Index

Action Program on Essential Drugs, 18,20,141-142 Adverse reactions section of label, 5,43-44 Advertising, pharmaceutical codes of conduct and, 131-139 detail men, 111 in developing countries, 110-112 fairness and balance test, 95 medical journals, 111-112 over-the-counter drugs, 11, 95-96 prescription drugs, 11,95-96 reminder advertisements, 18, 137 WHO ethical criteria, 16-17, 133-135 Alcohol as an ingredient, 41 AMA. See American Medical Association AMA Drug Evaluations, 32, 106 American Hospital Formulary Service, 106 American Law Institute, 13, 118 American Medical Association, 32, 106 Anabolic steroid study, 156-157 Antibiotics: The Wrong Drugs for Diarrhoea, 151 Antidepressant drugs, 152 Antidiarrhea drugs, 151-152, 155-156 Antitrust laws, 120-121 APED. See Action program on Essential Drugs Argentina, drug advertising, 111 Association of the British Pharmaceutical Industry, 146

Bad Medicine: The Prescription Drug Industry in the Third World, 42
Balasubramaniam, K., 150
Batch certificates, 19, 145
Bitter Facts About Drugs, 151

Boycotts, 13, 117, 123, 131 Brazil drug advertising, 111 drug labeling, 164 drug registration, 163-164 obtaining product labels, 28-29 package inserts, 29 sample product selection, 28 selection for study, 27 Breast-Milk Substitutes Code. See International Code of Marketing of Breast-Milk Substitutes Bristol-Myers Squibb Co., 115 BUKO, 152 Bush, George, economic sanctions against Iraq, 122 Cancer treatment, off-label prescribing and, 105-106 Carter, Jimmy, freezing of Iranian assets, 122 Certificates for pharmaceutical products, 19 Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, 19,20, 142-146 Chetley, Andrew, 151 Chloramphenicol study, 155 CIOMS. See Council for International Organizations of Medical Sciences Clayton Act, 120 Cleared for Export, 151 Clinical pharmacology section of label, 4,40 Clioquinol study, 155-156 Code of Conduct for Companies Operating in South Africa, 15 Code of Conduct for Translational Corporations, 15-16,23,24, 128, 130-131

Code of Pharmaceutical Marketing Practices, 9, 17-18 criticisms of, 138-139 description, 135-136 implementation, 136-137 reporting and resolution of violations, 137-138 Codes of conduct, 15-18,23-24 under international law, 128-135 Collaborating Center for Monitoring of Adverse Drug Reactions, 20 Collaborating Centre for International Drug Monitoring, 146-147 Combination drugs, 103-104 Comity principle of international law, 118-119 Consumer Action and Resource Kit on Pharmaceuticals, 149 Consumer Alerts, 150 Consumer groups health advocates, 149-153 IFPMA ethical criteria and, 134-135 infant formula and, 132 international programs and, 21 Consumer Interpol, 149-150 Contraindications section of label, 5,4243 Council for International Organizations of Medical Sciences, 24, 135

Data Sheet Compendium, 146 DEACs. See Drug Export Act countries Description section of label, 4,40 DESI. See Drug Efficacy Study Implementation Detail men, 111 Dictionaire Vidal, 146 Dingell, John, 2 DMP. See Drug Management and Policies Division, World Health Organization Dosage and administrative section of label, 5-6,44 Drug Diplomacy: Decoding the Conduct of a Multinational Pharmaceutical Company, 151 Drug Disinformation: What British and Multinational Drug Companies Tell Doctors About Their Products, At Home and Abroad, 152 Drug Efficacy Study Implementation, 95 new drug review, 103-104 Drug Export Act countries, 45,49 Drug Export Act of 1986,2,6-7,45,96-98 Drug Facts and Comparisons, 32

Drug Information for the Health Care Professional, 32.106 Drug Labeling studies, 155-162 Drug Management and Policies Division, World Health Organization, 18-19, 142, 146 The Drugging of the Americas, 158, 159, 161 Drugs and Primary Health Care, 151 Drugs and World Health, 152 Drugs Used in Anesthesia, 146 Drugs Used in Mycobacterial Diseases, 146 Drugs Used in Parasitic Diseases, 146 EAA. See Export Administration Act Economic sanctions, 121-123 Effects principle of international law, 13, 14, 117-118, 125 Enforcement Report, 148 The Essential Drugs Monitor, 18, 142 "Ethical and Scientific Criteria for Pharmaceutical Advertising," 16, 133 "Ethical Criteria for Medicinal Drug Promotion," 16-17, 18, 24, 133-135 European Community, codes of conduct, 15 Expert Advisory Panel on Drug Evaluation, 7,49 Expert Review Group first review, 31-32 medical importance standard, 30 original label examination, 29 scoring review, 36 Export Administration Act, 13, 121-123 Exported drugs FDCA and, 11 labeling, 11,96-98 tropical disease drugs, 12,98 unapproved drugs, 11, 96 Extraterritorial jurisdiction antitrust laws, 120-121 health and safety of foreign nationals and, 14-15, 125-126 international law principles, 12-13, 117-119, 125-126 U.S. laws allowing, 13-14 Fairness and balance test, 95 FCPA. See Foreign Corrupt Practices Act FDA. See Food and Drug Administration FDA Consumer Information, 148

FDA Medical Bulletin, 148

FDCA. See Food, Drug, and Cosmetic Act Federal Congress of Development Action Groups. See BUKO Federal Register, 148 Federal Trade Commission, 23 Federal Trade Commission Act, 120 Food, Drug, and Cosmetic Act, 9,91 export of pharmaceuticals, 11 1962 amendments, 95 Food and Drug Administration cooperation with WHO programs, 148 exported pharmaceuticals labeling, 11 extraterritorial jurisdiction, 12-15 FDCA and, 91 international activities, 20, 143, 147-148 labeling standard, 3 tropical disease drug export, 12 unapproved drug export, 11 unlabeled indications, 104 U.S. drug labeling, 9-11 Foreign Corrupt Practices Act, 13-14,22-23, 123-125, 126 Foreign relations law, 118-120 France drug approval process, 107 drug efficacy standards, 107 GAIT. See General Agreement on Tariffs and Trade General Accounting Office export of unapproved drugs, 96 off-label prescribing study, 105 General Agreement on Tariffs and Trade, 15 Germany drug approval process, 107 labeling, 107 Global Marketing of Pharmaceuticals: Prescription for Disaster, 150 "Good Practices in the Manufacture and Quality Control of Drugs," 142 Guidelines for Multinational Corporations, 15, 128 "Guiding Principles for Small National Authorities," 20.148 HAI. See Health Action International

HAI News, 151 "The Hartog and Schulte-Sasse Study," 152, 161 Harvard Medical School, 153 Health Action International

code of conduct, 150-151 description, 21, 149, 150 ethical criteria critique, 151 IFPMA critique, 151 Health Horizons, 137 Hoechst, 152 House Subcommittee on Health and the Environment of the Committee on Energy and Commerce, 98 IBFAN. See International Baby Food Action Network IEEPA. See International Emergency Economic Powers Act IFM, See International Association of Infant Food Manufacturers IFPMA. See International Federation of Pharmaceutical Manufacturers Associations ILO. See International Labour Office India multinational corporations and, 116 WHO collaborating center, 146 Indications section of label, 4-5,41-42 Indonesia, multinational corporations and, 116 IND. See Investigational new drug exemption Inert ingredients, 41 Infant formula, 16,23-24, 125, 131-133 Ingredients section of label, 4,4041 INRUD. See International Network for the Rational Use of Drugs INRUD News, 153 Institutional Review Boards, 100 Insult or Injury? An Enquiry into the Marketing and Advertising of British Food and Drug Products in the Third World, 151 Interfaith Center on Corporate Responsibility, 131 International Affairs Staff, Food and Drug Administration, 147 International Association of Infant Food Manufacturers, 16, 132 International Baby Food Action Network 131, 132 International Chamber of Commerce, 15, 128 International Code of Marketing of Breast-Milk Substitutes, 16,23-24, 128 description, 131-132 implementation, 132-133 International Conference of Drug Regulatory Authorities, 20

International Emergency Economic Powers Act, 13, 122-123 International Federation of Pharmaceutical Manufacturers Associations codes of conduct, 16, 17-18.24, 128, 133, 135-139 drug advertising, 111 product promotion guidelines, 9 International Labour Office, 15, 128 International law codes of conduct, 15-18, 128-135 foreign relations law, 118-120 multinational corporations, 116-120 principles, 12-13, 117-119, 125-126 rule of reasonableness and, 119 International Network for the Rational Use of Drugs, 21, 148, 153 International Non-proprietary Name, 136 International Organization of Consumers Unions, 21, 132, 149-150 labeling studies, 155-162 International Pharmaceutical Federation, 49 International programs for labeling improvement consumer groups, 21, 149-153 FDA international activities, 20, 143, 147-148 prescribing information distribution, 7, 18-19,49, 146 safety and efficacy information access, 19-20 USAID programs, 20-21, 145-146, 148-149 WHO Certification Scheme, 19,20, 142-146 "International Regulation of the Supply and Use of Pharmaceuticals," 152 International Union of pharmacology, 49 International Workshop on Consumer Health and Drug Information and Education, 149 Investigational new drug exemptions application, 99-100 exemption for clinical trials in human beings, 96 IOCU. See International Organization of Consumers Unions IRBs. See Institutional Review Boards Italy, bribery of officials, 124

Japan

bribery of officials, 123-124 inert ingredients database, 41 Journal of the American Medical Association, 106

Kennedy, Edward, 2 Kenya drug registration and labeling, 164-165 obtaining product labels, 29 package inserts, 29 sample product selection, 28 selection for study, 27 Labeling changes, prescription drugs, 94 Laws. See specific laws and regulations by name; U.S. drug labeling laws and regulations Lee. See Silverman, Lydecker, and Lee, labeling studies Lockheed Corp., 123-124 Lydecker. See Silverman, Lydecker, and Lee, labeling studies MaLAM, See Medical Lobby for Appropriate Marketing Management Sciences for Health, 153 Manual for Rural Health Workers: Diagnosis and Treatment with Essential Drugs, 18, 142 Marketing. See Advertising Medawar, Charles, 152 Medical Bulletin, 20, 147 Medical Devices and Radiological Health, 148 Medical importance standard, 3,30-31,32,35,4049, 104 Medical Lobby for Appropriate Marketing, 21, 137-139, 152-153 Medicines Control Agency, 107 Merck & Co., 115 MNCs. See Multinational corporations Model Guide to Good Prescribing, 18, 142 "Model List of Essential Drugs," 7,49, 142, 161 Model Prescribing Information, 142 Moscow Olympics boycott, 123 Multinational corporations bribery of foreign officials, 13-14, 123-125, 126 codes of conduct and, 15, 114, 128-139 description, 113-114 drug advertising, 111 drug labeling influences, 8 extraterritorial jurisdiction and, 120-126 growth of. 114-115 health and safety of foreign nationals, 14-15, 125-126 host country laws, 106

international law, 116-120 joint venture arrangements, 115 labeling studies, 155-162 legal control, 8-9 markets, 7-8 proprietary products licensing to foreign companies, 116 structure, 8, 115-116 trade embargoes and economic sanctions, 121-123 U.N. standards for, 9, 130-131 NAS. See National Academy of Sciences National Academy of Sciences, new drug review, 103-104 Nationality principle of international law, 12, 13, 117, 125-126 NDA. See New Drug Application Nestle Corp., 131-133 Nestle Infant Formula Audit Commission, 132 New Drug Applications, 91,99, 101-102 over-the-counter drugs, 95 New drug approval clinical trials, 100-101 definition of "new," 98-99 Investigational New Drug exemption, 99-100 NDA review, 101-102 preclinical research, 99 Nigeria, labeling study, 160-161 OECD. See Organization for Economic Co-operation and Development Off-label prescribing, 104-106 Office of International Affairs, U.S. Public Health Service, 147 One Drug at a Time: A Report on the Limitation of Fixed Ratio Combination Drugs, 152 Options for Congressional action, 21-24 Organization for Economic Co-operation and Development, 14, 15, 124-125, 128 Osifo, Nosakhare Guy, 160-161 OTA Labeling evaluation process analysis and final results, 37 company response evaluation, 32-34 Expert Review Group reviews, 31-32,36 interim and revised overall scores, 37

medical importance standard, 30-31, 32, 35, 40-49

provision of scoring sheets to companies, 34-36

preliminary screening, 31

labeling, 10-11,94-95 package inserts, 29 Overdosage section of label, 6,44 Package inserts, 10,29-30,92-93, 107 in developing countries, 109-110 Package labels for prescription drugs, 92-93 PAHO. See Pan American Health Organization Pan American Health Organization, 147, 148 Panama drug registration and labeling, 165-166 obtaining product labels, 28-29 package inserts, 29 prescribing guides, 3 sample product selection, 28 selection for study, 27 PDR. See Physicians' Desk Reference Peddling Placebos: An Analysis of Cough and Cold Remedies, 151 Pediatric drug prescribing, 105-106 Pfizer, Inc., 115 Pharma-Brief, 152 Pharmaceutical labeling studies, 155-162 Pharmaceutical Manufacturers Association, 7,28,45, 135 Physicians' Desk Reference, 31, 146 Physicians' Desk Reference for Nonprescription Drugs, 31 Pills, Profits and Politics, 158 PMA. See Pharmaceutical Manufacturers Association Policies and Strategies on Drug Pricing Regulations: International Experiences, 150 Policy Options in Pharmaceutical Patents for Developing Asian Countries, 150 Post-marketing surveillance, 102-103 Power and Dependence, 152 Precautions section of label, 5,43

queries to companies, 32

scoring of labels, 34-36,4049

OTC. See Over-the-counter drugs

Over-the-counter drugs

classes, 95

advertising, 11,95-96

summary sheets for additional responses, 36-37

Prescribing guides, 3, 30

in developing countries, 110 Prescription drugs

advertising, 11,95-96

labeling changes, 94 labels, 10,92-93 package inserts, 29,92-93 standards of evidence, 94 Prescription for Death: The Drugging of the Third World, 159, 162 Problem Drugs, 151 Product documents, 107-108 Promoting Health or Pushing Drugs? A Critical Examination of Marketing of Pharmaceuticals, 151 Protective principle of international law, 117 The Provision and Use of Drugs in Developing Countries, 151 Qualitative results of OTA survey, 3940,54-91 Quantitative results of OTA survey company analysis, 6,44 country analysis, 6,44-54 labeling category analysis, 40-44 other industrialized country comparison, 6-7,45-49 overall analysis, 40 WHO model prescribing information, 7,49 Queries to companies, 32-34 A Question of Control, 151

The Rational Use of Drugs: A Universal Concept, 150
Reagan, Ronald, Breast-Milk Substitutes code and, 133
Reminder advertisements, 18, 137
Reporting requirements, new drugs, 102-103
Restatement (Third) of the Law: The Foreign Relations Law of the United States, 13-15,118
Rhodesia, economic sanctions against, 123
Rule of reasonableness, 119
Sample selection, OTA Survey company identification, 28 country selection, 27-28 label translations, 30 sample products, 28-30

Schulte-Sasse. See "The Hartog and Schulte-Sasse Study"
SCRIP World Pharmaceutical News, 137
Searle Pharmaceuticals, 151-152 export of unapproved drugs, 96 Sherman Act, 120-121 Silverman, Lydecker, and Lee, labeling studies, 42, 158-160 Social Audit, 151-152 labeling studies, 157-158 Statements of licensing status, 19, 145 Survey, OTA category of information analysis, 4-6 company analysis, 6,44 country analysis, 6,4445 labeling evaluation process, 30-37 other industrialized country comparison, 6-7,45-49 process, 2-3,27-37 qualitative results, 39-40,54-91 quantitative results, 40-54 results, 3-7 sample selection, 27-30 scoring categories, 3-6, 34 WHO model prescribing information and, 7,49

Syntex Corp., 116

Ten Year Report on the IFPMA Code, 137 Territorial principle of international law, 12-13, 117 Thailand drug registration and labeling, 166-167 obtaining product labels, 29 package insets, 29-30 sample product selection, 28 selection for study, 28 Third International Conference of Drug Regulatory Authorities, 143 Trade embargoes, 13, 117, 121-123 Translation of foreign language labeling, 30 Translational Code. See Code of Conduct for **Transnational Corporations** Treaties, codes of conduct and, 129 Tropical disease drugs, 98 export, 12 U.N. Centre on Translational Corporations, 130-131 labeling studies, 160 U.N. Conference on Trade and Development Code of Conduct on Restrictive Business Practices, 15, 128

U.N. Council for Trade and Development, 133

Unapproved drugs, 96-98

export, 11,96-98

United Kingdom drug approval process, 107 sales representatives, 111 United Nations. See also specific divisions by name codes of conduct, 15-16, 23, 24, 128, 130-131 standards for MNCs, 9 United Nations International Court of Justice, 116 United Nations Participation Act, 123 United States Pharmacopeial Convention, 106 U.S. Agency for International Development, 19 cooperative agreement with U.S. Pharmacopoeia, 20-21, 148-149 WHO and, 20, 145-146, 148 U.S. Department of State, 147-148 U.S. drug labeling laws and regulations. See also specific laws and regulations by name **DESI** review, 103-104 exported drugs, 96-98 new drug approval, 98-102 off-label prescribing, 104-106 over-the-counter drugs, 94-96 post-marketing surveillance, 102-103 prescription drugs, 92-94 U.S. Pharmacopoeia, 148-149 agreement with USAID, 20-21 U.S. Public Health Service, 147 U.S. Securities and Exchange Commission, 123 U.S. Senate Committee on Labor and Human Resources, 105 U.S. Trade Representative, 147 USAID. See U.S. Agency for International Development

USP DI. See Drug Information for the Health Care Professional Veterinary Medicine, 148 Warnings section of label, 5,43 Waxman, Henry, 2 WHO. See World Health Organization WHO Drug Information, 20, 146 WHO Model Prescribing Information, 18-19, 146 WHO Pharmaceutical Newsletter, 20, 146 World Federation of Proprietary Medicine Manufacturers, 49 World Health Assembly, 135, 143 World Health Organization Action Program on Essential Drugs, 18,20, 141-142 Certification Scheme, 19,20, 142-146 codes of conduct, 16, 128 collaborating centers, 20, 146-147 Division of Drug Management and Policies, 18-19, 142, 146 drug advertising, 111 ethical criteria for drug promotion, 16-17, 24 Expert Advisory Panel on Drug Evaluation, 7,49 FDA and, 20 infant formula hearings, 125 prescribing information, 7, 18-19,49, 146 The Wrong Kind of Medicine?, 152

Yudkin, J. S., 157

U . S . GOVERNMENT PRINTING OFFICE : 1993 0 330-065 QL 3

