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The largest pharmaceutical companies in the world have sales of over one billion dollars annually and operate across the globe. While every company has headquarters in a particular country, they all have manufacturing and other facilities in other countries. Foreign operations may be managed or controlled by the headquarters, but they are subject most directly to the laws of the countries in which they are located. For U.S.-based multinational corporations (MNCs), U.S. law applies fully to a company's domestic operations, but only certain aspects of foreign operations that affect U.S. commerce directly are governed by U.S. law. The extent to which drug labeling in developing countries can be influenced by U.S. law is, therefore, limited, The discussion of U.S. extraterritorial jurisdiction in this chapter is key to understanding the potential for the United States to extend its control over labeling beyond U.S. borders. This chapter also describes MNCs generally, including their basic structure and operations, and more specifically, characteristic features of typical U.S. pharmaceutical MNCs.

> *"A strange justice that is bounded by a river"*
>
> Pascal

THE MULTINATIONAL CORPORATION

The distinguishing characteristic of an MNC is that it has direct investments in several countries. The MNC does not merely market its product in other countries, but owns or controls production or service facilities in foreign countries. This is often referred to as direct foreign investment, which under U.S. law means ownership of at least 10 percent of voting securities of a corporation or an equivalent interest in an unincorporated firm (236). (Others define it as investment accompanied by significant ownership of at least 10 to 25 percent of stock in the foreign company or significant management control (256)). The MNC's foreign investments are directed and managed according to a business strategy that links the entire enterprise (80). Some scholars further distinguish MNCs as those enterprises that transact a substantial amount of business abroad so that their financial status is dependent on operations in several countries and their management decisions take into account multinational alternatives (80).

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Suburban pharmacy in Latin America displaying products from around the world.

It may be somewhat misleading to refer to an MNC as a single entity when it actually consists of a number of separate corporations linked economically, operating in different countries (80). Some experts use the term MNC to describe the headquarters of the enterprise, and describe the entire operation as a "multinational enterprise." In this report, the term MNC is used to refer to the entire enterprise.

The Rise of the U.S. Multinational Corporation

U.S. MNCs have existed since the early 1900s, but have attained their great prominence since the 1950s (253). In the early expansionary years, there was considerable concern that direct investment by multinationals could pose a threat to national sovereignty and hinder rather than promote economic development of host countries. This was of particular concern to developing countries. These concerns led to the negotiation of codes of conduct that set standards of behavior for MNCs (255). The codes, voluntary agreements between countries, were negotiated between industrial countries and within the United Nations to address the concerns of investment in developing countries (125,255).

The concern over foreign direct investment has largely dissipated, and it is, on the whole, seen as a positive force, especially for developing countries. One reason may be that developing countries have become more comfortable and sophisticated in controlling foreign investment and in insuring that it meets their countries' economic needs (255).

Expansion of U.S. MNCs has continued in the 1980s as Eastern Europe, the former Soviet Union, and China began to allow direct foreign investment, mainly through joint ventures with domestic partners. The dominance of U.S. MNCs has eroded, however, as non-U.S. multinationals, primarily from Western Europe and Japan, have taken a larger role in the world economy (92). In 1960, U.S. direct investment abroad accounted for one-half of all foreign investment in the world; by 1987, it accounted for one-third (238). The number of MNCs based in developing countries has also increased, but they are still few and small relative to the multinational giants of the industrial countries (225).

The rapid growth of MNCs has transformed the world economy in just 30 years. According to one U.S. business magazine, "competition for goods, services, and ideas pays no respect to national borders or the old geopolitical divides that supposedly separate North from South, East from West" (124). However, while the MNC has changed the nature of global markets, the international legal system has continued to treat the separate corporate entities of an MNC as separate corporations, subject to the laws of their host countries. One commentator has noted that, "while the home country regulates the head and shoulders of the MNC, various other countries regulate its limbs and extremities" (172). Although the MNC is a single corporate enterprise and major strategic business decisions are made at corporate headquarters for all operations, individual subsidiaries are usually managed by nationals of the country in which they are located, and national legal systems address the individual parts.

The Structure of U.S. Multinational Pharmaceutical Corporations

A U.S. MNC is a company with headquarters in the United States and with subsidiaries in other countries. The foreign subsidiaries often are incorporated under the laws of the "host" countries in which they are located. The country in which corporate headquarters is located is referred to as the "home" country. A large U.S. pharmaceutical MNC may have up to 50 or more foreign subsidiaries, of which perhaps a third are major operations. For example, the 1989 Bristol-Myers Squibb Company's annual report filed with the U.S. Securities and Exchange Commission (29) (the "1989 10-K") states that the company owns 22 major manufacturing facilities in Australia, Brazil, Canada, Denmark, England, France, Italy, Japan, the Netherlands, the Philippines, and Venezuela, and has well over 100 foreign subsidiaries. Pfizer Inc.'s 1989 10-K (176) states that its major manufacturing facilities are located in Great Britain, Ireland, France, West Germany, Japan, Brazil, India, Mexico, Argentina, Spain, and South Korea, with an additional 40 plants around the world, and a total of more than 150 foreign subsidiaries.

Subsidiaries of these companies that do not produce pharmaceuticals may be small marketing facilities, they may be "holding companies" whose sole function is to own stock in or supervise the management of other companies, or they may be engaged in other commercial activities. In addition to making pharmaceuticals for human use, Merck & Co., for example, is a diversified corporation that develops and markets animal health and agricultural products and specialty chemicals, e.g., for water treatment, oil field drilling, food processing, cleaning, and disinfecting (155).

In the pharmaceutical industry, foreign operations are usually carried out by subsidiaries owned entirely or in the majority by the parent corporation. Complete ownership is preferred because it allows the company to protect its technology and trademarks, maintain control over the quality of production, and ultimately, protect its reputation (65). But joint venture arrangements, in which a certain percentage of the subsidiary's stock is held by host country nationals, are common. A joint venture may be the only way a company is a!lowed by a foreign government to operate the subsidiary. This is particularly true in some developing countries whose governments

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Pharmaceutical paekaging in Latin America.

are attempting to promote national businesses (181). It is the smaller MNCs, however, that are more likely to be forced by host governments to enter into joint ventures, because they do not have the bargaining power to insist on complete ownership (65).

Developing countries account for less than 10 percent of worldwide pharmaceutical production (68), and in 1980 (the latest year for which data are available) a handful of developing countries-Argentina, Brazil, Egypt, India, Mexico, and the Republic of Korea—accounted for two-thirds of it (68). Developing countries rely heavily on imports of finished products or bulk products which are then repackaged for sale by subsidiaries of MNCs (223). Certain developing countries, however, are beginning to require that MNCs establish more sophisticated manufacturing facilities in their countries.

Indonesia recently passed legislation requiring all foreign-controlled pharmaceutical companies to establish Indonesian production of at least one raw material used in pharmaceuticals sold there

PHOTO CREDIT: W. LINDWER, WHO

Drug packaging in Kenya.

(135). Similarly, in India, foreign companies must establish a certain percentage of bulk drug manufacturing capacity, rather than just formulation and packaging plants (140). Producing active ingredients involves more investment and transfer of technology than does formulation. Because the risk of disclosing trade secrets is also higher, companies generally prefer to avoid transferring technology (182).

By selling the rights to its patents, a manufacturing process, a trademark, marketing services, or other technical skills, MNCs also may license their proprietary products to a foreign company for production and sale. In return, the MNC receives royalties on the products. This arrangement allows the company to sell its product abroad without taking the risks of direct investment (18 1). Syntex Corporation, for example, told OTA that at least one of its products included in the OTA survey was produced and marketed in Panama under a licensing arrangement with another company, and another one was produced and marketed in Thailand by a subsidiary of another MNC (213). The degree of control exercised by the licenser over the way in which a product is marketed or labeled is determined by the licensing contract.

INTERNATIONAL LAW AND EXTRATERRITORIALITY

Most international law is "customary" law, embodying general principles recognized by most civilized nations (105). The goal of international law is to promote stability among nations. Long-range interests of individual nations and the need for reciprocity in international relations determine the legal domain which each nation will claim as its own (136). International law is made by countries entering into treaties in which they agree to take, or refrain from taking, certain actions. International agencies, such as the United Nations, can influence the development of international law by promulgating guidelines or codes of conduct, but such proclamations are effective only if adopted by individual states. The United Nations International Court of Justice (ICJ) was setup to resolve disputes among countries, but the system works only when countries submit to the Court's jurisdiction and adhere to its decisions. To date, the ICJ's docket has been very light (6).

A nation's decision to exercise extraterritorial jurisdiction is usually guided by the basic principles of international law: the territorial principle, the nationality principle, and the protective principle. The *territorial principle* remains the fundamental doctrine of international law. It provides that each nation has the exclusive right to regulate the conduct of all residents, individuals, and corporations within its borders (82). A corollary to the territorial principle is that foreign governments do not have the right to interfere in the internal affairs of another State. Therefore, under an absolutist interpretation of the territorial principle, the United States would never have the right to exercise jurisdiction over a foreign subsidiary of a U.S. company because such action would impinge on the sovereign interests of the country in which the subsidiary operates (73).

The territorial principle, however, is not absolute. The *protective principle* recognizes a country's right to extend its jurisdiction to conduct occurring outside its borders if the action threatens the national security or functioning of government activities. Examples of such conduct are counterfeiting currency or forging entry visas outside a country's boundaries (189). A broader exception is the *nationality principle,* which recognizes a country's interest in maintaining some degree of control over its citizens residing or traveling in other countries. Other examples are the U.S. policy of requiring its citizens to pay certain income taxes when residing abroad (237), and the selective service law, which requires all male U.S. citizens, regardless of foreign residence, to register for U.S. military service (50 U.S.C. App. § 453).

The nationality principle may also be applied to corporations, which, in legal terms, are "persons." However, there is international disagreement on how the nationality of a corporation is determined. Most nations assert that a corporation is a citizen of the country in which it is incorporated, or the country housing the center of the corporation's activities. A subsidiary, although part of a larger corporation with headquarters in another country, is usually considered a national of the country in which it operates. The United States, however, has exercised jurisdiction over foreign corporate subsidiaries based on ownership or control by a U.S. corporation, primarily to enforce trade embargoes and boycotts, a practice that is a source of international controversy (2,218).

The United States is also a proponent of extraterritorial jurisdiction based on the effects *principle,* which holds that a nation may exercise jurisdiction over certain conduct occurring outside its territory if it has a "substantial," "direct," or "adverse" effect within the country. It is usually limited to acts "generally recognized as constituent elements of a crime or tort under the laws of the States that have reasonably developed legal systems" (73). The effects principle can be viewed as a modification of the territorial principle in that jurisdiction is based on addressing an adverse effect within the territory. The effects principle, however, is not universally accepted as a legitimate basis for extraterritorial jurisdiction under international law (218).

The United States has used the effects principle primarily to enforce economic laws, antitrust laws in particular. The effects principle was first pronounced in a 1945 case in which a U.S. court was asked to decide whether U.S. antitrust laws could be applied to an anticompetitive agreement between several European companies and a Canadian corporation. The Canadian corporation had corporate links to the United States. The court decided that "a state may impose liabilities, even upon persons not within its allegiance, for conduct outside its borders that has consequences within its borders which the state reprehends" (228). The controversial U.S. position on antitrust law is discussed later in this chapter.

Principles of international law can only provide general guidance, especially when debating extraterritorial jurisdiction. Application of one principle may lead to results that are contradictory to another principle. Which principle should be given greater weight in a particular situation can be determined only by examining the competing interests of the countries and other parties involved. In many situations, one country may believe a particular extraterritorial act is in accordance with international law, and another will see it as contrary. As one U.S. court stated, "[f]rom the body of international law, Congress may pick and choose whatever recognized principle of international jurisdiction is necessary to accomplish the purpose sought by the regulation" (229). To understand the U.S. position on extraterritorial jurisdiction, it is helpful to examine U.S. statutes, court cases, and other actions concerning extraterritorial jurisdiction in the field of foreign relations law.

U.S. Foreign Relations Law

The American Law Institute's recent *Restatement (Third) of the Law: The Foreign Relations Law of the United States (6) (the* "Restatement"), developed by prominent U.S. judges, legal academicians, and lawyers, is the most thorough analysis of U.S. foreign relations law. The Restatement brings together all relevant precedents in an attempt to develop a coherent doctrine that addresses the question of extraterritorial jurisdiction "as it would be pronounced by a disinterested tribunal, whether United States or some other national or an international tribunal."

In international law, where no single body provides a definitive legal opinion (as the Supreme Court does for U.S. constitutional law), the Restatement is very influential. A criticism of the Restatement is that it reflects the U.S. view of international law and, especially with respect to extraterritorial jurisdiction over U.S. foreign subsidiaries, the U.S. interpretation of international law is at odds with most other countries (186, 220). The Restatement should be cited with caution because it not only summarizes the law as reflected in judicial cases and legislative and executive actions, it expands on the precedents and prescribes what direction the law should take, so it does not necessarily reflect current law.

The Restatement recognizes that the territorial, nationality, and effects principles provide a basis for exercising jurisdiction over an activity, person, or corporation. With respect to MNCs, the general rule is that *country A* may not exercise jurisdiction over a subsidiary incorporated under the laws of *country B* merely because it is owned or controlled by citizens of *country A.* There are, however, limited exceptions to this rule, including regulations directed at the parent corporation (located and incorporated in *country A),* requiring that *uniform* accounting standards be used for all MNC operations; regulations requiring that certain information about foreign operations be disclosed to investors; and regulations requiring that tax returns of the entire MNC be consolidated. These laws may be important to the regulating country and should not interfere in the internal affairs of the host country.

The Restatement also recognizes that, in certain circumstances, regulation of foreign subsidiaries is necessary to further important national interests. The United States has regulated foreign subsidiaries to enforce trade sanctions in time of war or when it has felt the actions of another country threatened U.S. interests. The Restatement cautions that these actions should not be taken unless it is important for carrying out an essential national program, and the regulation will not conflict with the laws or policies of the host country. The Restatement specifically rejects asserting extraterritorial jurisdiction over "predominately local issues, such as industrial and labor relations, health and safety practices."

The framework provided by the Restatement invariably leads to conflicts with the foreign country sovereign right to regulate activities within its territory. The United States has been more willing than most countries to regulate extraterritorially (186) and not surprisingly, the Restatement attempts to present concrete guidelines for resolving the types of conflict that have arisen when the United States has enforced its extraterritorial laws and regulations.

The Restatement's approach to resolving disputes over extraterritorial jurisdiction is based on the longstanding international doctrine of comity. Comity captures in a single word a complex and ill-defined concept used by courts in setting limits on their extraterritorial powers. It has been defined by the U.S. Supreme Court as (94):

> ...neither a matter of absolute obligation on the one hand, nor one of mere courtesy and good will upon the other. . .it is the recognition which one nation gives to the legislative, executive, or judicial acts of another nation, having due regard both to international duty and convenience, and to the rights of its own citizens or of other persons under the protection of its laws.

U.S. courts have relied on the comity doctrine to decline jurisdiction to show respect for foreign sovereignty, protect parties' expectations in international commerce, and to avoid interference in foreign relations (175).

Elements of the principle of comity have been integrated into the Restatement's "rule of reasonableness," which can be used to decide whether an extraterritorial action is in accordance with international law. According to the rule, a nation should exercise extraterritorial jurisdiction only if: 1) it has a legal basis for exercising jurisdiction under the nationality or effects principle, and 2) it determines that it is reasonable to exercise jurisdiction in the particular situation. For example, if the United States wanted to regulate foreign subsidiaries operating in Latin America, it should consider the links between the business carried out by the foreign subsidiaries and the United States. The United States is less justified in regulating a foreign subsidiary engaged in purely local business transactions, or one that is owned partially by foreign nationals than it is in regulating one with significant business transactions with the United States and owned entirely by the parent company.[1]

The character of the activity to be regulated may also be relevant. For example, if the foreign subsidiary's main activity is building roads or hospitals under contract to the foreign government, U.S. legislation affecting this contract will interfere with the foreign government's sovereignty. Consideration should also be given to the expected impact of the regulation on current business practices and on whether reasonable commercial expectations will be disrupted.

Finally, the Restatement instructs the United States to evaluate the impact that the proposed legislation would have on the current international political, legal, and economic system and on the likelihood of direct conflicts with the other country's laws (6). These considerations involve balancing the competing interests of the countries involved directly in the situation, and the impact the decision will have on international economic and social discourse (136). Depending on the weight given to various factors, analyses using the rule of reasonableness could support two contradictory positions, providing for little predictability **(73).**

The Restatement claims that the rule of reasonableness is emerging as a principle of international law (6), but there is debate over this point in international legal circles (175). Even the U.S. Government has not endorsed the approach unconditionally, and might choose to exercise extraterritorial jurisdiction when the factors enumerated above appear to weigh against the decision (25). The rule of reasonableness is relevant to the debate because it reflects, to some degree, U.S. interpretation of extraterritorial jurisdiction and sets forth some of the factors that lead to disagreement in related disputes. It should be noted, however, that many other countries believe that U.S. extraterritorial jurisdiction does not extend as far as provided for in the Restatement 186).

A final issue not considered by the Restatement, but important in international economic and business policy, is national treatment. The U.S. Government often protests the actions of foreign governments when they give preferential treatment to their own national companies, placing U.S. foreign subsidiaries at a disadvantage.

[1] Other countries would object to the United States exercising jurisdiction on the basis of U.S. ownership of a corporation that is located and incorporated abroad (2),

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By passing U.S. legislation intended to control the operations of foreign subsidiaries of U.S. MNCs, and also expecting the host government to extend preferential treatment to those subsidiaries as if they were national companies, the U.S. Government may itself be perceived as a source of unfairness (25).

Extraterritorial Jurisdiction in the US. Courts

U.S. courts are concerned primarily with illegal conduct within the United States, but sometimes the courts apply U.S. law to acts occurring outside the country.[2] One area in which U.S. courts have been particularly active with respect to foreign corporations, including subsidiaries of U.S. companies, is in antitrust law. There are other areas of law in which U.S. courts struggle with the proper limits of extraterritorial jurisdiction over foreign subsidiaries; however, antitrust law has been particularly fertile and the doctrines developed by the courts are generalizable to other areas of judicial action.

The primary antitrust statute is the Sherman Act (15 U.S.C. § 1-7), which makes it illegal for an individual or corporation to enter into any agreement, conspiracy, or combination that restrains trade among the States or among foreign nations, or to take any action to monopolize trade (i.e., to control prices or preclude competition). The Federal Trade Commission Act (15 U.S.C. § 45 et. seq.) and the Clayton Act address other aspects of anticompetitive behavior. These three statutes have been called by the Supreme Court the "Magna Carta of Free Enterprise" (230).

The application of U.S. antitrust laws extraterritorially has not been without controversy, and has been opposed by a number of foreign governments (73,218). Opposition stems from the fact that antitrust law was originally unique to the American legal system. The United States was, therefore, prosecuting companies for actions that were legal in the countries in which they took place. Although a number of European countries have recently passed antitrust laws, few impose penalties as severe as those in the United States (104). Most controversial have been private antitrust suits brought by U.S. citizens. Because they are private, the U.S. Government cannot readily use diplomatic channels to ease the conflicts they engender (185).

In 1982, Congress amended the Sherman Act with the effect of constraining the extraterritorial reach of antitrust law. The changes were made in response to concern that U.S. businesses were being hindered from entering into international transactions because of uncertainty about the applicability of U.S. antitrust laws (234). Congress noted that there was a lack of consistency both among judicial interpretations and between the judiciary and the executive branch over the "quantum and nature of the effects required to create jurisdiction" (234). For example, while one court required conduct that "directly affect[s] the flow of foreign commerce into or out of this country" (221), another court reasoned that "it is probably not necessary for the effect on foreign commerce to be both substantial and direct as long as it is not *de minimus" (50).*

To remedy this situation, the amendments provided that a transaction between two foreign firms, even if U.S.-owned, would not be subject to U.S. antitrust laws unless there was a direct, substantial, or reasonably foreseeable effect on domestic commerce (15 U.S.C. § 6a, 15) (58). Absent a significant adverse effect, a foreign transaction that violates U.S. antitrust laws and involves U.S. companies or their subsidiaries is subject only to the laws of the country in which the business is conducted (234). In addition, Congress stated in the legislative history that the amendments were not designed to alter the right

[2] The court must decide that a case: 1) concerns conduct that is under the jurisdiction of U.S. law and 2) that it has jurisdiction over the defendants. This section addresses only issues of the former type ("subject jurisdiction") and not of the latter type ("personal jurisdiction").

of U.S. courts to "recognize the special international character of transactions" and to employ notions of comity to decline to exercise jurisdiction over a case, even when the antitrust act specifically gave the court the authority to prosecute the case (234).

The instruction on employing notions of comity gave U.S. courts the right to take into account diplomatic and political considerations in deciding whether to exercise jurisdiction, even when there is an effect on U.S. commerce. The factors that courts consider are (27,141 ,219):

1. the degree of conflict with foreign law or policy,
2. the nationality and allegiance of the parties and the principal places of the business of any corporations,
3. the extent to which enforcement in either country can be expected to achieve compliance,
4. the relative effect of the conduct on the United States as compared to other nations,
5. whether there was intent to harm the United States, and
6. the relative importance of the violations under U.S. law versus the law of the foreign country in which the conduct occurred.

Trade Embargoes and Economic Sanctions

Trade embargoes and other economic sanctions have been used by the United States in times of war to conserve U.S. resources, to cut off critical supplies to enemies, and to preserve neutrality (161). More recently, trade sanctions have been used to express opposition to domestic and foreign policies of other countries, e.g., violating human rights laws, supporting terrorism, or using military force within another country's borders (218).

A trade embargo or economic sanction is usually implemented after the President issues an Executive order, pursuant to congressional authority, announcing the sanctions and the reasons for them. The Executive order will often instruct an executive agency, e.g., the U.S. Department of Commerce or Treasury, to promulgate regulations to implement the sanctions. A trade embargo may prohibit all U.S. export trade with a certain country, or may be limited to certain goods, such as military equipment. Alternatively, the United States may halt all financial transactions with a country and may freeze its financial assets held within the United States. To make the embargo more effective, the United States sometimes orders U.S.-owned or -controlled foreign subsidiaries to cease trading with a targeted country (76). Several statutes authorize the President to take such action during peacetime.[3]

The Export Administration Act (EAA) (50 U.S.C. App. § 2401 et. seq.) permits extraterritorial export controls. The EAA authorizes the President to restrict the export of goods and technology that would "make a significant contribution to the military potential of another country" or prove detrimental to the national security of the United States, or to impose such restrictions as necessary to further "significant foreign policy goals" of the United States. (50 U.S.C. § 2402, 2404, 2405).

The EAA's extraterritorial provisions were first applied to limit the compliance of U.S.-controlled foreign subsidiaries with an Arab trade boycott of Israel, The antiboycott provision, however, applied only to transactions relating directly to "U.S. commerce," which occur when the foreign subsidiary acquires goods and services from a person in the United States to fill a *specific order* for a person outside the United States

[3]The Trading with the Enemy Act of 1917 (50 U.S.C. § 5(b)) authorizes the imposition of embargoes during times of congressionally declared war.

(15 C.F.R. § 769.1 (1991)). Foreign subsidiaries were also exempted if the national laws of their host country required compliance with the boycott, recognizing the host country's sovereign right to regulate commerce within its borders (218).

The second statute commonly used to impose economic sanctions is the International Emergency Economic Powers Act (IEEPA)(50 U.S.C. § 1701-1706).

Enacted in 1977, the IEEPA authorizes the President to act when faced with:

> . . . any unusual and extraordinary threat, which has its source in whole or substantial part outside the United States, to national security, foreign policy or the economy of the United States, if the President declares a national emergency with respect to such threat (50 U.S.C. § 1701).

The President is authorized to investigate, regulate, or prohibit certain financial transactions, such as transactions in foreign exchange, banking transactions, and property transfers. (50 U.S.C. § 1702). The IEEPA was used by President Carter in 1981 to freeze Iranian assets held by U.S. corporations or their foreign subsidiaries. In addition, President Carter prohibited all U.S. banks and their wholly owned foreign banking subsidiaries from engaging in financial transactions with Iran (218). In 1990, President Bush invoked the IEEPA, as well as the EAA, to impose comprehensive economic sanctions against Iraq.[4]

Under each of these statutes, the President may assume jurisdiction over a foreign subsidiary based on its ownership or control by a U.S. corporation or U.S. citizen (133).[5] However, this extraordinary power is available only during a national emergency or when foreign policy considerations make such action imperative (218).

Before issuing regulations under these statutes, the President must make a case that important U.S. interests are being threatened and no amount of compromise or negotiation can address the problem. Sanctions cannot be implemented under the EAA or the IEEPA until the President has consulted with Congress and, in the case of the EAA, with the affected industries. The EAA requires the President to conclude that (162):

1. export controls are likely to achieve the intended foreign policy purpose;
2. the United States can effectively enforce the sanctions;
3. the sanctions are consistent with U.S. foreign policy objectives;
4. the benefit to U.S. foreign policy objectives exceeds any adverse effects the sanctions will have on U.S. exports and international competitiveness, including the impact on the reputation of U.S. companies as reliable suppliers of goods; and
5. reasonable effort has been made to achieve the desired aim through negotiation or other means (50 App. U.S.C. § 2405).

There are comparable procedural requirements under the IEEPA (50 U.S.C. § 1703). Despite the limits on using these sanctions, a number of foreign countries contend that the United States does not have the legal right to exercise jurisdiction over foreign incorporated subsidiaries under any circumstances (59).

In response to these objections, the United States has, at times, controlled the actions of U.S. -owned foreign subsidiaries by regulating the behavior of the U.S. citizens or domestic corporations responsible for the operations and corporate policies of the subsidiaries. This approach is less controversial because the right to exercise some control over private citizens, whether they

[4] See also 55 FR 31803, 55 FR 31805, 55 FR 33089, and 55 FR 33091.

[5] The use of control as a test for exercising jurisdiction over separate corporate entities is also found in domestic law. See e.g., 47 U.S.C. § 2 19(a), 49 U.S.C. § 310, and 26 U.S.C. § 825c. See also reference number 19.

reside at home or abroad, is recognized under international law, as is the right to regulate domestic corporations.

The effectiveness of indirect controls depends on the situation. For example, the 1970 regulations that implemented trade sanctions against Rhodesia in support of a United Nations effort to promote self-determination for the black majority population (The United Nations Participation Act, 22 U.S.C. §287 (1979)) were worded very broadly to capture almost all possible transactions. The regulations prohibited U.S. citizens and residents who were officers, directors, and principal managerial personnel of foreign subsidiaries from *authorizing* or *permitting the* foreign subsidiary to engage in a prohibited transaction with Rhodesia. A U.S. citizen could be in violation of the regulations even if he did not actively engage in the transaction (218).

The Rhodesian regulations contrast with similar regulations implemented during the 1980 boycott of the Moscow Olympics, under which U.S. citizens and domestic corporations were prohibited from "actually" authorizing, arranging, directing, or participating in a prohibited transaction (15 C.F.R. § 385.2 (d)(3) (1982)) (218). These terms imply that direct involvement was a necessary element for attributing liability to a U.S. citizen or corporation. This left open the possibility of U.S.-owned foreign subsidiaries engaging in business transactions related to the Moscow Olympics.

The indirect approach to regulating foreign operations of U.S. MNCs does not interfere directly with another country's sovereign right to control the actions of corporations operating within its borders. Wholly owned subsidiaries that are managed almost exclusively by foreign nationals may escape regulation. However, even indirect regulations may cause international tension because U.S.-owned foreign subsidiaries may feel pressure to support U.S. policy or may be directed to do so by the corporate parent, even if technically exempted from the regulations.

The Foreign Corrupt Practices Act

In the examples discussed above, foreign subsidiaries were caught in disputes between the United States and foreign governments. In some cases, the actions of U.S.-owned foreign subsidiaries themselves may prompt regulation. The prime example is the Foreign Corrupt Practices Act (FCPA) of 1978, which addresses the bribery of foreign officials by U.S. MNCs. The FCPA is one of the few pieces of legislation that requires foreign operations of a U.S. MNC to comply with the same standards for corporate behavior that govern domestic companies. However, the FCPA does not regulate the foreign subsidiary directly, but instead imposes liability on a U.S. domestic corporation or it officers, directors, stockholders, agents, or employees if they knowingly bribe a foreign official or authorize a payment that they know will be used as a bribe (15 U.S.C. § 78dd-1, 78dd-2).

In 1977, the U.S. Securities and Exchange Commission (SEC) revealed that approximately 400 U.S. companies, including 117 large and prominent corporations, had used secret "slush funds" to bribe or make questionable payments totaling over $300 million to foreign officials (26,231). Twenty-two pharmaceutical and health care companies admitted to making total payments of more than $31.4 million (210).[6] Most of these transactions occurred in other countries, and according to some corporations, were necessary to compete there.

Congress, however, concluded that such bribery could lead to public scandals with serious foreign policy implications. According to a House of Representatives report, the 1976 revelation that Lockheed Corp. had made significant payments to certain government officials in

[6] See generally reference numbers 233 and 240.

Japan "shook the Government of Japan to its political foundations and gave opponents of close ties between the United States and Japan an effective weapon to drive a wedge between the two nations" (233). Alleged payments by U.S. corporations to certain officials in the Italian Government were judged to have "jeopardized U.S. foreign policy. . with respect to the entire NATO alliance" (233).

Foreign policy implications were not, however, the only concern. Congress believed that corporate bribery offended the moral expectations and values of the American public and distorted the competitive market because firms that were too inefficient to compete on price, quality, and service were able to compete with bribes. In addition, exposure of these illegal payments could lead to costly lawsuits, cancellation of contracts, and even appropriation of assets, thereby adversely affecting U.S. investors and destroying investor confidence in U.S. corporations (122, 233).

The FCPA was passed despite testimony by the U.S. Department of State that it would be "presumptuous" and "counterproductive" to impose U.S. standards in countries with differing histories and cultures, and despite opposition from business leaders who claimed they would no longer be able to compete in certain countries (26). The legislation attacked the problem of corruption on two fronts: 1) accounting practices for public corporations were changed to prevent companies from hiding such payments and 2) bribery of foreign officials by any U.S. citizen, resident, or U.S. domestic corporation was made a criminal act.

Under the latter provision, U.S. citizens and U.S. corporations, their directors, officers, employees, agents, or stockholders are prohibited from offering or promising money or anything of value to any other person, knowing that all or part of the gift would be offered, given, or promised to any foreign official to influence an official act or decision (15 U.S.C, § 78dd-2(2),(4)). A payment is illegal if it "induce[s] the recipient to misuse his official position" (66). The FCPA permits payments designed to facilitate routine governmental actions (so-called "grease payments") as may be necessary to obtain permits, licenses, visas, work orders, phone service, power, and water supply. (15 U.S.C. § 78dd-l(b),(f)(3)(A), 78dd-2(b),(h)(4)). In addition, a U.S. citizen or corporation is not guilty if he or she makes a payment without knowing that it will be used improperly. However, this knowledge will be imputed if the circumstances warrant (66):

> . . .a knowledge of the facts will be inferred where the defendant had notice of the high probability of the existence of the fact and failed to establish an honest, contrary belief.

Violations of the FCPA are punishable by substantial monetary penalties and in certain cases, imprisonment (15 U.S.C. § 78dd-l(a), 78dd-2(b), 78dd-l(g)) (66).

The original bill introduced into the House of Representatives applied the bribery provisions to U.S.-owned foreign subsidiaries directly, because Members believed that failure to include them would create a "massive loophole" through which questionable payments could be made (233). Congress eventually rejected direct regulation of corporate subsidiaries operating abroad because of the "inherent jurisdictional, enforcement, and diplomatic difficulties raised by inclusion of foreign subsidiaries of U.S. companies in the direct prohibitions of the bill" (232). However, by allowing courts to impute knowledge to a company or individual if the circumstances warrant, the FCPA is designed to apply to most transactions.

Despite the fact that the FCPA has such broad extraterritorial reach, it has engendered little international opposition. One reason might be that it applies only to U.S. nationals and domestic corporations, over which the United States clearly has jurisdiction. In addition, almost every country has national laws prohibiting bribery, extortion, kickbacks, and other such payments (204). At the time the FCPA was passed, the

Organization for Economic Cooperation and Development, which consists of the United States, Japan, and most Western European countries, issued voluntary guidelines for MNCs including a statement that MNCs should not bribe or make any other improper payments or illegal political contributions to public officials (49). The United Nations was also considering a resolution condemning corrupt practices in international commerce and calling for unilateral and multilateral action to end such practices (204). Therefore, despite the fact that many countries were not prepared to take unilateral action against their MNCs, there was international consensus that bribery of foreign officials by multinational enterprises should be controlled.

Extraterritorial Regulations Relating to the Health and Safety of Foreign Nationals

The Restatement leaves activities that primarily affect the health, safety, and welfare of the national population in the exclusive domain of national laws. Attempts to regulate these domestic issues would impinge on the sovereignty of the host country to control activities within its borders (6).

There are few examples of U.S. legislation that force foreign subsidiaries to comply with domestic health, safety, and labor standards when operating abroad and those that do exist are mostly designed to protect U.S. citizens. For example, the United States recently extended the protections afforded by age-discrimination laws to American citizens working for U, S.-owned or -controlled foreign subsidiaries (29 U.S. C, § 623(h)) (43,293),

Although it may be risky to draw conclusions about the limits of U.S. extraterritorial jurisdiction relating to health and safety from the lack of such regulations, this lack and some related history cannot be ignored. In the late 1970s, for example, strong evidence linked the aggressive marketing of infant formula by subsidiaries of U.S. companies in developing countries to an increase in infant mortality. (See ch. 6.) Legislation was introduced in the House of Representatives to regulate these marketing practices. The legislation did not pass and instead, Members of Congress asked the World Health Organization to convene an international meeting *on* the issue (250). The injuries caused by the marketing practices primarily affected foreign nationals, many in developing countries. Congress deferred to an international forum rather than trying to change the situation through U.S. law.

Deference to an international forum is consistent with the principles of international law. To justify an exercise of *unilateral* extraterritorial jurisdiction, the United States must have a strong foreign policy interest that cannot be served by any alternative action. Under the effects principle, the action the United States seeks to regulate must have an adverse effect within the United States. This is sometimes further limited to foreign actions that violate criminal or civil laws of countries with developed legal systems (59,73). In the case of the FCPA, Congress recognized that bribery of foreign officials could lead to scandals that could both damage foreign relations and have domestic financial implications if investors lost faith in U.S. companies. In addition, bribery is almost universally seen as a crime.

The U.S. interest in promoting the health and safety of foreign nationals is not analogous to preventing bribery, and it is difficult to find support under international law for exercising extraterritorial jurisdiction over foreign drug labeling. The United States has limited authority, if any, to regulate the subsidiaries under the effects principle. This study assumes that U.S. corporations are in compliance with national laws and are, on the whole, providing information that is at least as good as, or better than, information provided by other companies. There is no evidence that U.S. companies are violating laws or acting in a manner that could lead to sanctions or other actions that could erode investor confidence. This leaves the nationality principle; however, the United States is virtually alone in its position that foreign subsidiaries incorporated in foreign countries can be considered nationals of the United States for purposes of U.S. laws.

The justification for exercising extraterritorial jurisdiction over pharmaceutical labeling would be a moral interest in having U.S. pharmaceutical companies lead the way in providing comprehensive and informative labeling, as defined by U.S. standards. This probably does not reach the “major national interest” required by U.S. precedents and the Restatement. In addition, the United States’ interest must be weighed against the factors that do not support U.S. jurisdiction, primarily the fact that many developing countries have laws regulating pharmaceutical labeling, and the U.S. law would primarily protect foreign citizens. These countervailing factors do not necessarily preclude all forms of extraterritorial jurisdiction, but they cannot be ignored.

SUMMARY

From a business perspective, MNCs operate as unified corporations, but their actions in each country are governed almost entirely by host country laws, and to only a limited extent by the laws of the home country. This is consistent with the main principle of international law, which recognizes the sovereign right of each country to regulate activities within its borders. This right is not absolute, however, and the United States has assumed extraterritorial jurisdiction over activities in foreign countries in a number of cases, more than the rest of the world has generally approved of.

Many examples of U.S. extraterritorial jurisdiction over foreign subsidiaries concern trade and economic sanctions implemented during times of war or international tensions. Under these laws and regulations, the United States is controlling foreign subsidiaries of U.S. companies because their actions may undermine important foreign policy goals. In a sense, the subsidiaries become pawns in an international dispute rather than being the focus of the action.

The debate over extraterritorial jurisdiction revolves around determining to what extent a U.S. foreign policy interest or a domestic interest is significant enough to support extraterritorial action. The only obvious precedent for regulating drug labeling by foreign subsidiaries is the Foreign Corrupt Practices Act. In the FCPA, the behavior of foreign subsidiaries was the focus of the legislation because bribery had adverse impacts on U.S. foreign relations, as well as domestic interests. The FCPA does encroach on the sovereignty of foreign nations because it addresses bribery of foreign officials. It does not, however, directly regulate the actions of the foreign subsidiaries, and limits the criminal penalties to U.S. corporations or U.S. citizens. Moreover, it does not conflict with other nations’ laws because most counties forbid bribery. There are significant problems applying this precedent to the issue of drug labeling, however.

Direct regulation of the drug labeling practices of U.S.-controlled foreign subsidiaries would be a bold step beyond current U.S. interpretations of international law. Although many developing countries appear committed to improving the labeling of pharmaceuticals, it is not known whether the governments of such countries would welcome *unilateral* action by the United States. Even indirect regulation of U.S. subsidiaries would be an extraordinary approach to the problem of inadequate labeling. Although the United States has amoral interest in ensuring that its corporations do not cause injury to any consumer, regardless of citizenship, the United States cannot ignore the sovereign right of the foreign country to set its own consumer safety standards. Problems related to extraterritorial jurisdiction could be avoided through a collaborative effort with developing countries, or by including in any legislation a provision for national regulatory authorities to reject U.S. attempts to control foreign labeling, in whole or in part.