INTERNATIONAL REGULATION OF PHARMACEUTICALS: A WHO INTERNATIONAL CODE OF CONDUCT FOR THE MARKETING OF PHARMACEUTICALS?

I. INTRODUCTION

The international pharmaceutical trade is important to both exporting and importing countries. Exporting countries are concerned with maintaining and further expanding their foreign pharmaceutical markets.[1] Importing countries, especially developing or less developed countries (LDC's),[2] are concerned with the price and quality of drugs that they import.[3] Poor and newly independent states[4] that have no pharmaceutical industry of their own are the most vulnerable in the international pharmaceutical trade.[5] They must rely on exports from the more developed nations. The likelihood of these LDC's importing drugs of unacceptable quality is high[6] because they usually buy at the lowest prices available and have no reliable quality control systems of their own.[7] These LDC's are also greatly disadvantaged in their negotiations with the multinational corporations (MNC's)[8] that manufacture pharmaceutical products.[9] The World Health Organization (WHO) has

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1. D. KAY, THE INTERNATIONAL REGULATION OF PHARMACEUTICAL DRUGS 23 (1976).

2. Stanley, *International Codes of Conduct for MNC's: A Skeptical View of the Process*, 30 AM. U. L. REV. 973, 974 (1981).

3. KAY, *supra* note 1, at 37.

4. The newly independent states of Africa and Asia are examples. These states share serious health needs and create a large market for pharmaceutical products. They have little foreign exchange available to purchase quality drug products and few inspectors to check drug quality. *Id.*

5. *Id.*

6. *Id.*

7. *Id.*

8. "MNC" is the most common term used in the United States to describe companies that operate in many countries. Other terms include: transnational enterprise (TNE), multinational enterprise (MNE), and transnational corporation (TNC). Stanley, *supra* note 2, at 973 n.1.

For further information concerning the characteristics of MNC's, see Vagts, *The Global Corporation and International Law*, 6 J. INT'L L. & ECON. 247, 247-48 (1972); Behrman, *The Multinational Enterprise: Its Initiatives and Governmental Reactions*, *id.* at 215, 216-20; Note, *Taming the Transnationals: An Examination of Structural Solutions to Regulation of Transnational Enterprise and the Theoretic Problem of Sovereignty*, 7 W. ST. U.L. REV. 187, 188-89 (1980); Von Mehren & Gold, *Multinational Corporations: Conflicts and Controls*, 11 STAN. J. INT'L STUD. 1, 1-4 (1976).

9. Note, *International Regulation of Pharmaceuticals: The Role of the World Health*

adopted international regulatory programs[10] that attempt to rescue LDC's from the dangers surrounding the purchase of low quality pharmaceuticals.[11] Both developed and developing countries, however, have expressed their dissatisfaction with the application[12] and adequacy of these programs.[13]

This Note will discuss the current major programs in the international regulation of pharmaceuticals. Discussion will also focus on the recent proposals for regulation, with particular emphasis on an international code of conduct for the marketing of pharmaceuticals. After examining how a code of conduct can become customary international law, this Note predicts the likelihood of the adoption and the legal effect of an international code for the marketing of pharmaceuticals. Finally, this Note suggests a solution for LDC's that implicates product liability law.

II. PAST EFFORTS IN THE INTERNATIONAL REGULATION OF PHARMACEUTICALS

Although other governmental and nongovernmental international organizations[14] participate in the international regulation of drug products, the World Health Organization (WHO)[15] is the prin-

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Organization, 23 VA. J. INT'L L. 331, 332 (1983).

For an analysis of LDC's reaction to MNC's in general, see Note, *Multinational Corporations and Lesser Developed Countries—Foreign Investment, Transfer of Technology, and the Paris Convention: Caveat Investor*, U. DAYTON L. REV. 105, 109-13 (1980); Behrman, *supra* note 8, at 224-28; Von Mehren & Gold, *supra* note 8, at 4-8; Vagts, *supra* note 8, at 253-54.

10. *See, e.g.*, Good Practices in the Manufacture and Quality Control of Drugs, World Health Organization, *Official Records*, No. 226, Annex 12 (1975); Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, *id.*; Action Programme on Essential Drugs, World Health Assembly, Report by the Executive Board Ad Hoc Committee on Drug Policies on Behalf of the Executive Board, W.H.O. Doc. A35/7 (1982).

11. KAY, *supra* note 1, at 37-38.

12. Complaints concerning the application of these programs include expense, uneven national inspection, and lack of support from pharmaceutical MNC'S. *Id.* at 38-39, 45, 46-47.

13. Complaints concerning the adequacy of these programs stem from the fact that the programs do not cover all aspects of drug manufacture and distribution. For an example of one program which does not cover packing, transit, shelf life, and storage, see *id.* at 47.

14. For a list of various governmental and nongovernmental organizations which participate in pharmaceutical regulation, see *id.* at 33.

For an example of recent governmental participation, see Wassermann, *Annapolis Conference of Drug Registration Authorities*, 15 J.W.T.L. 363 (1981).

15. WHO is a specialized agency established within the terms of article 57 of the Charter of the United Nations. CONSTITUTION OF THE WORLD HEALTH ORGANIZATION, in BASIC DOCUMENTS, preamble (33d ed. 1983) [hereinafter cited as WHO CONST]. WHO's objective is the "attainment by all peoples of the highest possible level of health." *Id.* art. 1.

WHO is composed of the World Health Assembly (WHA), the Executive Board, and the Secretariat. *Id.* art. 9. WHA, which consists of all the members of WHO each represented

cipal assemblage dealing with the regulation of pharmaceuticals. WHO's efforts in drug regulation began in the 1950's.[16] WHO did not, however, develop its major programs until late in the 1960's and through the 1970's.[17] These major programs are: Good Practices in the Manufacture and Quality Control of Drugs,[18] Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce,[19] and Action Programme on Essential Drugs.[20]

A. *Good Practices in the Manufacture and Quality Control of Drugs*

WHO intended that Good Practices in the Manufacture and

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by up to three delegates, determines WHO policy. *Id.* arts. 10, 11, 18(a). It has the authority to adopt conventions, agreements, and certain regulations and make recommendations to member countries. *Id.* arts. 19, 21, 23. The Executive Board consists of thirty persons each elected to serve for three years. *Id.* arts. 24, 25. It gives effect to the decisions and policies of WHA. *Id.* art. 28(a). The Secretariat is composed of the Director-General, who is appointed by WHA, and any technical and administrative staff that WHO may need. *Id.* arts. 31, 32. The Director-General is the chief technical and administrative officer of WHO. *Id.* art. 31.

Although WHO headquarters is located in Geneva, a great amount of its work occurs in its six regional offices or organizations. For the composition and functions of the regional organizations, see *id.* arts. 44-54.

For further information on the background and work of WHO, see F. Brockington, World Health 149-74 (3d ed. 1975); Gutteridge, *The World Health Organization: Its Scope and Achievements*, 37 Temp. L.Q. 1 (1963); Note, *International Regulation of Pharmaceuticals: The Role of the World Health Organization*, 23 Va. J. Int'l L. 331, 340-46 (1983) [hereinafter cited as *International Regulation*].

16. Kay, *supra* note 1, at 35.

In 1951, the Executive Board called for a meeting of various countries' drug authorities to discuss uniform methods for the control of drugs in international commerce. E.B. Res. 7.R79 (1951), *reprinted in* 1 World Health Organization, Handbook Of Resolutions And Decisions Of The World Health Assembly And The Executive Board 130 (1973) [hereinafter cited as 1973 Handbook Of Resolutions].

17. WHA requested the development of Good Practices in the Manufacture and Quality Control of Drugs in 1967. W.H.A. Res. 20.34 (1967) 1 1973 Handbook Of Resolutions, *supra* note 16, at 132.

WHA urged member states to adopt the Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce in 1969. W.H.A. Res. 22.50 (1969) *id.* at 133.

In January 1978, the Executive Board appointed an ad hoc committee to consider the feasibility of the Action Programme on Essential Drugs. World Health Organization, *Official Records*, No. 244, 30 (1978).

18. World Health Organization, *Official Records*, No. 226, Annex 12 (1975) [hereinafter cited as GMP].

19. World Health Organization, *Official Records*, No. 226, Annex 12 (1975) [hereinafter cited as Certification Scheme].

20. World Health Assembly, Action Programme on Essential Drugs: Report by the Executive Board Ad Hoc Committee on Drug Policies on Behalf of the Executive Board, W.H.O. Doc. A35/7 (1982) [hereinafter cited as APED].

Quality Control of Drugs (Good Manufacturing Practices Act or GMP)[21] have three major purposes:

> (1) to serve as guidelines for drug manufacturers in their own quality control efforts;
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> (2) to serve as guidelines for national health authorities in their monitoring of drug manufactures and in drafting national regulations; and
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> (3) to serve in the case of imported drugs as a set of criteria by which the importing country . . . is assured that the drugs it imports have been properly manufactured in the country of origin.[22]

GMP serves as a guideline in many major phases of the drug manufacturing process.[23] It first sets forth educational[24] and prac-

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21. WHO began work on GMP in 1967. In May 1967, WHA requested the Director-General to formulate principles for quality control procedures to be used in good manufacturing practice. W.H.A. Res. 20.34 (1967) 1 1973 HANDBOOK OF RESOLUTIONS, *supra* note 16, at 132. Between 1967 and 1969, the Director-General, in consultation with the WHO Expert Committee on Specifications for Pharmaceutical Preparations, drafted recommendations on GMP. KAY, *supra* note 1, at 42. For the unrevised GMP, see World Health Organization, *Official Records*, No. 176, Annex 12 (1969). In July 1969, WHA recommended that member states adopt the unrevised GMP. W.H.A. Res. 22.50 (1969) 1 1973 HANDBOOK OF RESOLUTIONS, *supra* note 16, at 133. In May 1970, WHA requested member states to inform the Director-General of their steps taken to implement the unrevised GMP and to submit suggestions for improvement on the text. W.H.A. Res. 23.45 (1970) *id.* The WHO Expert Committee on Specifications for Pharmaceutical Preparations received the replies of member states and recommended textual changes. World Health Organization, *Official Records*, No. 197, 148 (1971). In 1974, the Committee adopted a final revised text. *Id.*, No. 221, 119 (1974). In May 1975, WHA adopted the revised text of GMP and recommended that member states apply the revised provisions. W.H.A. Res. 28.65 (1975) 2 World Health Organization, HANDBOOK OF RESOLUTIONS AND DECISIONS OF THE WORLD HEALTH ASSEMBLY AND THE EXECUTIVE BOARD 114 (5th ed. 1983) [hereinafter cited as 1983 HANDBOOK OF RESOLUTIONS]. For the revised GMP text, see GMP, *supra* note 18.

22. KAY, *supra* note 1, at 42.

23. GMP, *supra* note 18, § 1, para. 4.

GMP defines "manufacturing" as "[a]ll operations involved in the production of a drug, including processing, compounding, formulating, filling, packaging, and labelling." *Id.* § 2.

GMP defines "drug" as

> [a]ny substance or mixture of substances that is manufactured, sold, offered for sale, or represented for use in (1) the treatment, mitigation, prevention, or diagnosis of disease, an abnormal physical state, or the symptoms thereof in man or animal; or (2) the restoration, correction, or modification of organic functions in man or animal.

Id.

24. "Experts . . . should possess the qualifications of scientific education and practical experience required by national legislation." *Id.* § 3, para. 1. This section of GMP also specifies appropriate courses of study for an expert's education. *Id.*

tical experience[25] qualifications for experts supervising the manufacture and quality control of drugs.[26] GMP next describes suitable premises for the manufacture[27] and storage[28] of drug products. It also requires that manufacturing equipment be designed and maintained to facilitate use and minimize contamination.[29] GMP provides for sanitation[30] by suggesting the availability of a written sanitation program.[31] Starting materials[32] should be properly labeled, stored, sampled, and tested.[33] The guidelines for manufacturing operations are the most extensive.[34] They include requirements for personnel,[35] sanitation,[36] equipment and containers,[37] manufacturing procedure documents,[38] and batch manufacturing records.[39] GMP makes suggestions for proper packaging and labeling of drugs, including information to be properly displayed on labels.[40] It also sets forth the duties of the quality control department and laboratory.[41] Finally, GMP provides for the adequate maintenance of distribution records[42] and the proper receipt of and response to complaints regarding drug quality.[43]

WHO adopted these GMP provisions as recommendations because it intended GMP to serve as a guideline.[44] Recommenda-

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25. GMP suggests that experts undergo a preparatory period during which they exercise their duties under professional supervision. *Id.*

26. *Id.*

27. *Id.* § 4.1.

28. *Id.* § 4.2.

29. *Id.* § 5.

30. GMP does not define "sanitation," but it does specify that the manufacturing premises should be "clean and free from accumulated waste, orderly, and free from vermin." *Id.* § 6, para. 1.

31. *Id.* § 6.

32. GMP defines "starting materials" as "[a]ll substances, whether active or inactive or whether they remain unchanged or become altered, that are employed in the manufacture of drugs." *Id.* § 2.

33. *Id.* § 7.

34. *Id.* § 8.

35. *Id.* § 8.4.

36. *Id.* §§ 8.1, 8.3. *See also supra* note 30.

37. *Id.* § 8.2.

38. *Id.* § 8.5.

39. *Id.* §§ 8.6, 8.7.

GMP defines "batch" as "[a] quantity of any drug produced during a given cycle of manufacture." *Id.* § 2.

40. *Id.* § 9.

41. *Id.* § 10.

42. *Id.* § 12.

43. *Id.* § 13.

44. KAY, *supra* note 1, at 44.

tions of the World Health Assembly (WHA)[45] are not legally binding on member states.[46] In addition to GMP's nonbinding effect, WHO intended the provisions to be somewhat ambiguous.[47] This ambiguity facilitates compliance by member countries, especially those developing countries moving into pharmaceutical production.[48] As these GMP recommendations can only be enforced by those national authorities that choose to adopt them,[49] the developing countries prefer a more reliable method of ensuring quality drug imports.[50] In order to allay the concerns of developing countries, WHO pursued a certification scheme for pharmaceutical products.[51]

B. *Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce*

WHO intended that the Certification Scheme on the Quality

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45. "The Health Assembly shall have authority to make recommendations to Members with respect to any matter within the competence of the Organization." WHO Const, *supra* note 15, art. 23.

WHA also has "authority to adopt conventions or agreements with respect to any matter within the competence of the Organization." *Id.* art. 19. Each member must notify the Director-General within eighteen months of action taken to accept the convention or provide the Director-General with reasons for its non-acceptance. *Id.* art. 20.

WHA may also adopt regulations concerning "standards with respect to the safety, purity and potency of biological, pharmaceutical and similar products moving in international commerce. . . ." *Id.* art. 21. WHA regulations come into force for all member states except for those that notify the Director-General of their rejections or reservations within a specified time. *Id.* art. 22.

These procedures for the adoption of conventions, agreements, and regulations have been viewed as a great improvement on the slow and uncertain ratification procedures employed by other agencies. Codding, *Contributions of the World Health Organization and the International Civil Aviation Organization to the Development of International Law*, 1965 Am. Soc'y Int'l L. Proc. 147-48.

46. Kay, *supra* note 1, at 44.

47. For example, GMP recommends that experts have the "scientific education and practical experience required by national legislation." GMP, *supra* note 18, § 3, para. 1. It also recommends that "[m]anufacturing premises should be maintained in accordance with sanitary standards issued by the appropriate health authority." *Id.* § 6. These recommendations leave extensively different national policies untouched. Kay, *supra* note 1, at 44.

GMP is also ambiguous because it fails to define major terms, such as "sanitation." *See supra* note 30. GMP also states that an "adequate number of technically trained personnel should be available to carry out the manufacturing and quality control operations. . . ." GMP, *supra* note 18, § 3, para. 3. It fails, however, to specify what constitutes an "adequate number."

48. Developing states lack the regulatory facilities of the more developed nations. As these developing states slowly move into pharmaceutical production, they will rely on GMP in setting their national policies. These countries will use GMP as a guideline in drafting their own GMP codes. Kay, *supra* note 1, at 45.

49. *Id.*

50. *Id.*

51. *Id.*

of Pharmaceutical Products Moving in International Commerce (Certification Scheme)[52] serve two major purposes. The Certification Scheme is to assure importing countries that the imported drug product is "authorized for sale or distribution within the exporting Member State . . . ."[53] It also assures importing countries that the manufacturer complies with GMP.[54]

The Certification Scheme provides for certification of pharmaceutical products[55] and exchange of information concerning defective products.[56] Upon the request of an importing country, the competent authority[57] of the exporting country certifies a pharmaceutical product by issuance of a Certificate of Pharmaceutical Products.[58] The Certificate of Pharmaceutical Products certifies that the product is authorized for sale within the exporting state and that the manufacturer complies with GMP.[59] The competent health authority of the importing country then decides whether to allow sale or distribution of the product within its borders.[60] The manufac-

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52. The development of the Certification Scheme closely paralleled the development of GMP. In July 1969, WHA recommended that member states adopt the then unrevised Certification Scheme. W.H.A. Res. 22.50 (1969) 1 1973 HANDBOOK OF RESOLUTIONS, *supra* note 16, at 133. For the text of the unrevised Certification Scheme, see World Health Organization, *Official Records*, No. 176, Annex 12 (1969). In May 1970, WHA requested member states to inform the Director-General of their steps taken to implement the Certification Scheme and to submit suggestions for improvement on the text. W.H.A. Res. 23.45 (1970) 1 1973 HANDBOOK OF RESOLUTIONS, *supra* note 16, at 133. In 1972, WHA received several comments from member states concerning technical and administrative aspects of the Certification Scheme. World Health Organization, *Official Records*, No. 205, 153 (1973). The exporting countries and pharmaceutical manufacturers resisted the original requirements for batch certification. They argued that batch certification would be expensive and surpass the capabilities of the national quality control facilities. KAY, *supra* note 1, at 46. In 1973, WHA prepared a draft revised Certification Scheme, which corrected many of the difficulties with batch certification. WHA adopted the revised Certification Scheme in May 1975. W.H.A. Res. 28.65 (1975) 2 1983 HANDBOOK OF RESOLUTIONS, *supra* note 21, at 114. For the revised Certification Scheme text, see *supra* note 19. By the end of 1981, seventy-one member states had agreed to participate in the Certification Scheme. BIENNIAL REPORT OF THE DIRECTOR-GENERAL, THE WORK OF WHO 1980-1981, 86 (1982) [hereinafter cited as BIENNIAL REPORT].

53. Certification Scheme, *supra* note 19, Part I § 3(a).

54. *Id.* Part I § 3(b).

55. *Id.* Part I.

A pharmaceutical product is "any medicine in its finished dosage form, intended for human use, that is subject to control by legislation in the exporting Member State and in the importing Member State." *Id.* Part I § 1.

56. *Id.* Part II.

57. The Certification Scheme does not define "competent authority," which is used throughout the recommendation.

58. Certification Scheme, *supra* note 19, Part I § 2.

59. *Id.* Part I § 3(a), (b).

60. *Id.* Part I § 2.

turer or health authority of the exporting country may also issue certificates to individual batches of products.[61]

Upon its discovery of a quality defect[62] in imported drug products, the importing country is to notify the exporting country's authority about the incident with a "request to institute inquiries."[63] Conversely, the exporting country's health authority should notify the importing country's authority about any serious quality defects it may discover.[64] Each participating member state must police its own health authority and pharmaceutical industry to ensure that its health authority employs proper testing procedures,[65] that its drug industry complies with GMP requirements,[66] that its authority conducts appropriate investigations,[67] and that its health authority inspectors are appropriately qualified.[68]

As with GMP, WHO adopted the Certification Scheme as a recommendation, wholly nonbinding on member states.[69] Some authorities view this scheme as an important first step in the direction toward the international registration of pharmaceuticals.[70] Other authorities, however, have identified certain problems that the scheme does not address.[71]

A major problem is that some countries[72] do not require registration of drugs produced for export. These countries cannot attest that their products are authorized for domestic sale.[73] Addi-

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61. *Id.* Part I § 4.

62. The Certification Scheme does not define "quality defect," but it does state that notification is necessary when the quality defect is "considered to be of a serious nature . . . not attributable to local conditions and circumstances. . . ." *Id.* Part II § 2.

63. *Id.*

64. *Id.*

65. *Id.* Part III § 2(a).

66. *Id.* Part III § 2(b).

67. *Id.* Part III § 2(c).

68. *Id.* Part III § 2(d).

69. *See supra* note 45.

70. Wassermann, *WHO Pharmaceutical Certification Scheme*, 10 J.W.T.L. 185, 187 (1976).

71. KAY, *supra* note 1, at 47.

72. For example, the United Kingdom, Switzerland, France, and Italy. Drugs produced for export in these major drug exporting states are exempted from national regulatory requirements. *Id.* at 46.

73. *Id.* at 47.

The United States can attest that its drug products are authorized for domestic sale. United States drug establishments which manufacture, prepare, or process drugs are "required to register and to submit a list of every drug in commercial distribution. . . ." 21 C.F.R. § 207.20(a) (1984). Furthermore, "[e]very foreign drug establishment whose drugs are imported . . . into the United States must also comply with these drug listing requirements." *Id.* § 207.40(a).

tionally, quality inspection by national authority is irregular and may not be a government responsibility.[74] The Certification Scheme fails to make provision for transportation, storage, or shelf life which may cause quality defects in drugs.[75] WHO, however, did not cease its efforts with the Certification Scheme, but moved forward to establish a more comprehensive program for regulation.[76]

C. *Action Programme on Essential Drugs*

In February 1981, WHO established the Action Programme on Essential Drugs (APED),[77] a more comprehensive program for regulation, which includes the Certification Scheme. APED assists nations in "increasing the availability and utilization of drugs at the lowest possible cost for primary health care, particularly through the formulation and implementation of national drug policies."[78]

APED enumerates the steps necessary for the elimination and prevention of disease through drugs.[79] The first step is to determine the health care needs of a country,[80] choose the drugs that

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74. KAY, *supra* note 1, at 47.

75. *Id.*

76. APED, *supra* note 20.

77. *Id.*

WHA first envisioned APED in May 1975, when it requested the Director-General "to develop means by which the Organization can be of greater direct assistance to Member States in . . . advising on the selection and procurement . . . of essential drugs of established quality corresponding to their national health needs. . . ." W.H.A. Res. 28.66 (1975) 2 1983 HANDBOOK OF RESOLUTIONS, *supra* note 21, at 110.

In January 1978, the Executive Board also called upon the Director-General to "appeal to governments and the pharmaceutical industry to participate in WHO's action programme of technical cooperation aimed at making available to governments of the less developed countries essential drugs and vaccines. . . ." E.B. Res. 61.R17 (1978) *id.* at 111. The Executive Board also appointed an ad hoc committee to consider the feasibility of a formal Action Programme on Essential Drugs. World Health Organization, *Official Record*, No. 244, 30 (1978).

In May 1978, WHA further urged the Director-General to "submit . . . a comprehensive action programme . . . aimed at fostering technical cooperation among developing countries. . . ." W.H.A. Res. 31.32 (1978) 2 1983 HANDBOOK OF RESOLUTIONS, *supra* note 21, at 112. In May 1979, WHA again requested the Director-General "to establish a special programme on essential drugs . . ." and urged member states "to participate in the action programme on essential drugs. . . ." W.H.A. Res. 32.41 (1979) *id.*

In conformity with the preceding resolutions, WHO formally established APED in February 1981. BIENNIAL REPORT, *supra* note 52, at 88. For a discussion of regional participation in APED, see *id.* at 88-90.

78. BIENNIAL REPORT, *supra* note 52, at 88.

79. APED, *supra* note 20, at 6, para. 27, *cited in International Regulation, supra* note 15, at 351.

80. *Id.*

are essential to these health care needs,[81] and estimate the quantities of drugs required.[82] The second step is to assist a country in developing an adequate drug supply system.[83] The third step is to guarantee the proper use of drugs by providing information to users and suppliers.[84]

APED calls upon WHO to coordinate international health and technical matters.[85] WHO is to induce cooperation among governments, international organizations,[86] pharmaceutical industries,[87] and experts.[88] WHO is also to develop international policies, provide guidelines for national drug policies, and distribute information concerning drug qualities, prices, and suppliers.[89]

APED is thus a voluntary program of international cooperation for the international quality control of drugs. Many experts, however, have proposed that WHO play a more direct role in the international regulation and quality control of drugs.[90]

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81. *Id.*

WHA devised a model list of essential drugs, which was the basis for cooperation with member states. BIENNIAL REPORT, *supra* note 52, at 88. By the end of 1981, more than forty countries had developed a national list. *Id.*

82. APED, *supra* note 20, at 6, para. 27, *cited in International Regulation, supra* note 15, at 351.

Many member states cooperated in the quantification of drug needs. BIENNIAL REPORT, *supra* note 52, at 88.

83. This step includes the procurement of drugs at affordable prices and the improvement of storage, quality control, and distribution facilities. APED, *supra* note 20, at 6, para. 27, *cited in International Regulation, supra* note 15, at 351-52.

84. APED, *supra* note 20, at 6, para. 27, *cited in International Regulation, supra* note 15, at 352.

In 1980 and 1981, WHO proposed the preparation of information sheets on essential drugs aimed at professional and nonprofessional health care workers. BIENNIAL REPORT, *supra* note 52, at 90.

85. APED, *supra* note 20, at 7-8, paras. 29-34, *cited in International Regulation, supra* note 15, at 352.

86. Two international organizations were quick to respond. The International Federation of Pharmaceutical Manufacturers Associations and the World Federation of Proprietary Medicine Manufacturers provided training for government-sponsored quality control technicians. BIENNIAL REPORT, *supra* note 52, at 90.

87. Some WHA members believed a "solution to the problem was more likely to be found at the level of the users rather than in an approach to those who sold drugs." World Health Organization, *Official Records*, No. 248, 423 (1978) (statement of Professor Koumare of Mali). Pharmaceutical companies have, however, supplied funds and personnel in an attempt to assist developing countries. *International Regulation, supra* note 15, at 352.

88. *International Regulation, supra* note 15, at 352.

89. APED. *supra* note 20, at 7-8, paras. 30-32, *cited in International Regulation, supra* note 15, at 352.

90. *International Regulation, supra* note 15, at 352-53.

III. RECENT PROPOSALS FOR INTERNATIONAL REGULATION

Two recent proposals for WHO's direct involvement in international regulation are Scientific Evaluation Documents and an international code of conduct for the marketing of pharmaceuticals.[91]

A. SCIENTIFIC EVALUATION DOCUMENTS

In 1981, the WHO European Regional Committee proposed the Scientific Evaluation Document (SED) system.[92] The SED system would assist countries in their determination of whether or not to register a drug for domestic sale.[93]

The SED system endorses the operation of an international drug evaluation agency.[94] Pharmaceutical companies would provide the agency with all pertinent information regarding a drug. This information would include all chemical data, clinical studies, and medical information concerning correct use.[95] After studying this information and determining that a drug meets proper quality, efficacy, and safety standards, the agency would issue a Scientific Evaluation Document.[96] The existence of these documents would aid developing countries in deciding whether or not to purchase and import a drug for domestic sale.[97]

The SED system, however, remains a proposal primarily because of opposition by the pharmaceutical industry.[98] Pharmaceutical companies fear that the SED system would constitute a type of supranational control which would impose insuperable regulatory barriers.[99]

B. AN INTERNATIONAL CODE OF CONDUCT FOR THE MARKETING OF PHARMACEUTICALS

In May 1978, WHA requested the Director-General to consider

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91. *Id.* at 353.

92. WHO Regional Office for Europe, Consultation on an International Scheme for Drug Evaluation: Summary Report, No. 1CP/DPM 003(S) Rev. 1, 5927B (1981) [hereinafter cited as SED].

93. SED, *supra* note 92, at 2, *cited in International Regulation, supra* note 15, at 353.

94. This agency would operate much like a national drug registration system. *Id.*

95. *Id.*

96. SED, *supra* note 92, at 1, *cited in International Regulation, supra* note 15, at 353.

97. SED, *supra* note 92, at 2, *cited in International Regulation, supra* note 15, at 353.

98. *International Regulations, supra* note 15, at 354.

99. *Id.*

"the development of a code of marketing practices, with special emphasis on pharmaceutical products essential for the populations of developing countries . . . ."[100] Such a code of conduct,[101] if adopted and adhered to by member states and pharmaceutical manufacturers, could provide the best means yet for international regulation.

The purpose of a code of conduct for pharmaceutical marketing would be the establishment of a standard of pharmaceutical marketing practices to promote drug quality, especially the quality of drugs needed by developing countries. The code would apply to the marketing of all drug products and the availability of information concerning the use of these products. Code provisions would probably restrict the advertising and promotion of drug products, establish quality standards that the products must meet,[102] and control packaging and labeling so that all product ingredients appear on labels. The code may provide that member states adopt national legislation or regulations to implement the code.[103] The code may also provide that governments monitor the code's application and call upon nongovernmental organizations,[104] professional groups,[105] and consumer groups to aid the governments.[106]

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100. W.H.A. Res. 31.32 3(6) (1978) 2 1983 HANDBOOK OF RESOLUTIONS, *supra* note 21, at 112.

101. A code of conduct is a "legal instrument embodying a set of principles and rules (norms) adopted by states that establish standards and limits for the behavior of international actors." Fatouros, *On the Implementation of International Codes of Conduct: An Analysis of Future Experience*, 30 AM. U.L. REV. 941, 943 (1981).

102. The code may specify the quality standard to be used. For example, the International Code of Marketing of Breastmilk Substitutes requires that infant formulas meet the standards of the Codex Alimentarius Commission, a sub-group of WHO. International Code of Marketing of Breastmilk Substitutes, Annex W.H.O. Doc. A34/VR/15 art. 10.2.

103. Fatouros, *supra* note 101, at 958.

The International Code of Marketing of Breastmilk Substitutes provides for governmental adoption of national legislation or regulations. International Code of Marketing of Breastmilk Substitutes, *supra* note 102, art. 11.1.

104. For example, the International Federation of Pharmaceutical Manufacturers Association. This association assisted in the development of technical expertise in GMP inspections. World Health Organization, *Official Records*, No. 248, 425 (1978).

105. For example, the International Pharmaceutical Federation which is made up of national pharmaceutical associations of over sixty countries representing about 300,000 pharmacists. *Id.* at 435.

106. The International Code of Marketing of Breastmilk Substitutes provides for the help of nongovernmental and professional organizations. International Code of Marketing of Breastmilk Substitutes, *supra* note 102, art. 11.4.

IV. AN INTERNATIONAL CODE OF CONDUCT FOR THE MARKETING OF PHARMACEUTICALS AS INTERNATIONAL LAW

A. CODES OF CONDUCT AS CUSTOMARY INTERNATIONAL LAW

1. Codes of Conduct

International organizations have spent an enormous amount of time and energy drafting codes of conduct.[107] Codes have recently become popular in the area of controlling multinational corporations (MNC's).[108] This popularity stems from the realization that MNC's can affect national policies and possess a very rapid growth rate.[109] There is also a general consensus that MNC's can frustrate national development strategies and escape national regulation.[110] Most important to the recent popularity of codes is the lack of equilibrium between developed and developing countries.[111]

The lack of equilibrium between developed and developing countries has led to diverging views on the legal effect of codes of conduct.[112] The developed countries, including the United States, favor nonbinding or voluntary codes, which serve merely as guidelines for states and MNC's.[113] They argue that nonbinding codes help to standardize national policies,[114] that MNC's on their own initiative cooperate with the standards set forth in the codes,[115] and that voluntary codes help equalize the bargaining power between developing countries and MNC's.[116] Developing countries, on the

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107. Rubin, *Transnational Corporations and International Codes of Conduct: A Study of the Relationship Between International Legal Cooperation and Economic Development*, 30 AM. U.L. REV. 903, 907 (1981).

For a discussion of recently adopted international codes of conduct affecting MNC's, see Vagts, *Multinational Corporations and International Guidelines*, 18 COMMON MKT. L. REV. 463 (1981); Fikentscher, *United Nations Codes of Conduct: New Paths in International Law*, 30 AM. J. COMP. L. 577 (1982).

108. Rubin, *supra* note 107, at 907.

109. *Id.*

110. *Id.* at 907-08.

111. *Id.* at 908.

112. Stanley, *supra* note 2, at 981-82; Fatouros, *supra* note 101, at 949; Davidow & Chiles, *The United States and the Issue of the Binding or Voluntary Nature of International Codes of Conduct Regarding Restrictive Business Practices*, 72 AM. J. INT'L L. 247, 249 (1978).

113. Stanley, *supra* note 2, at 981.

114. Coonrod, *The United Nations Code of Conduct for Transnational Corporations*, 18 HARV. INT'L L.J. 273, 303 (1977).

115. *Id.* at 304.

116. *Id.* at 305.

other hand, do not believe that "guideline" codes alter the behavior of MNC's.[117] They, therefore, support legally binding codes.[118] A binding code takes on the status of a treaty[119] because it obligates its signatories to implement the code through national legislation.[120]

2. Codes as Customary International Law

A code of conduct can become customary international law[121]

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117. Davidow & Chiles, *supra* note 112, at 256.

Developing countries also view themselves as powerless against the MNC's within their borders. *Id.*

118. *Id.* at 257.

119. A treaty is an instrument which is "concluded among a number of countries acting in their joint interest. . . . [A] treaty is obligatory originally only on such states as signed and ratified it." G. VON GLAHN, LAW AMONG NATIONS 17 (4th ed. 1981).

120. Stanley, *supra* note 2, at 982.

Many interesting alternatives have been suggested to alleviate the tension between developing and developed countries on the legal effect of codes of conduct. One such alternative is the "zebra code" in which some provisions are adopted in a binding form while others are adopted in a nonbinding form. Fatouros, *supra* note 101, at 950. Other alternatives include: international arbitration, international consultation, norm refinement, and follow-up procedures. Davidow & Chiles, *supra* note 112, at 263-70.

121. Article 38(1) of the Statute of the International Court of Justice, which sets forth the sources of international law, provides:

> the Court, whose function is to decide in accordance with international law such disputes as are submitted to it, shall apply:
>
> a. international conventions, whether general or particular, establishing rules expressly recognized by the contesting states;
>
> b. international custom, as evidence of a general practice accepted as law;
>
> c. the general principles of law recognized by civilized nations;
>
> d. subject to the provisions of Article 59, judicial decisions and the teachings of the most highly qualified publicists of the various nations, as subsidiary means for the determination of rules of law.

Stat. I.C.J. art. 38(1), *reprinted in* DOCUMENTS ON THE INTERNATIONAL COURT OF JUSTICE 79 (S. Rosenne 2d ed. 1979).

Article 38(1)(b) contains two consecutive elements of customary international law: " '(1) a general practice of states and (2) the acceptance by states of the general practice as law.' " H. THIRLWAY, ITERNATIONAL CUSTOMARY LAW AND CODIFICATION 46 (1972), *citing* G. SCHWARZENBERGER, A MANUAL OF INTERNATIONAL LAW 32 (1967).

Customary international law has three weaknesses which have caused the international treaty to move to the forefront as a source of international law. VON GLAHN, *supra* note 119, at 23. First, the formulation of customary law is a slow process. After the lengthy process of formulation and recognition, a new customary rule may actually be archaic and outdated. *Id.*

Second, the process can be unfair to a newly originated state. *Id.* A state is not bound by a customary rule if it objected to the rule during the formulation process, but a *new* state is bound by all customary international law at the time the new state originates. *Id.*

Third, evidence of custom may be very difficult to piece together. Any act or declaration of a state may be evidence of custom. J. BRIERLY, THE LAW OF NATIONS 60 (6th ed. 1963).

if it meets the requirements of state practice[122] and *opinio juris.*[123] States may modify their practices to conform with even voluntary code provisions[124] and may police the actions of MNC's within and without their borders to ensure compliance with code provisions.[125] These state actions can constitute state practice, one necessary element of customary international law.[126] States may further view their compliance with code provisions as obligatory, so that they expect punishment or sanctions to result from their deviation from provisions.[127] Their belief that code provisions are obligatory can

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122. The material element in the formulation of customary law is the requirement of general practice or usage. THIRLWAY, *supra* note 121, at 56. The practice or usage must be followed sufficiently and consistently by a number of states. "Practice or usage consists of an accumulation of acts which are material or concrete in the sense that they are intended to have an immediate effect on the legal relationships of the State concerned. . . ." *Id.* at 58-59.

123. *"Opinio juris sive necessitatis"* is translated as "understanding of the law of necessity." CASSELL'S LATIN DICTIONARY (5th ed. 1968).

Opinio juris, the acceptance by states of the general practice as law, is the second element in the formulation of customary law. Stat. I.C.J., *supra* note 121, art. 38(1)(b). States must generally recognize the practice as obligatory, so that a deviation from the practice entails the possibility of punishment or sanction. BRIERLY, *supra* note 121, at 59.

International legal authorities, however, possess differing views on the definition of *opinio juris.* For a discussion of these differing views, see THIRLWAY, *supra* note 121, at 47-56; Note, *Formulating Customary International Law: An Examination of the WHO International Code of Marketing of Breastmilk Substitutes,* 5 B.C. INT'L & COMP. L. REV. 377, 397-98 (1982) [hereinafter cited as *Formulating Customary International Law*].

One authority, D'Amato, has attempted to reformulate the entire theory of customary law. He has proposed the abolishment of practice and *opinio juris* and has substituted in their places an "act or commitment" and "articulation." A. D'AMATO, THE CONCEPT OF CUSTOM IN INTERNATIONAL LAW 73-87 (1971).

124. Davidow & Chiles, *supra* note 112, at 255.

125. *Formulating Customary International Law, supra* note 123, at 399.

126. *See supra* note 122.

Some scholars, however, doubt that customary international law can be developed in international organizations. O. ASAMOAH, THE LEGAL SIGNIFICANCE OF THE DECLARATIONS OF THE GENERAL ASSEMBLY OF THE UNITED NATIONS 52 (1966). They argue that resolutions and recommendations of international organizations are not evidence of state practice because: (1) it is difficult to determine when this practice becomes law, (2) the independent practice of states is confused with the acts of the organization, and (3) resolutions are not formal practice within the meaning of article 38. *Id.*

Because only state actions can qualify as state practice, it has been argued that the behavior of MNC's cannot contribute to the formulation of customary law. *See Formulating Customary International Law, supra* note 123, at 398. Nevertheless, states which police the actions of MNC's to insure compliance with code provisions can provide sufficient state practice for the formulation of customary law. *Id.* at 398-99.

127. Davidow & Chiles, *supra* note 112, at 255.

A state which departs from code provisions may be subject to the pressure or moral persuasion of other states. This subjection to pressure or persuasion would amount to sanction. *Id.*

constitute *opinio juris,* the second necessary element in the formulation of customary international law.[128] Even a nonbinding code, therefore, can become customary international law when sufficient state practice and *opinio juris* are present.[129] An example of a recent nonbinding code, which can become customary law, is the International Code of Marketing of Breastmilk Substitutes.[130]

B. *International Code of Marketing of Breastmilk Substitutes—An Example of a Recent WHO Code of Conduct*

In May 1981, WHA adopted the International Code of Marketing of Breastmilk Substitutes (Code of Breastmilk Substitutes).[131] The Code's purpose is to stress the superiority of breastfeeding over bottle feeding,[132] especially in developing

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128. *See supra* note 123.

129. Davidow & Chiles, *supra* note 112, at 255.

130. International Code of Marketing of Breastmilk Substitutes, Annex W.H.O. Doc. A34/VR/15 [hereinafter cited as Code of Breastmilk Substitutes].

131. W.H.A. Res. 34.22 (1981) 2 1983 Handbook Of Resolutions, *supra* note 21, at 78; Code of Breastmilk Substitutes, *supra* note 130.

A joint WHO/UNICEF Meeting on Infant and Young Child Feeding held in October 1979 recommended "an international code of marketing of infant formula and other products used as breastmilk substitutes." W.H.A. Res. 33.32(1) (1980) 2 1983 Handbook Of Resolutions, *supra* note 21, at 76. In May 1980, WHA requested the Director-General to prepare, in collaboration with experts, an international code of marketing of breastmilk substitutes. W.H.A. Res. 33.32(6(4)) (1980) *id.* WHA further requested the Director-General to submit the Code to the Executive Board and WHA with proposals for implementation either as a regulation or recommendation. W.H.A. Res. 33.32(6(5)) (1980) *id.* In January 1981, the Executive Board endorsed the Draft International Code, and in May 1981, WHA adopted the Code as a recommendation. E.B. Res. 67.R12(1) (1981) *id.* at 77; W.H.A. Res. 34.22(1) (1981) *id.* at 78.

132. Animal milks were not recognized as an alternative to mother's milk until quite recently. In the 1880's, scientists modified cow's milk to provide digestible infant formulas. World Health Organization, Contemporary Patterns Of Breast-Feeding—Report On The WHO Collaborative Study On Breast-Feeding 3 (1981). In the 1930's, the food industry began preparation of formulas which before had been processed at home. *Id.* at 4. Breastmilk substitutes became more widespread and are now used routinely in developing countries. *Id.* Problems in these developing countries have, however, caused infant formulas to have a detrimental effect on infant health. These problems include: poor sanitation and water supply, inadequate facilities for proper cleaning of bottles, and a poor economic situation in which the high cost of formula leads to overdilution. *Id.*

Studies in the United States and abroad showed that the mortality rate for bottle-fed infants was two to six times that for breast-fed infants in the 1930's. *Id.* at 4-5.

In the 1960's, authorities questioned the decline in breastfeeding and developed arguments in favor of its revival. *Id.* at 6. They argued that breastfeeding creates a bond between mother and child, that manufactured formulas can never copy the anti-infective

countries.[133] The Code restricts manufacturers of breastmilk substitutes in their direct advertising to the general public,[134] in their provision of free samples to the general public,[135] and in their provision of information to health professionals.[136] The Code also calls upon governments to adopt the Code as national legislation.[137]

The Code of Breastmilk Substitutes is the result of WHO's first attempt to deal with a public health problem by controlling the marketing practices of MNC's.[138] Despite WHA's adoption of the Code as a voluntary recommendation,[139] the United States voted against its adoption.[140] Manufacturers of infant formula have also opposed the Code. One such manufacturer believes that certain articles of the Code have no connection with infant health,[141] that the Code sets a distasteful precedent for supranational legislation,[142] and that the Code is not applicable to developed countries, including the United States.[143] In May 1982, WHA, after noting that few member states had adopted and adhered to the Code, again urged

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properties of human milk, and that breastfeeding is a child's only fair chance at survival in low income and poorly educated populations. *Id.*

Since the 1960's, various international organizations have worked to promote breastfeeding in developing countries. Some of these organizations are: the La Leche League International, the Protein-Calorie Advisory Group of the United Nations System, the International Pediatric Association, the International Union of Nutritional Sciences, and the International Planned Parenthood Federation. *Id.* at 6-8.

133. W.H.A. Res. 33.32(4)(b) (1980) 2 1983 HANDBOOK OF RESOLUTIONS, *supra* note 21, at 77.

WHA discovered that the decline in breastfeeding contributes "to infant mortality and malnutrition, in particular in the developing world. . . ." W.H.A. Res. 27.43 (1974) *id.* at 76.

134. Code of Breastmilk Substitutes, *supra* note 130, art. 5.1.

135. *Id.* art. 5.2.

136. *Id.* art. 7.2.

137. *Id.* art. 11.1.

138. *See Formulating Customary International Law, supra* note 123, at 386.

For additional information on the control of multinational infant formula corporations, see Note, *Influencing Multinational Corporations: The Infant Formula Marketing Controversy*, 10 N.Y.U.J. INT'L L. & POL. 125 (1977).

139. "The Thirty-four World Health Assembly . . . ADOPTS, in the sense of Article 23 of the Constitution, the International Code of Marketing of Breastmilk Substitutes. . . ." W.H.A. Res. 34.22(1) (1981) 2 1983 HANDBOOK OF RESOLUTIONS, *supra* note 21, at 78.

140. *See Formulating Customary International Law, supra* note 123, at 382.

For a discussion of U.S. action prior to the WHO Code of Breastmilk Substitutes, see Note, *Innocents Abroad: Infant Food Technology at the Law's Frontier*, 20 VA. J. INT'L L. 617 (1980).

141. *Company Agrees to WHO Code in Developing Nations*, Bristol-Myers USA, Sept. 1983, at 4, col. 1.

142. *Id.*

143. *Id.*

member states to "adopt national legislation, regulations or other suitable measures to give effect to the International Code . . . ."[144] As of June 17, 1983, however, only one American manufacturer of infant formula has agreed to comply with the Code.[145]

C. *The Possible Adoption and Legal Effect of an International Code of Conduct For The Marketing of Pharmaceuticals*

WHO's first attempt to promote health in developing countries by controlling the marketing practices of MNC's has been met with opposition, especially by the MNC's themselves.[146] Unless this opposition gradually evaporates, WHO may be reluctant to proceed with a code that would control the marketing practices of MNC's that manufacture pharmaceuticals. WHO may view the Code of Breastmilk Substitutes as a failure, and, therefore, be hesitant to draft another code that may fail. The adoption of an international code of marketing for pharmaceuticals is unlikely, in the near future, because of state and MNC opposition and the length of time required to draft a satisfactory code of conduct.

If, however, WHO were to develop and adopt such a code of conduct, it would probably take the form of a nonbinding recommendation.[147] Recommendations do not require the elaborate approval procedures of binding instruments.[148] Additionally, states

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144. W.H.A. Res. 35.26 (1982) 2 1983 HANDBOOK OF RESOLUTIONS, *supra* note 21, at 79.

145. Despite its reservations about the Code, Bristol-Myers, on June 17, 1983, announced its decision to comply with the Code. Bristol-Myers USA, *supra* note 141, at 4, cols. 1, 3.

Secretary of Health and Human Services, Margaret M. Heckler, has recently commended Bristol-Myers on its decision to comply with the Code. Secretary Heckler stated that Bristol-Myers' decision "will help considerably in ending the controversy surrounding the Code and in allowing various involved groups to work toward improving the health of infants and young children." *Company's WHO Code Policy Wins Praise*, Bristol-Myers USA, Jan. 1984, at 3, cols. 1, 2 (statement of Secretary Margaret M. Heckler).

A Bristol-Myers' official voiced the company's continuing concern that "certain sections of the Code are inappropriate to countries like the U.S. and other developed nations." *Id.* at 3, cols. 2, 3 (statement of Marvin Koslow, Senior Vice-President of Bristol-Myers). Secretary Heckler's response was that "many of the Code's provisions . . . are considered inappropriate here because our social and economic circumstances are different from those in the developing nations, which were the primary target of the Code." *Id.* at 3, col. 3 (statement of Secretary Margaret M. Heckler).

Senator Edward Kennedy, who, in 1978, conducted hearings on the marketing of infant formula in developing countries, also commended Bristol-Myers on its compliance with the Code. *Id.* at 3, col. 4.

146. *See supra* notes 141-144 and accompanying text.

147. *See supra* notes 45-46 and accompanying text.

148. *See Formulating Customary International Law, supra* note 123, at 390. *See also supra* note 45.

appear to be more willing to adopt nonbinding instruments.[149] The voluntary Code of Breastmilk Substitutes has even been opposed by infant formula manufacturers based in those developed countries that favor nonbinding instruments.[150]

The likelihood of an international code for the marketing of pharmaceuticals becoming customary international law is even more speculative. The formulation of customary international law is a slow process.[151] If a number of countries comply with the code and require their pharmaceutical industries to also comply, state practice could exist.[152] If states come to view the code as obligatory, so that noncomplying states would feel pressure to also comply, sufficient *opinio juris* could exist.[153] Both state practice and *opinio juris* require the participation of a substantial number of states.[154] Because the Code of Breastmilk Substitutes has, as of yet, not obtained substantial compliance, a similar code for pharmaceuticals would also probably not receive substantial compliance to become customary international law. Thus, both time and the noncompliance of states would hinder a code of conduct for the marketing of pharmaceuticals from acquiring the status of international law.

Although a voluntary code may not achieve the status of customary law, it may still be a valuable tool in the international pharmaceutical trade.[155] Pharmaceutical MNC's, while not complying with the entire code, may employ certain code provisions and policies in establishing or changing their own marketing practices. The code could certainly serve as a model for those MNC's that "want to demonstrate . . . awareness that there are differences between the developing and developed world to which ethical marketers must be sensitive."[156]

D. A Suggested Solution For Less Developed Countries

The WHO regulatory programs[157] and proposals[158] fail to supply less developed countries (LDC's) with adequate relief from the im-

149. *See Formulating Customary International Law, supra* note 123, at 391.
150. *See supra* notes 113-116 and accompanying text.
151. VON GLAHN, *supra* note 119, at 23.
152. *See Formulating Customary International Law, supra* note 123, at 399.
153. Davidow & Chiles, *supra* note 112, at 255.
154. THIRLWAY, *supra* note 121, at 58.
155. Fatouros, *supra* note 101, at 959.
156. Bristol-Myers USA, *supra* note 141, at 4, cols. 1-2.
157. *See supra* notes 21-90 and accompanying text.
158. *See supra* notes 92-106 and accompanying text.

portation of defective drug products.[159] Additionally, not all LDC's can afford either the funds or the manpower to establish their own elaborate regulatory schemes.[160] LDC's should, therefore, pool what little resources they have and coordinate their efforts at regulation. These LDC's, in a collaborative effort, should develop and implement a comprehensive product liability law[161] that makes foreign manufacturers more strictly accountable for drug-related injuries.[162]

This comprehensive product liability law should encourage the importation of goods into LDC's as well as promote the protection of users.[163] It should introduce the theory of strict liability[164] to LDC's[165] and grant LDC courts jurisdiction over foreign manufacturers in transnational product liability suits.[166]

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159. *See supra* notes 21-106 and accompanying text.

160. Note, *Influencing Multinational Corporations: The Infant Formula Marketing Controversy*, 10 N.Y.U.J. INT'L L. & POL. 125, 163 (1977).

For example, few governments of developing countries regulated infant formulas before the development of the Code of Breastmilk Substitutes. Note, *Innocents Abroad: Infant Food Technology at the Law's Frontier*, 20 VA. J. INT'L L. 617, 638 (1980).

161. Product liability law concerns the "legal liability of manufacturers and sellers to compensate buyers, users, and even bystanders, for damages or injuries suffered because of defects in goods purchased." BLACK'S LAW DICTIONARY 1089 (5th ed. 1979).

162. An example of a product liability law which makes foreign manufacturers more strictly accountable for product-related injuries is the recently proposed directive of the European Economic Community (EEC). Amendment of the Proposal for a Council Directive Relating to the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning Liability for Defective Products, 22 O.J. EUR. COMM. (No. C271) 3 (1979) [hereinafter cited as EEC Directive].

163. The EEC Directive contains a similar objective and seeks to accomplish its objective by creating general obligations for all manufacturers of defective products and imposing liability without fault to facilitate recovery of damages for consumers. Recent Development, *The EEC's Proposed Directive on Products Liability: A Call for Reappraisal in Light of the Model Uniform Product Liability Act*, 6 B.C. INT'L & COMP. L. REV. 315, 320-21 (1983).

164. Strict liability is a "concept applied by the courts in product liability cases in which a seller is liable for any and all defective or hazardous products which unduly threaten a consumer's personal safety." BLACK'S LAW DICTIONARY 1275 (5th ed. 1979).

165. The EEC Directive imposes strict liability on manufacturers: "[t]he producer of an article shall be liable for damage caused by a defect . . . [t]he producer shall be liable even if the article could not have been regarded as defective in light of the scientific and technological development at the time when he put the article into circulation." EEC Directive, *supra* note 162, at 7-8.

166. The EEC Directive facilitates a consumer in obtaining jurisdiction over the producer within the EEC. Recent Development, *supra* note 163, at 330.

Jurisdiction over pharmaceutical MNC's may not, however, be a problem because states, in civil trials, "claim jurisdiction over all sorts of cases and parties having no real connection with them and . . . this practice has seldom if ever given rise to diplomatic protests." Akehurst, *Jurisdiction in International Law*, 46 BRIT. Y.B. INT'L L. 145, 170 (1972-1973).

The main basis of jurisdiction in common law countries is the defendant's presence within the state. *Id.* A company is present within the state if it conducts business in the state even

Although this suggested solution may also pose problems,[167] it does reflect the growing feeling among LDC's that "transfer of technology disputes are exclusively within the jurisdiction of the [LDC's]."[168]

V. CONCLUSION

The ongoing debate between developed and developing countries concerning the legal effect of codes prevents the adoption of codes that affect the marketing practices of MNC's. It seems apparent that until this debate is resolved and countries realize the advantageous aspects of codes, the development of a code for the marketing of pharmaceuticals is unlikely. After considerable time, a code could become customary international law and, as such, bind even those countries and their MNC's that initially object. Furthermore, a code of conduct would do much to standardize the marketing of pharmaceuticals and protect developing countries from the importation of defective products.

While the debate over the legal effect of codes continues and the development of a code of conduct for the marketing of pharmaceuticals in unlikely, developing countries can protect themselves from defective drug products by expanding their product liability law. In order to protect and compensate drug product users, this law should include the theory of strict liability and allow drug users jurisdiction over foreign pharmaceutical manufacturers.

Molinda Schoepe

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if the business is brief and not connected with the subject matter of the litigation. *Id.* at 170 n.5.

Some countries claim jurisdiction whenever the defendant has assets within the country concerned. *Id.* at 171.

Some foreign courts have jurisdiction based on the plaintiff's nationality, domicile, or residence. *Id.* at 172-73.

167. Some problems may include: manufacturers' refusals to do business with these LDC's, an increase in the cost of insuring products, and increased consumer prices to cover the cost of damages and insurance payments.

168. Report of the Intergovernmental Experts on an International Code of Conduct on Transfer of Technology on its Fourth Session, U.N. Doc. TD/AC.1/11, Annex 11 (Nov. 23, 1977), *reprinted in* 17 I.L.M. 453, 472-73 (1978).