened scope of U.S. patent law provisions combine with the 1992 Cuban Democracy Act to place top-tier, often unique, medical products out of Cubans’ reach. The results are obvious: critical shortages of even the most basic medicines and medical hardware and a serious threat to ordinary Cuban citizens’ health and medical care.

Analyzing just how Cuba’s medical supply crisis stems from the interrelationship between U.S. patent law, the Cuban Democracy Act, and pharmaceutical industry mergers requires a brief overview.

U.S. Patent Law: An Overview

U.S. patent law, codified by the 1952 Patent Act (the Act),²⁶ provides this country’s highest level of intellectual property protection. It grants the patentee and his or her successors in title²⁷ a 17-year exclusive right over a patented invention’s or process’s²⁸ manufacture, use, and sale.²⁹ The Act also bars nonpatentees from actively inducing patent infringement;³⁰ engaging in contributory infringement;³¹ selling es-

24. Richard A. Nuccio, *Prospects for a Peaceful, Democratic Transition in Cuba: A U.S. Perspective*, Remarks to the West Point Society of South Florida (Sept. 8, 1995) [hereinafter Nuccio].

25. *Id.*

26. 35 U.S.C. §§ 1-376 (1952).

27. *Id.* at § 100 (d).

28. *See id.* at § 100 (a), (b).

29. *Id.* at § 271 (a).

30. *Id.* at § 271 (b).

31. *Id.* at § 271 (c).

sential components to induce foreign production of a patented invention;³² and importing into the United States, or selling or using within this country, any product created through a patented process.³³

In the pharmaceutical arena, an ingenious chemical composition devised to produce a salutary medical result would be patentable, as would the process or processes invented to create such composition.³⁴ The underlying chemicals themselves may or may not be patentable: man-made chemicals contained in the composition might receive patents, while naturally occurring substances such as oxygen could not.

Of course, different people may hold the respective patents involved in pharmaceuticals. Theoretically, a lone scientist could hold a patent for the process by which a drug is created. Someone else may hold the patent on the drug's actual composition, while a third person may hold a patent for an improved version of the drug's production process, use, or composition.

Drug patents are valid for 17 years. Yet drug manufacturers must get FDA approval after patent issuance and before full-scale marketing. Because FDA approval can take seven to ten years, a manufacturer may only have ten to seven years left on the patent term. Driven to recoup investments and realize maximum profits, the manufacturer must adjust supplies and prices accordingly to compensate for the marketing and sales opportunities lost to the shortening of the patent's useful life. To address this, Congress used Patent Act § 156 to permit patent term extensions for certain products requiring FDA approval before sale.³⁵

The Megamerger Trend among U.S. and Foreign Pharmaceutical Companies

Worldwide mergers among large-scale pharmaceutical companies, particularly between U.S. and foreign corporations, make first-rate drugs and medical technology progressively less accessible to Cuba's needy population. U.S. drug companies' acquisitions of foreign counterparts extend the reach of U.S. patent protection and bring acquired companies under the CDA's discouraging, time-consuming, and often bewildering licensing requirements.

In medicine, time is critical where lives are at stake. For Cuba's medical establishment, such precious time is lost trying to identify a shrinking number of sources for alternatives to the drugs and technology made increasingly out of reach due to megamergers that only lengthen the shadow cast by U.S. patent protection and CDA restrictions.

The past few years have witnessed large-scale pharmaceutical industry mergers and acquisitions. These include drug company purchases of competitors as well as strategic pharmaceutical buys of key drug distributors.

- In 1993, for example, Merck & Co., an industry giant, acquired distributor Medco Containment Services, Inc.³⁶
- On May 2, 1994, Roche Holding Ltd., another main industry player, agreed to pay \$5.3 billion for Syntex Corp., a commercial counterpart.³⁷ Just four years earlier, Roche purchased 60% of Genentech, Inc., a leading biotechnology concern.³⁸ Around the time of the Syntex acquisition, SmithKline Beecham PLC outlined an agreement to buy distributor Diversified Phar-

32. *Id.* at § 271 (f).

33. *Id.* at § 271 (g).

34. This assumes the Patent and Trademark Office determines that the product or process meets the statutory standards for novelty, utility, nonobviousness, and originality.

35. R. Dreyfuss & R. Kwall, *Intellectual Property* 247 (Foundation Press 1994); *see also* 35 U.S.C., *supra* note 26, at § 156.

36. Joseph Weber et al., *Drug-Merger Mania*, *Bus. Wk.*, May 16, 1994 [hereinafter *Drug-Merger Mania*].

37. *Id.*

38. *Id.*

maceutical Services, Inc. for \$2.3 billion “and to ally with Diversified's parent, powerhouse health maintenance organization United HealthCare Corp.”³⁹

- In 1995, Upjohn Co. and Swedish firm Pharmacia, two respected pharmaceutical entities, engaged in a 7 billion-dollar stock-swap merger.⁴⁰
- That same year, Britain's Glaxo Holdings PLC paid \$14 billion for Burroughs Wellcome, and Hoechst acquired Marion Merrell Dow for \$7.1 billion.⁴¹
- In February 1996, Johnson & Johnson acquired cardio-technology manufacturer Cordis Corp. for \$1.8 billion.⁴²
- Finally, St. Jude Medical, Inc., looked forward to a 1996 finalized acquisition of Daig Corporation and Cyberonics, Inc., companies that will “provide St. Jude Medical entry into two additional therapeutic markets—interventional cardiology and interventional neurology.”⁴³
- Early in 1996, speculation regarding future acquisitions included Bristol-Myers Squibb Co. and Eli Lilly & Co. as possible buyers of such companies as Searle & Co. and Warner-Lambert Co.⁴⁴

Industry mergers and acquisitions are radically reshaping the medical product landscape “as giant multinational producers search for new products and wider distribution.”⁴⁵ In time, “the way pharmaceuticals are invented, made, and sold will bear little resemblance to the methods of a decade ago.”⁴⁶ While industry consolidation will slow in pace, “the merger trend among drug companies ... [is not] over. ... [C]ombinations ... [will] continue until only 10 or 15 giants are left.”⁴⁷

U.S. pharmaceutical companies are rapidly growing in their percentages of global market share. For example, Merck, one of the industry's largest members, “controls about 5% of the worldwide market.”⁴⁸ Glaxo Wellcome, the largest pharmaceutical manufacturer formed by the merger of Glaxo Holdings and Burroughs Wellcome, held 6% of the world market as of January 1996.⁴⁹ Yet during 1975-1989, 47 of 97 world-class drugs originated in the United States.⁵⁰ And in 1994 alone, U.S. patents accounted for 78%—109 out of 140—of “new genetic engineering patents for health-care products issued by the U.S. Patent and Trademark Office.”⁵¹

U.S. pharmaceutical megamergers give U.S. corporations and their exclusive patents greater control of global market share. Roche's acquisitions, for example, “will give ... [the company] a broader product line to sell [to] big customers in the U.S.”⁵² and pre-

39. *Id.*

40. Joseph Weber, *Robust and Ready to Brawl*, Bus. Wk., Jan. 8, 1996 [hereinafter *Robust and Ready to Brawl*].

41. *Id.*; see also Joan Warner & Heidi Dawley, *Drug Stocks to Watch in '96*, Bus. Wk., Jan. 22, 1996.

42. Richard Jacobson, Reuters, Apr. 16, 1996.

43. PRNewswire, Apr. 17, 1996.

44. *Robust and Ready to Brawl*, *supra* note 39.

45. *Drug-Merger Mania*, *supra* note 35.

46. *Id.*

47. Warner & Dawley, *supra* note 41.

48. *Drug-Merger Mania*, *supra* note 36.

49. Warner & Dawley, *supra* note 41.

50. Pharmaceutical Research and Manufacturers of America, *World Class Drugs: Origin of 97 “Globalized” Drugs 1975-1989* (citing P. E. Barral, *Fifteen Years of Results of Pharmaceutical Research in the World*, Perspective et Santé Publique (Paris: 1985; updated 1990)).

51. Pharmaceutical Research and Manufacturers of America, *1994 Patent Analysis Results: U.S. Pharmaceutical Industry Continues Leadership in Biotechnology Research* (Mar. 1995).

52. *Drug-Merger Mania*, *supra* note 36.

sumably abroad. Johnson & Johnson's purchase of Cordis has already yielded J&J "about one-third of the worldwide market for heart intervention products."⁵³

To secure global market control and increase revenue, "the big [pharmaceutical] producers are scrambling to build market share by selling more products. To fight the growing might of [pharmaceutical] distributors, they're buying the distributors."⁵⁴ The acquisition of distributors will eliminate "the middlemen that have forced ... [drug companies' profit] margins down."⁵⁵ That will affect pricing, market distribution, gross sales, and even health-care plan administration, including insured individuals' drug choices.⁵⁶

Joining Forces: Megamergers, U.S. Patents, and the CDA

Megamergers mean the global marketplace features fewer, bigger, and more powerful providers of world-class drugs and technology. Fewer competitors may mean higher prices, less consumer freedom of choice, and less industry scrutiny or accountability. More importantly, because many of these commercial titans are U.S. companies, the extraterritorial reach of U.S. patent protection and CDA trade restrictions removes the best medicines and medical equipment from Cuba's reach.

The reasons are clear: as foreign pharmaceutical firms and distributors become part of U.S. entities, they fall under the Cuban Democracy Act's burdensome licensing provisions. Prospective acquisition targets thus face a difficult choice. They can pursue sales contracts with Cuba and forgo a potentially lucrative

merger with a U.S. company, or they can complete a merger and sever possibly profitable ties with Cuba. Once acquired by a U.S. firm, the foreign, formerly independent corporation must avoid, cancel, or decline to renew commercial sales contracts with Cuba. Megamergers are therefore quickly shutting off Cuba's access to non-U.S. sources of important drugs and medical technology.

As importantly, acquired companies are likely to work with the patented drugs and technology of their U.S. parent company. Respecting the parent company's U.S. patents would mean not competing with or illicitly pirating such patents. Additionally, powerful U.S. pharmaceutical companies, made even larger through mergers and acquisitions, would have the resources to seek patent protection in as many countries as possible. Because U.S.-patented items fall under the Cuban Democracy Act's licensing provisions, the effect is to cut Cuba off—company by acquired company—from its non-U.S. medical suppliers.

Goods under exclusive U.S. patents are only available from U.S.-owned or -controlled sources and thus are inaccessible to Cuba. Alternative, parallel products available from third countries are often inferior or (in the case of drugs) inflict undesirable side effects.⁵⁷ Finally, because some Cuban medical professionals deem other countries' pharmaceutical testing standards to be lower than those of the U.S. Food and Drug Administration, Cuban doctors have less confidence in the quality, safety, and effectiveness of third-country drugs and other goods.⁵⁸

Lack of drugs of guaranteed reliability may ultimately degrade patient care and damage the Cuban medi-

53. Jacobson, *supra* note 42.

54. *Drug-Merger Mania*, *supra* note 36.

55. *Id.*

56. *Id.*

57. Aff. of Anthony F. Kirkpatrick, M.D., Ph.D., at 2-3, 4, 8, in Anthony F. Kirkpatrick, M.D., Ph.D., *Adverse Effects of the U.S. Economic Embargo on the Health of Cuba's Children* (Feb. 3, 1995) (presented before the Inter-Am. C.H.R.); *see also* Emergency Petition Requesting a Declaration that the U.S. Trade Embargo against Cuba Has Resulted in a Medical Crisis in Cuba and Requesting a Declaration that Said Embargo Violates International Human Rights Laws 6-7 (Oct. 4, 1994) (filed with the Inter-Am. C.H.R.); interview with Senovio González de León, Director of Public Relations, Hospital Nacional Hermanos Ameijeiras, Centro Habana, Havana, Cuba (Mar. 27, 1995).

58. Interview with Senovio González de León, *supra* note 57.

cal system's world-renowned reputation. It may also erode Cuban citizens' faith in the adequacy of their country's health care, prompting both ill and healthy Cubans to forgo preventive and diagnostic care by shying away from a medical system the competence of which they may have come to doubt.⁵⁹

With fewer options and sources for the best medical goods, Cuba must resort to non-U.S. products, whether under foreign patents or pirated abroad. Resorting to pirated products (inexpensive copies of patented drugs, produced without patentees' permission), however, would only compromise already strained political relations between the United States and Cuba, making political and economic rapprochement less likely.

INTERNATIONAL LAW RAMIFICATIONS OF THE CUBAN DEMOCRACY ACT

Extraterritoriality

Since its enactment in 1992, the CDA has provoked an outpouring of protests from various nations around the world as well as official denunciations by international and regional bodies such as the United Nations and the Organization of American States. The objections of many major U.S. trading partners have been made known through various demarches which criticize the extraterritorial aspects of the CDA, particularly those which place prohibitions on third-country ships from entering the U.S. within a six-month period of having docked in Cuba. These provisions, which seek to coerce and control the trade practices of other nations by penalizing them for continuing to do business with Cuba are an affront to the sovereign right of each nation to determine its own foreign commerce practices. On October 7, 1992, one day after Congress passed the CDA, the European Community made a formal demarche to the U.S. government warning that the law would be met with strong opposition and disapproval. The EC stated:

The European Community and its member states are seriously concerned about the reinforcement by the U.S. Congress of the trade embargo against Cuba. Furthermore, the Act's proposed sanctions for vessels that enter a port in Cuba would be in conflict with longstanding rules on comity and international law, and adversely affect international shipping as well as the European Community's trade with the United States. ... Although the EC is fully supportive of a peaceful transition to democracy in Cuba, it cannot accept that the U.S. unilaterally determines and restricts EC economic and commercial relations with any foreign nation which has not been collectively determined by the United Nations Security Council as a threat to peace or order in the world of nations.⁶⁰

The Canadian government made similar complaints, stating that the extraterritorial aspects of the CDA are an affront to the sovereignty of Canada and other nations that have the right to determine their own policies with regard to Cuba.

When the CDA's extraterritorial provisions went into effect in 1992, it signaled a reversal of the United States' earlier-stated policy that it would not seek to penalize third-country trade relations with Cuba. In fact, the inclusion once again of third-country penalties in the embargo against Cuba specifically contradicted actions taken by the United States in 1975 when the government acknowledged the impropriety of such provisions and removed them from earlier laws setting forth the terms of the embargo against Cuba.

In 1962, the Organization of American States adopted stringent resolutions mandating that all member states cut diplomatic ties with Cuba. The OAS also imposed a collective embargo against Cuba at that time. In 1962, the terms of the U.S. embargo against Cuba, the strongest of any of the nations in the hemisphere, included sanctions against other nations which continued to deal with Cuba, similar to those

59. *Id.*

60. European Community Press Release (Oct. 8, 1995), *reprinted in* United States Economic Measures Against Cuba: Proceedings in the United Nations and International Law Issues 195 (Michael Krinsky & David Golove eds., 1993) [hereinafter United States Economic Measures Against Cuba].

found in the CDA today which prohibit the entry into the United States of vessels having visited Cuba.

By 1975, a change in sentiment had taken place within the OAS as various member states asserted their right to determine their own policies with Cuba and some reestablished relations with the island nation. On July 29, 1975, the OAS adopted a resolution rescinding its mandatory embargo on Cuba. Based on the principle of nonintervention, a fundamental cornerstone of the OAS which is mentioned throughout the organization's Charter, the regional body called on each member state to freely determine its own policies with regard to trade and other relations with Cuba.⁶¹

In direct response to the 1975 OAS resolution, the U.S. modified its policies, removing those provisions of U.S. law which sought to penalize or control third countries' relations with Cuba. In a September 1975 official State Department Bulletin, the U.S. announced:

In keeping with the action by the OAS, the United States is modifying the aspects of our Cuban denial policy which affect other countries. Effective today, August 21, 1975, it will be U.S. policy to grant licenses permitting transactions between U.S. subsidiaries and Cuba for trade in foreign-made goods when those subsidiaries are operating in countries where local law or policy favors trade with Cuba ... In order to conform further with the OAS action, we are taking appropriate steps so that effective immediately countries which allow their ships or aircraft to carry goods to and from Cuba are not penalized by loss of U.S. bilateral assistance. We are initiating steps to modify regulations which deny bunkering in the United States to third-country ships engaged in the Cuba Trade.⁶²

Echoing this recognition of the inappropriateness of third-country penalties, William Rogers, then Assistant Secretary for Inter-American Affairs, testified be-

fore the U.S. Congress as to why the third-country constraints were being lifted:

As a logical and practical corollary to the termination of mandatory OAS sanctions, the U.S. government, on August 21, announced modifications of those aspects of our Cuban denial policy which affect other countries ... This was basically a measure to remove a recurrent source of friction between the United States and friendly countries both in this hemisphere and overseas which, for reasons of their own, have engaged in or never ceased to trade with Cuba.⁶³

The CDA restored the third-country constraint provisions in 1992 which had been specifically denounced by the U.S. government in 1975 as unacceptable to other nations and incompatible with the 1975 OAS resolution affirming the right of each member state to freely determine its own policies toward Cuba. The current U.S.-imposed embargo which punishes those who trade with Cuba patently violates the OAS resolution and runs counter to the OAS Charter, which upholds nonintervention as one of the fundamental principles upon which the organization is founded.

In addition to the individual protests of foreign trading partners prompted by the CDA's passage, the law has also brought about formal denouncements from the United Nations. In four consecutive sessions of the United Nations General Assembly, that body has passed resolutions condemning the U.S. embargo against Cuba and calling on the United States to rescind those aspects of its law which are violative of international law principles as well as of the U.N. Charter. In a resolution passed on November 15, 1995, entitled "Necessity of ending the economic, commercial and financial embargo imposed by the United States of America against Cuba," the U.N. General Assembly held, *inter alia*:

61. See Final Act, Sixteenth Meeting of Consultation of Ministers of Foreign Affairs, Serving as Organ of Consultation in Application of the Inter-American Treaty of Reciprocal Assistance, July 29, 1975, OEA/Ser.F/II.Doc.9/75, Rev. 2 (1975).

62. Dep't St. Bull., Sept. 15, 1975, at 404, *reprinted in* United States Economic Measures Against Cuba, *supra* note 60, at 215.

63. *U.S. Trade Embargo of Cuba: Hearings Before the Subcomm. on Int'l Trade & Com. & Int'l Organizations of House Comm. on Int'l Rel.*, 94th Cong., 1st Sess. 360 (1975), *quoted in* United States Economic Measures Against Cuba, *supra* note 60, at 217, 218.

Reaffirming, among other principles, the sovereign equality of States, non-intervention and non-interference in their internal affairs and freedom of international trade and navigation, which are also enshrined in many international legal instruments ...

Concerned about the continued promulgation and application by Member States of laws and regulations whose extraterritorial effects affect the sovereignty of other States and the legitimate interests of entities or persons under their jurisdiction, as well as the freedom of trade and navigation ...

Concerned that, since the adoption of its resolutions 47/19, 48/16 and 49/9⁶⁴ further measures of that nature aimed at strengthening and extending the economic, commercial and financial embargo against Cuba continue to be promulgated and applied, and concerned also about the adverse effects of such measures on the Cuban people and on Cuban nationals living in other countries ...

[The U.N. General Assembly] reiterates its call to all States to refrain from promulgating and applying laws and measures of the kind referred to in the preamble to the present resolution in conformity with their obligations under the Charter of the United Nations and international law which, inter alia, reaffirm the freedom of trade and navigation ...⁶⁵

Notwithstanding repeated U.N. resolutions calling for the rescinding of practices against Cuba and against nations that trade with Cuba which violate international law, the U.S. has defiantly maintained and even reinforced its policies.

International Law Violations Precipitated by the U.S. Embargo on Sales of Medicines to Cuba

The Cuban Democracy Act of 1992 violates the Charter of the Organization of American States

(hereinafter “the OAS Charter” or “the Charter”) by imposing a ban in fact (though not in law) on the sale (and, under some circumstances, the nonhumanitarian donation) of food, medicines, and medically related materials.

Extraterritoriality of Human Rights Obligations

in the Americas: The OAS Charter's language and history imply an intent to create a regional, extraterritorial human rights system for the Americas. Drafted in the spirit “of American solidarity and good neighborliness,”⁶⁶ the OAS Charter aspires to forge a hemispheric, American “order of peace and justice”⁶⁷ that promotes solidarity and collaboration and that defends American states' “sovereignty, ... territorial integrity, ... and independence.”⁶⁸ Understood more broadly, the Charter establishes an inter-American, hemispheric matrix of reciprocal human rights obligations protecting people from rights violations by their own or another American government.

It should hardly be news that the Americas intentionally established such a hemispheric web of reciprocal rights and duties for international protection of human rights. In fact, the records of international discussion culminating in the Charter show that human rights and regional responsibility have always been central to the inter-American sensibility. The Charter's history reveals that an intent to create a regional rights system has “been manifest since the very origin of the inter-American system. The Treaty of Perpetual Union, League and Confederation ... [a Charter precursor] ... recognized the principle of juridical equality of nationals of a state and foreigners.”⁶⁹

64. These numbers refer to the three previous resolutions passed by the U.N. General Assembly calling for the elimination of policies against Cuba which violate these principles.

65. G.A. Res. , U.N. GAOR, U.N. Doc. A/RES/50/10 (1995).

66. Charter of the Organization of American States, May 2, 1948, U.S.T. 2, Doc. 2394, T.I.A.S. no. 2361 (1948); U.S.T. 21, Doc. 607, T.I.A.S. no. 6847 (*as amended* 1970) (at introductory text).

67. *Id.* at art. 1; *see also id.* at art. 29, which seeks a hemispheric approach to rights (“The Member States, inspired by the principles of inter-American solidarity and co-operation, pledge themselves to a united effort to ensure social justice in the Hemisphere and dynamic and balanced economic development for their peoples.”).

68. *Id.* at art. 1.

69. Thomas Buergenthal et al., *Protecting Human Rights in the Americas: Selected Problems* 2 (N. P. Engel 1982).

While this speaks directly to equal treatment for foreigners and citizens living in the same country, it seems clear that the Charter's evolution involved the application of the same protection to peoples living in *different* (i.e., their respective) countries. Deliberations leading to the OAS Charter's creation suggest the creators envisioned extraterritorial human rights obligations that would hold nations accountable for those of their actions that violated the human rights of member states' citizens. Under this interpretation, a member state would therefore violate the spirit of the Charter and the inter-American system's codified norms if that state's law and/or administrative actions conflicted with "the exercise or enjoyment of rights protected by the [inter-American] system."⁷⁰

Bound by the OAS Charter: A full-fledged OAS Member State, the United States is bound to the spirit and word of the Charter. Obligated to adhere to Charter standards "in good faith,"⁷¹ the United States should "not invoke the provisions of its internal law as justification for its failure to perform a treaty."⁷²

As importantly, U.S. obligations under the Charter apply to Cuba. Contentions that Cuba's nebulous status within the OAS obviates the United States' international law duties toward Cuba under the Charter are arguably unsound. Though the OAS excluded Cuba from the organization in 1962⁷³ and directed member states to sever diplomatic and commercial

ties to the island,⁷⁴ the OAS later withdrew these sanctions and left "to each member state the right to determine its diplomatic and trade relations with Cuba."⁷⁵ Most importantly, the OAS, through the Inter-American Commission on Human Rights, recognizes the "Cuban State [rather than the Government of Cuba] ... [as] ... a party to ... the Charter of the Organization of American States."⁷⁶ Asserting that "Government and State are two juridical and institutionally differentiable concepts,"⁷⁷ the Commission has unequivocally stated that "[i]t was the Cuban Government—not the State—that was excluded from the inter-American system"⁷⁸ in 1962 and that such exclusion "was not [intended] to leave the Cuban people unprotected."⁷⁹ Thus the United States' human rights obligations within the inter-American system apply to Cuba.

Violating OAS Charter Provisions: By denying Cuba access to critical medical supplies, the Cuban Democracy Act directly endangers Cuban lives, denies Cubans' right to protection of life, and cripples the Cuban government's ability to meet the international human rights obligations it owes its people. The Act therefore violates the OAS Charter's spirit and purpose.

The Cuban Democracy Act violates the OAS Charter's prohibition on the use of "coercive measures ... to force the sovereign will of another State and obtain from it advantages of any kind."⁸⁰ Yet the CDA

70. *Id.* at 28.

71. Vienna Convention on the Law of Treaties, May 23, 1969, U.N. Doc. A/CONF. 39/27, art. 26.

72. *Id.* at art. 27.

73. Final Act, Eighth Meeting of Consultation of Ministers of Foreign Affairs, Serving as Organ of Consultation in Application of the Inter-American Treaty of Reciprocal Assistance, Punta del Este, Uruguay, January 22-31, 1962, OEA/ser. C/II.8 (1962).

74. Final Act, Ninth Meeting of Consultation of Ministers of Foreign Affairs, Serving as Organ of Consultation in Application of the Inter-American Treaty of Reciprocal Assistance, OEA/ser. C/II.9, doc. 48 rev. 2 (1964).

75. United States Economic Measures Against Cuba, *supra* note 59, at 213, *citing* Final Act, Sixteenth Meeting of Consultation of Ministers of Foreign Affairs, Serving as Organ of Consultation in Application of the Inter-American Treaty of Reciprocal Assistance, July 29, 1975, OEA/ser. F/II., doc. 9/75 rev. 2 (1975).

76. Inter-Am. C.H.R. 671, OEA/ser. L/V/II.95, doc. 7 rev. (1997) [hereinafter Inter-Am. C.H.R.].

77. *Id.* at 672.

78. *Id.* at 673.

79. *Id.*

80. Charter of the Organization of American States, *supra* note 65, at art. 19.

arguably violates other pertinent Charter provisions as well. These provisions are worded broadly enough to suggest that Charter obligations apply when one state's acts adversely affect another state and/or its people.

OAS Charter Article 10, for example, states that “[e]very American State has the duty to respect the rights enjoyed by every other State⁸¹ in accordance with international law.”⁸² Article 11 asserts that “[t]he fundamental rights of States may not be impaired in any manner whatsoever.”⁸³ Finally, Article 14 claims that “[t]he right of each State to protect itself and to live its own life does not authorize it to commit unjust acts against another State.”⁸⁴ Article 16 proclaims each state's “right to develop its cultural, political, and economic life freely and naturally.”⁸⁵

The Cuban Democracy Act violates these provisions individually and as they interrelate. The Act impairs (Article 11)—indeed, denies respect for (Article 10)—Cuban citizens' peremptory rights to life and health by denying them critical pharmaceuticals and equipment *solely* available from the United States. The CDA also violates Cuba's Article 16 “right to develop its ... economic life freely and naturally”⁸⁶ by

closing off Cuba's access to U.S. and U.S. subsidiaries' products, alternatives to which either do not exist or are prohibitively expensive to procure. Foodstuffs, medicines, and medically related materials and equipment are just some of commodities denied Cuba. Without them, and without items from countries fearful of damaging their *own* commercial ties with the United States, Cuba can hardly enjoy “free and natural” economic development. Nor can it realize its Article 14 right “to live its own life”⁸⁷ unimpaired “in any manner whatsoever.”⁸⁸ Under these conditions, Cuba cannot meet its duty to guarantee its citizens' *jus cogens*⁸⁹ rights to life and health. In its impact, therefore, the CDA represents an “unjust act[] against another State”⁹⁰ in direct violation of Article 14.

Article 18 denies any state “the right to intervene, directly or indirectly, ... in the internal or external affairs”⁹¹ of another state. This prohibition applies to *any* form of interference against another State. Article 19 prohibits “the use of coercive measures of an economic or political character ... to force”⁹² another state's “sovereign will.”⁹³ Finally, Article 20 confirms that “[t]he territory of a State is inviolable”⁹⁴ and that such territory cannot be the object of direct or indirect force.⁹⁵

81. Given the Inter-American Commission's statements regarding the Cuban State's inclusion in the inter-American system and its status as a party to the OAS Charter, Cuba qualifies as a “state” for Charter purposes and thus participates in the Charter's system of reciprocal rights and duties; see Inter-Am. C.H.R., *supra* note 75, at 671-673.

82. Charter of the Organization of American States, *supra* note 65, at art. 10.

83. *Id.* at art. 11.

84. *Id.* at art. 14.

85. *Id.* at art. 16.

86. *Id.*

87. Charter of the Organization of American States, *supra* note 65, at art. 14.

88. *Id.* at art. 11.

89. According to the Restatement (Third) of the Foreign Relations Law of the United States, *jus cogens* norms are “rules of international law ... recognized by the international community of states as peremptory, permitting no derogation. These rules prevail over and invalidate international agreements and other rules of international law in conflict with them.” See Restatement (Third) of the Foreign Relations Law of the United States sec. 102 cmt. k (1986).

90. Charter of the Organization of American States, *supra* note 65, at art. 14.

91. *Id.* at art. 18.

92. *Id.* at art. 19.

93. *Id.*

94. *Id.* at art. 20.

95. *Id.*

The CDA provisions effect both direct and indirect intervention in Cuba's internal affairs. The law is an economically coercive measure designed to force Cuba to "move toward democratization and greater respect for human rights."⁹⁶ No one doubts the Castro regime's historic brutality and denial of human rights. But legislatively endangering innocent lives represents a violative force that hardly jibes with the CDA's stated goal of promoting "a resumption of economic growth in Cuba through ... support for the Cuban people."⁹⁷

Affirmatively neglecting the human rights of another state's people seems a curious way to "vigorously ... oppose the human rights violations of the Castro regime."⁹⁸

The Humanitarian Exception of All Embargoes

The use of economic embargoes as a political sanction is not new. However, over the course of time, various standards have come to be recognized by the international community as to what is the proper scope of a permissible embargo. In short, international practice has come to include an exception for medicines, medical supplies and certain basic foodstuffs in any embargo in order to prevent unnecessary suffering among civilian populations.

Humanitarian exceptions permitting the free flow of medicines and food were features of multilateral embargoes imposed against North Korea, Vietnam, South Africa, Chile, El Salvador, the Soviet Union and Haiti. In the recent U.N.-supported embargoes against Iraq and the territories of the former Yugoslavia, the U.N. upheld the principle that food and medicines must be allowed through in order to serve the basic needs of the civilian population. In the case of Iraq, a special Sanctions Committee was established within the U.N. to ensure that shipments of food and medicines were permitted to get through to Iraqi civilians. In explaining the rationale for allow-

ing these exceptions to the embargo, U.N. Security Council officials stated that it is internationally "unacceptable to cause wide-spread suffering among civilians through impeding the shipment of food and medicines" in order to punish a country's leaders.⁹⁹

In addition to the U.N. General Assembly resolutions denouncing the U.S. embargo against Cuba for its extraterritorial aspects, the United Nations Commission on Human Rights has decried the embargo for its direct impact on the human rights of Cuban citizens who are harmed by its restrictions on food and medicine shipments. In Resolution 1994/47 entitled "Human Rights and Unilateral Coercive Economic Measures," the U.N. Commission on Human Rights particularly singled out the practice of large, developed nations such as the United States in targeting smaller, less-developed nations for unilateral embargoes. The U.N. Commission stated that such unilateral coercive measures against developing countries are in "clear contradiction of international law" and that "such unilateral coercive economic measures create obstacles to trade relations among States, adversely affect the socio-humanitarian activities of developing countries, and hinder the full realization of human rights by the people subject to those measures."

It should be noted that the purposeful impeding of food and medicines to civilians in time of war is expressly prohibited under customary international law and is codified in the Geneva Conventions. If international law requires a humanitarian exception for food and medicine even in times of war, then certainly the U.S. must achieve the same result in times of peace. Through the CDA, the U.S. creates a de facto blockade of Cuba which prevents the country's civilian population from obtaining adequate medicines, medical supplies and foodstuffs.

96. Cuban Democracy Act of 1992, *supra* note 2, at § 1703 (6).

97. *Id.* at § 1703 (1).

98. Cuban Democracy Act of 1992, *supra* note 2, at § 1703 (5).

99. *United Nations Eases Rules on Food and Fuel for Iraqis*, N.Y. Times, Mar. 23, 1991.

The Geneva Convention,¹⁰⁰ to which some 165 countries including the United States are parties, requires “free passage” of all medical supplies intended for civilians.¹⁰¹ This duty is placed on states even in times of war. Surely the recognition of the fundamental human right to medicines must be applied with equal diligence and vigor in the arena of peacetime international relations and trade sanctions. U.S. restrictions on sales by U.S. companies and their subsidiaries of medicines to Cuba and the penalties against third countries who continue to trade with Cuba (including through the sale of medicines) serve to severely restrict the flow of medicines to Cuba's civilian population.

Lastly, it should be noted that the 1962 multilateral embargo against Cuba, mandated by the OAS at the height of tensions with that nation, allowed for the sale of medicines to Cuba, noting that such a humanitarian exception is mandated by international law and practice. Indeed, the OAS's Inter-American Commission on Human Rights, in a February 1995 letter to the United States with regard to the de facto embargo on the sale of medicines to Cuba, stated:

[The Inter-American Commission on Human Rights] requests that the United States of America

faithfully observe the traditional exemption from an embargo under customary international law, of medicine, medical supplies and basic food items, for humanitarian reasons.

The Commission further stated:

[I]t is aware that the Cuban Democracy Act contains such exemptions, however the Inter-American Commission Human Rights has been informed that the bureaucratic and other requirements which have to be met in relation to those exemptions [i.e. on-site verification] render them virtually unattainable. Accordingly, the Inter-American Commission on Human Rights requests that the United States of America put in place mechanisms to ensure that the necessary steps are taken for exemption from the trade embargo in respect of medicine, medical supplies and basic food items, capable of effective and speedy implementation.¹⁰²

As it has ignored the resolutions of the U.N. General Assembly and the U.N. Commission on Human Rights calling for an end to the embargo against Cuba, so also has the U.S. ignored the pleas of the Organization of American States. The United States' de facto embargo on medicines remains in place unabated.

100. Convention Relative to the Protection of Civilian Persons in Time of War, Geneva Convention, No. IV, Aug. 12, 1949, Int'l Comm. of the Red Cross.

101. *Id.* at art. XXIII.

102. The Commission sent a copy of this letter to the petitioners as a means of notifying them that the letter had been sent to the U.S. Department of State.