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New Drug Research, The Extraterritorial Application of FDA Regulations, and the Need for International Cooperation

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NOTES

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ABSTRACT

In recent years, U.S. pharmaceutical companies have expanded their new drug trials beyond the borders of the United States. While the companies have a variety of reasons for making this move, among them may be a desire to avoid Food and Drug Administration (FDA) regulation and monitoring. Lack of adequate supervision of drug trials conducted in the developing world endangers both the subjects of the tests and the consumers in the United States. It is unclear whether the FDA can execute regulatory and supervisory authority abroad. The FDA statute does not clearly authorize the agency to regulate extraterritorially. Applying the presumption against extraterritoriality, the FDA should not, therefore, be allowed to regulate drug testing abroad. Exceptions to the presumption might, however, be applicable. Regardless of whether U.S. courts allow the FDA to bring actions against companies for violations abroad, international cooperation is needed to control drug testing.

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I. INTRODUCTION

In 1996, Pfizer, a large U.S. drug company, developed a new antibiotic called Trovan.[1] Wall Street analysts predicted that Pfizer could make as much as one billion dollars if Trovan were approved for all of its potential uses.[2] Yet, other drugs in Trovan's class had been found to cause joint damage during animal testing, and questions existed as to whether Trovan could have dangerous side effects in children.[3] To counter these concerns, the company wanted to obtain convincing evidence of the drug's safety for use on children.[4] As it happened, one potential application of Trovan was to treat an epidemic strain of bacterial meningitis.[5] Because spinal meningitis is relatively rare in the United States, the company was unable to find enough U.S. patients to conduct a clinical study on the scale required for full Food and Drug Administration (FDA) approval.[6]

In February 1996, a Pfizer physician learned of a meningitis epidemic in northern Nigeria.[7] Thus, Pfizer quickly obtained

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1. Joe Stephens, *Where Profits and Lives Hang in Balance; Finding an Abundance of Subjects and Lack of Oversight Abroad, Big Drug Companies Test Offshore to Speed Products to Market*, WASH. POST, Dec. 17, 2000, at A1.
2. *Id.*
3. *Id.*
4. *Id.* The FDA never approved the sale of Trovan for use on children in the United States. It was only briefly available to adults in the United States before it was severely restricted because of its association with fatal liver failures. The European Union banned Trovan outright. Joe Stephens, *Pfizer Experiment Spurs Criminal Probe*, WASH. POST, Sept. 8, 2001, at A15.
5. Stephens, *supra* note 1.
6. *Id.*
7. *Id.*

approval from the Nigerian government to begin tests.[8] Pfizer opened a clinic in a hospital in Kano, Nigeria that was also occupied by a Doctors Sans Frontiers clinic that was busy treating the epidemic.[9] The two organizations began to compete for hospital space and patients.[10] In the Pfizer experiment, researchers administered Trovan to 100 children, and a comparison drug to 100 other children.[11] Eleven children died in the study, and others suffered severe injuries including deafness and lameness.[12] Pfizer claimed that the fatality rate of the children in the study, and particularly the children treated with Trovan, was better than is typical in U.S. hospitals.[13]

After Pfizer obtained FDA approval for Trovan, many questions were raised regarding Pfizer's research practices. Allegations of failure to obtain consent of human subjects, mistreatment of patients, substandard levels of care, and reckless and inaccurate record keeping were leveled against Pfizer.[14] Children in the control group who improved while receiving a proven anti-meningitis drug were switched to one-third of the recommended dose in what Pfizer claimed was an attempt to "reduce the pain after initial injections" of the medicine.[15] According to a spokesman for the comparison drug's manufacturer, "clinical failures . . . and perhaps deaths of children could have resulted from the low dosing."[16] The researchers ceased all treatment at the close of the study, and did not follow up on the long-term effects of the drug on the children who were treated.[17]

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8. *Id. See also* Stephens, *supra* note 4 (alleging that the "Nigerian doctor who oversaw the experiment for Pfizer said in an interview that a key ethics approval document was created as long as a year after the trial concluded, and then backdated so it would appear to have been issued before the experiment began").

9. Stephens, *supra* note 1.

10. *Id.*

11. *Id.*

12. *Id.*

13. *Id.* A Pfizer spokeswoman said that the trial was "sound from medical, scientific, regulatory and ethical standpoints," and that it may have saved lives. *Drugs Giant Accused of Rights Violations*, AFRICA NEWS, Sept. 3, 2001, *available at* Westlaw, Africanews.

14. *See generally*, Stephens, *supra* note 1. Consent on the part of children poses special problems in the United States as well. At the behest of Congress, the department of Health and Human Services has begun to review the procedures for obtaining the consent of child clinical research participants, and their legally-authorized representatives. Best Pharmaceuticals for Children, Pub. L. No. 107-109, 115 Stat. 1408, 1416 (2002).

15. Stephens, *supra* note 1.

16. *Id.*

17. Pfizer does not claim to have lived up to all of the provisions of the Helsinki Convention; for example, the convention requires that "at the conclusion of the study, every patient entered into the study should be assured of access to the best proven . . . methods identified by the study." World Medical Association, *Ethical Principles for*

A lawsuit has been filed in U.S. federal court on behalf of 30 Nigerian families who claim that their children were "unwitting participants in the 'secret testing,'" and who suffered a variety of injuries including brain damage, paralysis, and death.[18] The suit contends that Pfizer's research methods were in violation of FDA regulations—particularly regulations requiring prior approval of the study by the local Nigerian authorities.[19] It also alleges that Pfizer failed to obtain the informed consent of the children and their families as required by FDA regulations and international human rights law.[20]

The FDA reportedly has now opened a criminal inquiry into Pfizer's allegedly improper medical experiments conducted in Nigeria.[21] Should charges result, this would be the first regulatory action brought by the FDA for corporate conduct abroad.[22] If the government brings an action against Pfizer, it could be argued that the United States lacks the extraterritorial jurisdiction necessary to enforce U.S. law. It is unlikely, however, that a criminal prosecution of Pfizer would be based on the statutory provisions on FDA drug approval.[23] Instead, such a prosecution would likely be based on the FDA's regulations concerning human experimentation and foreign clinical drug trials. While Congress has the power to apply U.S. law extraterritorially,[24] the courts have had a mixed response to extraterritorial application of U.S. law without specific congressional authorization.[25]

This Note addresses both the potential criminal prosecution of Pfizer regarding the experimentation Pfizer performed in Nigeria that was not in compliance with FDA regulations, as well as the problem of protecting human research subjects abroad. Part II of the Note discusses the growing problem of protecting human research subjects from reckless and unethical experimentation conducted by U.S. corporations and institutions. A number of recent scandals involving drug trials in the developing world have brought calls for increased regulation and oversight abroad by sponsor nations, such

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Medical Research Involving Human Subjects, adopted June 1964, *at* http://www.wma.net/e/policy/itcnote.pdf [hereinafter Helsinki Guidelines].

18. Stephens, *supra* note 1.

19. *Id.*

20. Kevin Gopal, *FDA Stays Silent on Trovan Charges*, PHARM. EXEC., Oct. 1, 2001, at 24.

21. Stephens, *supra* note 4.

22. Of course, the FDA could potentially bring actions against Pfizer based on providing false information to the government. This, however, is beyond the scope of this Note.

23. *Id.*

24. See RESTATEMENT (THIRD) OF THE FOREIGN RELATIONS LAW OF THE UNITED STATES § 402 (1987). The impact of the limitations on jurisdiction on Congressional power is unclear. *Id.* § 403.

25. *See infra* notes 109-29.

as the United States.[26] Part III examines the current status of extraterritorial application of U.S. law in the absence of a clearly expressed congressional intent to apply the law abroad. Part IV then evaluates the FDA's extraterritorial regulatory activities under the current law. The FDA lacks a clear mandate from Congress to act extraterritorially in a regulatory capacity, but the overall statutory scheme of the FDA and the FDA's need to protect U.S. consumers, provide a basis for allowing some FDA regulatory authority to extend extraterritorially. FDA regulations to be applied extraterritorially, however, must stem from the agency's authority to protect U.S. citizens, rather than a desire to protect the human rights of research subjects abroad.

Part V of this Note addresses the need for alternative approaches to protection of human research subjects abroad, regardless of whether the courts might allow the FDA regulations to be enforced. The doctrine of comity and general democratic principles suggest that the United States should not extend its protection of human research subjects abroad unilaterally.[27] Unilateral action by the United States would rob developing countries of their ability to affect their own policies. It could also cause friction between the United States and EU nations, whose concepts of human rights in drug research differ.

International law already provides a basic individual right to informed consent.[28] Human research subjects in the developing

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26. Congress and the Department of Health and Human Services have both expressed concern over overseas medical research. In 2001, the National Bioethics Advisory Commission issued a report recommending increased supervision by the FDA and tougher enforcement of informed consent rules by the FDA. Joe Stephens, *Panel Suggests Rules For Foreign Drug Tests*, WASH. POST, May 1, 2001, at A21. According to Public Citizen, implementation of the Commission's recommendations would actually provide protections below those of the Helsinki Guidelines. Press Release, Public Citizen, National Bioethics Advisory Commission Report Dangerously Weakens International Protections, April 30, 2001, *available at* http://old.citizen.org/press/pr-sid47.htm. Public Citizen said that the Commission's recommendations provide too much flexibility to drug companies in opting out of the requirements of the Helsinki Guidelines. *Id.*

27. *But see* Dawn Joyce Miller, *Research and Accountability: The Need for Uniform Regulation of International Pharmaceutical Drug Testing*, 13 PACE INT'L L. REV. 197, 227-28 (2001) (calling for the U.S. government to apply its regulatory protections extraterritorially to safeguard "vulnerable test populations"); *see also* Steven R. Ratner, *Corporations and Human Rights: A Theory of Legal Responsibility*, 111 YALE L.J. 443, 532-33 (2001) (suggesting that domestic public and private legal regimes should place human rights duties on corporations similar to antitrust, securities, and anti-bribery regulation).

28. International Convention on Civil and Political Rights, *opened for signature* Dec. 16, 1966, art. 7, 999 U.N.T.S. 171 (entered into force Mar. 23, 1976) (providing that "[n]o one shall be subjected without his free consent to medical or scientific experimentation"). This right is grouped with the prohibition of torture, and cruel, inhuman or degrading treatment or punishment. *Id.* The United States is a signatory to this treaty.

world may best be protected by a legally-enforceable set of international guidelines. These guidelines should be the result of a collaborative effort by both developed and developing nations, and should account for the role of corporate actors. The FDA's mandate clearly allows it to participate in an international collaborative effort.

II. THE GLOBALIZATION OF THE DRUG INDUSTRY AND THE FDA'S ATTEMPT TO KEEP PACE

A. *The Globalization of Pharmaceutical Research*

Protection for human subjects of biomedical research has become a global issue.[29] Transnational drug corporations based in industrialized countries rely on the developing world for a major pool of test subjects.[30] In turn, the governments of most developing countries rely on the regulatory processes of more-developed countries to determine which drugs are safe to use; a drug's use is thus permitted in a developing country once it has been approved for use in the country of manufacture.[31] "For Americans, it means some of the newest drugs on U.S. shelves are tested at sites far removed from U.S. regulators—sometimes in countries with few inspectors and little history of examining drugs for safety and effectiveness."[32]

Until recently, the United States required that regulatory approval of new drugs be based on domestic research data.[33] In 1994, however, the rules governing new drug research were liberalized to allow the use of foreign data.[34] Sponsors of pharmaceutical research have moved their experiments abroad in order to recruit research subjects more quickly, enabling companies to gain FDA approval and bring their drugs to market sooner.[35] Additionally, pharmaceutical companies are able to conduct experiments at a much lower cost overseas; the per-patient cost of a clinical trial in the United States

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29. Ileana Dominguez-Urban, *Harmonization in the Regulation of Pharmaceutical Research and Human Rights: The Need to Think Globally*, 30 CORNELL INT'L L.J. 245, 245 (1997).

30. *See id.*

31. *Id.* at 257.

32. Mary Pat Flaherty & Joe Stephens, *Testing Tidal Wave Hits Overseas; On Distant Shores, Drug Firms Avoid Delays—and Scrutiny*, WASH. POST, Dec. 18, 2000, at A1.

33. Dominguez-Urban, *supra* note 29, at 264.

34. 21 C.F.R. § 314.106(b)(1) (1994).

35. Office of Inspector General, Department of Health and Human Services, *The Globalization of Clinical Trials: A Growing Challenge in Protecting Human Subjects*, Sept. 2001, at 8, *available at* http://oig.lls.gov/oei/reports/oei-01-00-00190.pdf (hereinafter OIG Report).

averages $10,000, in Russia costs average $3,000, and in poor nations the average is much less.[36]

As early as 1986, approximately 18 percent of research studies conducted by the U.S. pharmaceutical industry took place abroad.[37] During the 1990s, the number of pharmaceutical researchers who worked abroad and voluntarily reported their experiments to the FDA increased approximately 16-fold, from 271 in 1990 to more than 4,400 in 1999.[38] The FDA currently lacks any way to track the total number of experiments conducted abroad, nor can it determine the number of new drugs that are approved on the basis of foreign clinical investigations.[39]

Foreign drug trials are sometimes conducted specifically to avoid U.S. government controls. One example is a Johns Hopkins University School of Medicine trial in India of an anti-cancer drug called M4N.[40] The experiment was conducted in secret after the FDA banned the drug from the United States.[41] California-based Maxim Pharmaceuticals, Inc. was prevented from testing a new drug in the United States because the FDA wanted more test results on animals.[42] It then went to Russia, where doctors were not told about the FDA's concerns.[43] A Pennsylvania drug company sought to conduct clinical trials on infants in Latin America using a placebo control, despite the availability of treatments for the disease.[44]

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36. S.N.M. Abdi, *Drug-Test Rules Aim to Protect the Poor*, S. CHINA MORNING POST, Jan. 9, 2002, *at* 2002 WL 2302949.

37. Dominguez-Urban, *supra* note 29, at 246. Tests conducted before 1994 were generally for the use of the drug company, not applied to gain FDA approval.

38. Joe Stephens & Mary Pat Flaherty, *More Oversight of Drug Trials Urged; Overseas Testings Pose 'a Serious Problem,' Study Says*, WASH. POST, Oct. 2, 2001, at A7; OIG Report, *supra* note 35, at 6. This data reflects the number of experiments that researchers reported to the FDA before the experiments began.

39. OIG Report, *supra* note 35, at 6. The OIG Report particularly criticized the FDA for its lack of information on where NDA research was being conducted, and which investigators were involved in new drug research. *Id.* at 20. The OIG Report indicates that FDA regulatory efforts were severely handicapped by its lack of knowledge as to these foreign investigations. *Id.* at 12-16.

40. Abdi, *supra* note 36.

41. *Id.* Johns Hopkins University investigated the experiments after allegations that the researcher did not obtain permission for the experiment from an internal review board at Hopkins that considers the safety of human studies. Jonathan Bor & Tom Pelton, *Hopkins Scientist is Probed in India Cancer Drug Study*, BALT. SUN, July 31, 2001, at A1. Hopkins found that the researcher did not perform adequate preliminary tests on animals before using the drug on human subjects. John Biemer, *Hopkins Sanctions Scientist for Drug Trial in India*, ASSOC. PRESS NEWSWIRE, Nov. 12, 2001, *available at* Westlaw, APWires Database. The university banned the researcher from serving as lead investigator on future research involving human subjects. *Id.*

42. Flaherty & Stevens, *supra* note 32.

43. *Id.*

44. See Miller, *supra* note 27, at 231.

HIV/AIDS research also provided an impetus for foreign clinical trials. To help improve access to needed treatments for HIV/AIDS, drug producers were encouraged to conduct clinical trials of vaccines and new drugs in developing countries.[45] Such research has led to charges of unethical behavior of, and exploitation by, Western researchers.[46] One such case was the comparison of the HIV treatment AZT with a placebo course. The researchers and their sponsor governments were accused of using an ethical "double standard" because the use of a placebo in a clinical trial would not have been allowed in a developed country.[47]

B. *The FDA's Role in Drug Testing Abroad*

Through the Federal Food, Drug, and Cosmetic Act (FDCA) and the FDA, the United States exercises control over the introduction of new pharmaceutical drugs into the U.S. marketplace.[48] The FDCA and FDA regulations place extensive research and human testing burdens on pharmaceutical companies seeking to bring new drugs to market, and heavily regulate that research and testing.[49]

The first step to new drug approval in the United States is usually an Investigational New Drug Application (IND).[50] Before a study is conducted, a new drug sponsor must submit an IND to the FDA.[51] Testing done under an IND is supervised by an institutional review board "designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research

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45. David Fidler, *"Geographical Morality" Revisited: International Relations, International Law, and the Controversy over Placebo-Controlled HIV Clinical Trials in Developing Countries*, 42 HARV. INT'L L.J. 299, 302 (2001). The United States has been slow to recognize the role of human rights in access to medicine. "The United States was the sole country out of fifty-three nations to veto the UN Human Rights Commission's declaration on access to HIV/AIDS treatment as a fundamental right." Rosalyn S. Park, *The International Drug Industry: What the Future Holds for South Africa's HIV/AIDS Patients*, 11 MINN. J. GLOBAL TRADE 125, 151 (2002).

46. Fidler, *supra* note 45, at 303.

47. *Id.* Generally, the FDA encourages the use of placebo groups in studies. *See* 21 C.F.R. § 314.126. However, placebo use is inappropriate where it would be contrary to the interest of the patient. *Id.* § 314.126(b)(2)(iv). For a discussion of the use of placebo controls in the United States, see Stuart L. Nightingale, *Challenges in Human Subject Protection*, 50 FOOD & DRUG L.J., 493, 498 (1995).

48. *See* 21 U.S.C. § 301 (2002).

49. For a general description of the domestic new drug approval process, see David W. Jordan, *International Regulatory Harmonization: A New Era in Prescription Drug Approval*, 25 VAND. J. TRANSNAT'L L. 471 (1992).

50. OIG Report, *supra* note 35, at 1-2. The purpose of the OIG Report was "to document the growth of non-U.S. clinical drug trials contributing data to New Drug Applications for Food and Drug Administration approval, and to assess the FDA's capacity to assure human subject protections in these trials. *Id.* at iii.

51. *Id.* at 1.

involving human subjects."[52] The primary purpose of institutional review is to "assure the protection of the rights and welfare of the human subjects."[53] After testing and research are complete, the drug sponsor submits a New Drug Application to obtain FDA approval to market the drug.[54] While all clinical drug research conducted in the United States must occur under the auspices of an IND,[55] this is not true of clinical studies conducted abroad.[56]

Foreign drug research data can be admitted one of two ways. A drug researcher may conduct its foreign clinical tests under the auspices of an IND, as it would for a U.S. clinical study.[57] Alternatively, the researcher may skip the IND, and instead conduct its foreign clinical tests in a manner consistent with either the 1989 Declaration of Helsinki guidelines[58] or local country guidelines.[59] The researcher is to comply with whichever guidelines provide the greater protection for the human test subjects.[60] The Helsinki guidelines concentrate on the protection of human subjects; while recognizing that "in current medical practice . . . most procedures involve risks and burdens," the guidelines place substantial

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52. 21 C.F.R. § 56.102(b)(21)(g) (2002). It has been suggested that U.S. regulations do not go far enough to ensure informed consent in domestic research. Jay Katz, *Human Experimentation and Human Rights*, 38 ST. LOUIS U. L.J. 7, 24 (1993). Specifically, that the regulations "do not go far enough in emphasizing the centrality of the inviolability of the human rights of research subjects." *Id.* "The regulations on informed consent should have been formulated in a way that place considerable restrictions on the use of patient-subjects." *Id.*

53. 21 C.F.R. §§ 56.102(b)(21)(g) (2002).

54. OIG Report, *supra* note 35, at 1.

55. *Id.* at 2.

56. *Id.*

57. The FDA has begun to inspect investigations conducted under INDs. OIG Report, *supra* note 35, at 10.

58. 21 C.F.R. § 312.120(c)(4) (2002) (codifying World Medical Association General Assembly, Declaration of Helskinki: Ethical Principles for Medical Research Involving Human Subjects). The Helsinki Guidelines, as adopted by the FDA, are considered by the international medical community to provide the highest standards of ethics in human experimentation. Barry R. Bloom, *The Highest Attainable Standard: Ethical Issues in AIDS Vaccines*, SCIENCE, Jan. 9, 1998, at 186.

59. 21 C.F.R. § 312.120(c)(1). The FDA's decision to waive the IND requirement is

> based on a recognition that much important clinical research is conducted throughout the world, which meets the legal and ethical standards of the countries in which it is conducted, but which is carried on without the kind of institutional review required under FDA's requirements. To insist on absolute adherence to FDA's IRB requirements would obligate the agency to reject valid scientific data generated overseas.

New Drug, Antibiotic, and Biologic Drug Product Regulations, 52 Fed. Reg. 8798 (Mar. 19, 1987). For a discussion of the function of Institutional Review Boards, see ROBERT J. LEVINE, ETHICS AND REGULATION OF CLINICAL RESEARCH 321-63 (2d ed. 1986).

60. 21 C.F.R. § 312.120(c)(1); OIG Report, *supra* note 35, at 2.

responsibility for the protection of human subjects on those who conduct medical trials.[61]

The FDA regulations generally require informed consent of human test subjects.[62] In the foreign setting, the FDA's new drug regulations require the implementation of institutional review boards, defined as bodies "designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects."[63] Foreign boards are expected to adhere to international ethical standards, including those set by the FDA, the countries' own regulatory agencies, and international agreements such as the International Conference on Harmonization.[64] The FDA directly oversees the protection of foreign human research subjects through its regulations of clinical investigators.[65] In addition, the FDA regulations place direct responsibility on the corporation who seeks to bring a drug to market, requiring that new drug sponsors must also monitor the investigators at the clinic level.[66] The FDA also expects that local government authorities in the hosting countries will oversee the monitoring of human subjects.[67]

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61. *Id.* § 312.120(c)(4).

62. Informed Consent of Human Subjects, 21 C.F.R. § 50.23 (2002) (including exceptions for cases meeting all of the following conditions: (1) the human subject is confronted by a life-threatening situation necessitating use of the test article, (2) informed consent cannot be obtained through inability to communicate or legal ineffectiveness of consent, (3) there is insufficient time to reach a legal representative, and (4) there is no better alternative treatment).

63. 21 C.F.R. § 56.102(b)(21)(g). Additionally, the FDA has created an Office of Human Research Protections (formerly the Office of Protection from Research Risks). The OHRP is to ensure that "[a]ll human subjects research in which American investigators are involved, and which would be subject to the federal regulations if it were conducted wholly within the United States, must comply with the federal regulations for the protection of human subjects in all material respects." U.S. Dept. of Health and Human Services, Office for Human Research Protection (OHRP), Investigational Review Boards: Internal Research, *available at* http://ohrp.osophs.dhhs.gov/irb/irb_chapter6ii.htm. However, the OHRP's compliance rules mostly continue to rely on self-reporting by drug researchers. *See generally id.*

64. OIG Report, *supra* note 35, at 3 (citing 21 C.F.R § 312.120(c) (2002)).

65. OIG Report, *supra* note 35, at 3. However, enforcement is far from rigorous. For example, when the FDA announced that it would require more verification from drug makers, its representative said, "We might, if the trial data came from a location unfamiliar to us, ask the sponsor just how they [gained informed consent], instead of just asking a company to assure us that it gained appropriate informed consent." *Foreign Trials Require Sponsors to Take on Monitoring Role*, WASH. DRUG LETTER, May 14, 2001, *available at* 2001 WL 8205176 [hereinafter *Foreign Trials Require Sponsors*].

66. OIG Report, *supra* note 35, at 3. As a result of the dependence on self-monitoring by the drug industry, it is currently "up to CEOs to recognize and stop shortcuts on patients' rights." Joanna Breitstein, *Protecting People Everywhere*, PHARM. EXEC., Dec. 1, 2001, at 12, *available at* 2001 WL 13574125.

67. OIG Report, *supra* note 35, at 3.

This system is prone to breakdowns at many levels. The pharmaceutical industry itself has raised concerns about the ability of foreign governments to provide adequate review of research.[68] One large pharmaceutical company was so concerned by the inadequacy of ethics boards in some regions that it contracted a U.S. institutional review board to train members of foreign institutional review boards overseeing its research.[69]

In recent years, the FDA has attempted to increase oversight of foreign experiments.[70] The FDA is concerned that research subjects in developing nations may not be fully informed of the risks involved, and may be unwilling participants in drug testing.[71]

III. EXTRATERRITORIAL APPLICATION OF U.S. LAW AND THE PRESUMPTION AGAINST EXTRATERRITORIALTY

Extraterritorial application of U.S. law has been inconsistent.[72] The presumption against extraterritoriality should operate equally in all areas of law: it is a canon of statutory construction, and the courts have never stated a reason not to apply it consistently in all cases. While in some areas of the law the presumption has been treated as nearly irrebuttable,[73] in other areas the courts have readily applied U.S. law extraterritorially.[74]

The traditional test for extraterritorial application is based entirely on a determination of congressional intent.[75] Originally, an outright rule existed against finding extraterritoriality in U.S.

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68. *Id.* at 15.

69. *Id.*

70. Stephens, *supra* note 1. The U.S. Department of Health and Human Services recently created an office responsible for oversight of experiments conducted by U.S. researchers on foreign patients. *Id.* According to the head of the FDA Office of Regulatory Affairs, Associate Commissioner Dennis Baker, international inspections are a top FDA Office of Regulatory Affairs (ORA) priority. *U.S. FDA Looks to Leveraging with Partners to Boost Resources, Face New Challenges*, MARKETLETTER, April 30, 2001, *available at* 2001 WL 9078545 [hereinafter *U.S. FDA Looks to Leveraging*]. But, due to limited resources, the FDA will practice a regulatory triage, concentrating on products and firms that pose the highest health risk.

71. *U.S. FDA Looks to Leveraging*, *supra* note 70.

72. Mark Gibney & R. David Emerick, *The Extraterritorial Application of United States Law and the Protection of Human Rights: Holding Multinational Corporations to Domestic and International Standards*, 10 TEMP. INT'L & COMP. L.J. 123, 132 (1996).

73. *Id.*

74. *Id.*

75. Suzanne Harrison, *The Extraterritoriality of the Bankruptcy Code: Will the Borders Contain the Code?*, 12 BANK. DEV. J., 809, 815 (1996).

statutes failing explicit congressional authorization.[76] In *American Banana Co. v. United Fruit Co.*, Justice Holmes provided the classic formulation of the rule of statutory construction in terms of the "territorial limits over which the lawmaker has general and legitimate power."[77] "Since the 'operation and effect' of an ambiguous statute could not be construed to go beyond Congress' legitimate jurisdictional interests, the rule of construction was inextricably linked to—if not synonymous with—the jurisdictional principles of territoriality."[78] This amounted to an irrebuttable presumption against extraterritorial application of U.S. law.

Commentators have hypothesized the existence of a market-versus-nonmarket effects distinction to explain both the courts' acceptance of extraterritorial application of antitrust and securities laws, and the refusal to apply labor and environmental statutes extraterritorially without explicit—or even persistent—congressional authorization.[79] While both labor and environmental cases may involve issues that are clearly "market"-based, courts seem to distinguish the perceived local conditions of those cases from the "presumed transnational character of antitrust and securities disputes."[80] The potential impact of anticompetitive trade practices abroad on the U.S. consumer and marketplace is more readily apparent than the effect of similar labor practices.[81]

A. *Application of the Presumption Against Extraterritoriality in Environmental and Labor Law*

The U.S. Supreme Court recently applied the presumption against extraterritoriality in *Equal Employment Opportunity Commission v. Arabian American Oil Co. (Aramco).*[82] There, the Court referred to the presumption both as a "longstanding principle" and as a "canon of construction."[83] The "longstanding principle" is that "legislation of Congress, unless a contrary intent appears, is meant to apply only within the territorial jurisdiction of the United States."[84] As a "canon of construction," it is an "approach whereby unexpressed congressional intent may be ascertained."[85] The Court's

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76. Jonathan Turley, *"When in Rome": Multinational Misconduct and the Presumption Against Extraterritoriality,* 84 NW. U. L. REV. 598, 608 (1990).

77. Am. Banana Co. v. United Fruit Co., 213 U.S. 347, 357 (1909).

78. Turley, *supra* note 76, at 608.

79. *Id.* at 601.

80. *Id.* at 617.

81. Harrison, *supra* note 75, at 821.

82. *See generally* Equal Employment Opportunity Comm'n v. Arabian Am. Oil Co. (Aramco), 499 U.S. 244 (1991).

83. *Id.* at 248.

84. *Id.* at 248 (citing Foley Bros. v. Filardo, 336 U.S. 281, 285 (1949)).

85. *Id.*

stated method of application of the presumption, however, is first to "look to see whether 'language in the [relevant Act] gives any indication of a congressional purpose to extend its coverage beyond places over which the United States has sovereignty or has some measure of legislative control.'"[86] Without an "affirmative intention of the Congress clearly expressed,"[87] there is a presumption that the statute is "primarily concerned with domestic conditions."[88] How the requirement of a "clearly expressed" congressional intent squares with ascertaining "unexpressed congressional intent" is unclear in the *Aramco* majority opinion.[89] The dissent complained that the majority perverted the presumption's purpose by eliminating the search for "unexpressed congressional intent" in favor of a requirement of "clearly expressed" Congressional intent.[90]

The Court's analysis was based on a finding that while plausible interpretations existed that would lead to extraterritorial application,[91] there were also plausible interpretations that involved no congressional intent to apply the statute abroad.[92] The Court further stated that "if we were to permit possible, or even plausible interpretations of language such as that involved here to override the presumption against extraterritorial application, there would be little left of the presumption."[93] This statement is consistent with a requirement for a "clearly expressed" intent. The Court was unclear as to whether the presumption could be overcome using outside evidence of intent, or how strong an indication of congressional intent would be required.[94]

The U.S. Supreme Court has stated that the primary purpose of the presumption against extraterritoriality is "to protect against the unintended clashes between our laws and those of other nations

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86. *Id.*

87. Justice Marshall's dissent argued that the *Foley Brothers* court was the relevant discussion of the presumption. There, Marshall said, the court analyzed the Act itself—the legislative history, the overall scheme of the Act, and the relevant administrative interpretations. This, Marshall argued, was not indicative of a "clear statement rule" as interpreted by the majority. *Id.* at 262. Instead, the dissent found that "the language, history, and administrative interpretations of the statute all support application . . . to United States companies employing United States citizens abroad." *Id.* at 278.

88. Equal Employment Opportunity Comm'n v. Arabian Am. Oil Co. (Aramco), 499 U.S. 244, 248 (1991).

89. *Id.* at 261-68.

90. *Id.* at 268.

91. These interpretations center around the use of "boilerplate language which can be found in any number of congressional Acts, none of which have ever been held to apply overseas." *Id.* at 251.

92. *Id.* at 250-51.

93. *Id.* at 253.

94. *See generally id.*

which could result in international discord."[95] The Court has long been concerned by the possibility of upsetting regulatory schemes abroad. In declining to give extraterritorial effect to the Eight Hour Law in *Foley Brothers v. Filardo*, the court said that the intention "to regulate labor conditions, which are the primary concern of a foreign country, should not be attributed to Congress in the absence of a clearly expressed purpose."[96]

The *Aramco* decision is in keeping with the line of cases where courts have interpreted the presumption against extraterritoriality to be essentially irrebuttable in employment cases, apparently requiring Congress to expressly mandate application abroad.[97] Arguments for overcoming the presumption with respect to the Age Discrimination in Employment Act (ADEA) were strong.[98] In the text of the statute, Congress stated that it viewed age discrimination as a "burden [on] commerce and the free flow of goods in commerce," and declared its scope to extend to "trade . . . among the several States; or between a State and any place outside thereof. . . ."[99] Plaintiffs in the ADEA cases argued that "any place outside" a state would naturally be a reference to foreign territory.[100] The courts instead considered this to be boilerplate language used by Congress without any such meaning behind it. In *Cleary v. United States Lines, Inc.*,[101] a federal district court used the presumption to deny application of the ADEA.[102] The court reached this decision despite its recognition that extraterritorial application of the ADEA would not lead to problems of comity or conflicts with foreign jurisdictions,[103] and that failure to apply the act abroad could undermine Congress' purpose because exclusively territorial application "invites [the Act's] circumvention by unscrupulous employers."[104]

After *Cleary*, Congress amended the ADEA to mandate extraterritorial application.[105] Even after Congress amended the statute, however, the courts persisted in finding that the presumption had not been rebutted, and even refused to accept the amendment as evidence of Congress' original intent in refusing to retroactively apply

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95. *Id.* at 248.
96. Foley Bros. v. Filardo, 336 U.S. 281, 285-86 (1949).
97. Turley, *supra* note 76, at 627.
98. Turley, *supra* note 76, at 625.
99. 29 U.S.C. § 621(a)(4) (1976).
100. Turley, *supra* note 76, at 625-26.
101. Cleary v. United States Lines, 555 F. Supp. 1251 (D.N.J. 1983), *aff'd*, 728 F.2d 607 (3d Cir. 1984).
102. *Id.* at 1263.
103. *Id.* at 1259.
104. *Id.* at 1263. This stands in contrast to the criminal cases where the courts disregard the presumption in an attempt to effectuate the purpose of the statute. *See infra* notes 166-76.
105. Turley, *supra* note 76, at 625.

the amendment extraterritorially.[106] The Fifth Circuit even went so far as to determine that the fact of Congress' amendment indicated clear original congressional intent not to apply the ADEA extraterritorially.[107]

Title VII contained "boilerplate" language that is also found in the Sherman Act and in the securities statutes. In *Aramco*, the U.S. Supreme Court found that the language was ambiguous, and because such language could be found in other statutes that are not held to apply abroad, the Court held that the language did not represent any intent on Congress' part to apply the statute extraterritorially.[108]

Environmental legislation is universally thought to apply only in domestic situations.[109] This is not necessarily due to the presumption against extraterritorial application, but because Congress has frequently made explicit its intent to apply the statutes domestically.[110] Nevertheless, controversy does surround the treatment of the National Environmental Protection Act (NEPA).[111] The NEPA contains no substantive requirements; it operates only procedurally.[112] It requires federal agencies to create an environmental impact statement for any major federal project or

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106. *Id.* at 625-26.

107. DeYoreo v. Bell Helicopter Textron, Inc., 785 F.2d 1282, 1283 (5th Cir. 1986). See also Pfeiffer v. Wm. Wrigley Jr. Co., 755 F.2d 554, 559 (7th Cir. 1985). The court refused to apply the ADEA extraterritorially because of ambiguous congressional intent, stating that,

> the legislative history of the 1984 amendment leaves totally obscure whether the amendment was meant to change the law, to state more clearly the original meaning of the law, or perhaps just to limit the extraterritorial application of the Act (to American citizens employed by American corporations or their subsidiaries in countries that do not have inconsistent laws).

Id. If Congress had not amended the act, the force of the presumption against extraterritoriality would have continued, and the act would never have been applied abroad. The U.S. Court of Appeals for the Seventh Circuit used similar reasoning. *See generally id.* The court argued that congressional debate surely would have ensued had there been any thought of applying the act abroad originally; the court understood the lack of any such debate to be an indication that Congress had not even considered the extraterritorial application. *Id.* However, the court then reasoned away the lack of debate of the amendment declaring extraterritoriality, stating that this was only an indication of the trivial nature of the amendment. *Id.*

108. *See* Equal Employment Opportunity Comm'n v. Arabian Am. Oil Co. (Aramco), 499 U.S. 244, 250-51 (1991).

109. Maj. Mark R. Ruppert, *Criminal Jurisdiction Over Enviormental Offenses Committed Overseas: How to Maximize and When to Say "No"*, 40 A.F. L. REV. 1, 14 (1996).

110. *See generally id.* at 14-16 (reviewing the definitions of environment, and the statements of purpose from various environmental statutes including CERCLA and the CAA).

111. *Id.* at 16.

112. *Id.*

actions "significantly affecting the requirement."[113] NEPA's processes are designed to gather information on environmental impacts, not necessarily to prohibit the proposed action.[114] Furthermore, the NEPA lacks any statements by Congress to suggest a strictly territorial application. The military has repeatedly been confronted with situations in which the NEPA could be considered to restrain its activities abroad. For example, in *Greenpeace USA v. Stone*,[115] the Department of the Army's attempt to remove chemical munitions from the Federal Republic of Germany was challenged by environmental groups.[116] The Army prepared environmental documents for the high seas and U.S. portions of the transport, but did not formally examine the environmental impacts of transporting the munitions within Germany.[117] Greenpeace's challenge to the Army's activities relied upon an extraterritorial application of the NEPA.[118] The U.S. district court noted the possible conflicts with Germany's sovereign right to regulate such activities within its own borders,[119] and did not apply the NEPA.[120] The court went beyond simply recognizing Germany's sovereignty within its own borders, and further held that the presumption against extraterritoriality should operate to prevent any interference with a state's territorial integrity.[121]

While Congress did not explicitly authorize extraterritorial application of the NEPA, arguably it did express such intent through the use of broad, sweeping language calling for global environmental protection.[122] An executive order sought to formally establish extraterritorial application of the NEPA, but added exceptions for situations where the foreign state is participating with the United States or not otherwise involved with the action.[123] Under a simple application of the presumption, the act probably would have been limited territorially. In *Environmental Defense Fund (EDF) v. Massey*, however, the D.C. Circuit applied three major criteria beyond congressional intent to determine whether an exception to the

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113. *Id.*

114. Royal C. Gardner, *Taking the Principle of Just Compensation Abroad: Private Property Rights, National Sovereignty, and the Cost of Environment Protection*, 65 U. CIN. L. REV. 539, 569 (1997).

115. Greenpeace USA v. Stone, 748 F. Supp. 749 (D. Haw. 1990).

116. *Id.* at 752-54.

117. *Id.* at 753-54.

118. *Id.* at 745.

119. Gardner, *supra* note 114, at 569.

120. *Greenpeace*, 748 F. Supp. at 760.

121. Gardner, *supra* note 114, at 569.

122. Silvia M. Riechel, *Governmental Hyprocrisy and the Extraterritorial Application of NEPA*, 26 CASE W. RES. J. INT'L L. 115, 130 (1994).

123. Exec. Order No. 12114, 44 Fed. Reg. 1957 (Jan. 9, 1979). These provisions should have protected against possible infringements on the sovereignty of the host country.

presumption against extraterritoriality is appropriate: (1) whether adverse effects in the United States will result from a lack of extraterritorial application,[124] (2) whether extraterritorial application will cause international discord, and (3) whether the conduct sought to be regulated occurs in U.S. territory.[125] The court imported the examination of "adverse effects" from prior application of the presumption in other parts of the law.

B. *The "Effects Test" Exception to the Presumption Against Extraterritoriality in Antitrust and Securities Law*

The old, broadly restrictive rule against extraterritoriality was essentially swept aside in *United States v. Aluminum Co. of America (Alcoa).*[126] This case adopted Judge Learned Hand's "effects"[127] test. Alcoa attempted to monopolize the international market of aluminum ingot. The government attempted to use the Sherman Antitrust Act to restrain Alcoa's anticompetitive practices that took place beyond the borders of the United States.[128] While the Sherman Act is silent on the extraterritorial question, the Act expressly makes illegal any restraint of trade or commerce "among the several States, or with foreign nations."[129] Judge Hand did not rely on this language in applying the act extraterritorially,

> We are not to read general words, such as those in [the Sherman] Act, without regard to the limitations customarily observed by nations upon the exercise of their powers; limitations which generally correspond to those fixed by the "Conflict of Laws." We should not impute to Congress an intent to punish all whom its courts can catch, for conduct which has no consequences within the United States.[130]

Hand focused neither on the language of the statute, nor on its legislative history, to determine the intent of Congress.[131] Instead,

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124. The court specifically referred to Steele v. Bulova, 334 U.S. 280 (1952) (trademark), United States v. Aluminum Co. of Am. (Alcoa), 148 F.2d 416 (2d Cir. 1945) (antitrust), and Schoenbaum v. Firstbrook, 405 F.2d 200 (2d Cir. 1968) (securities).

125. Environmental Defense Fund v. Massey, 986 F.2d 528, 531 (D.C. Cir. 1993).

126. *Alcoa*, 148 F.2d at 443.

127. The Hand effects test closely follows the jurisdictional rule for U.S. interstate criminal law found in *Strassheim v. Milton Daily*, 221 U.S. 280, 285 (1911) (stating that "acts done outside a jurisdiction, but intended to produce and producing detrimental effects within it, justify a state in punishing the cause of the harm as if he had been present at the effect, if the state should succeed in getting him within its power").

128. *Alcoa*, 148 F.2d at 443.

129. 15 U.S.C. §§ 1, 2 (2002).

130. *Alcoa*, 148 F.2d at 443.

131. *Id.*

Hand speculated as to what conduct Congress probably intended to reach.[132] He assumed that Congress "certainly did not intend" the Act to cover "agreements made beyond our borders not intended to affect imports."[133] He also rejected extraterritorial application of agreements intended to have an effect on imports, but actually lacking any such effect.[134] Hand concluded that the Act covers agreements "intended to affect imports or exports" that could be "shown actually to have had some effect upon them."[135] The effects test was not grounded upon any language from Congress; Hand only assumed that Congress would have wished to apply the statute extraterritorially in order to protect the U.S. marketplace.[136]

This effects test became the standard applied to most market-oriented cases—both in antitrust and securities law—and resulted in a sharp increase in the number of extraterritorial actions.[137] Courts gradually came to apply the "effects doctrine" to permit liability under U.S. antitrust laws whenever an actual or presumed anticompetitive effect on U.S. markets could be shown.[138] Ultimately, the extension of the extraterritorial reach of antitrust law did not result from congressional amendment to the legislation, or any change in apparent congressional intent, but rather from "new

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132. *Id.*

133. *Id.*

134. *Id.*

> That situation might be thought to fall within the doctrine that intent may be thought to be a substitute for performance in the case of a contract made within the United States; or it might be thought to fall within the doctrine that a statute should not be interpreted to cover acts abroad which have no consequences here.

Id. at 443-44.

135. *Id.* at 444. This was a departure from the U.S. Supreme Court precedent cited by Hand. Previously, the cases involved agents sent into the United States to effect the performance of the anticompetitive agreements. Hand stated that an agent "does not differ from an inanimate means" of effecting the anticompetitive purpose. *Id.*

136. The Ninth Circuit discussed an expanded approach to the effects test in *Timberlane Lumber Co. v. Bank of America*, 549 F.2d 597, 613 (9th Cir. 1976). The court proposed a three-part test in antitrust cases. First, does the alleged conduct affect, or is it intended to affect, the foreign commerce of the United States? Second, is the conduct's type and magnitude sufficient to recognize it as a violation of U.S. antitrust law? Third, do matters of comity and fairness outweigh the U.S. interest in regulation? *Id.* For a further discussion of the test, see Joseph J. Norton, *Extraterritorial Jurisdiction from a Differing Perspective: Section 416 of the Restatement (Third) and "Jurisdiction to Regulate Activities Related to Securities," in* COMMENTARIES ON THE RESTATEMENT (THIRD) OF THE FOREIGN RELATIONS LAW OF THE UNITED STATES 52 (ABA Section of International Law and Practice 1992).

137. Turley, *supra* note 76, at 611.

138. *Id.* It has been suggested that the effects test is only part of an analysis for an exception to the presumption. The Ninth Circuit stated that the "effects test by itself is incomplete because it fails to consider other nations' interests. *Timberlane Lumber Co.*, 549 F.2d at 611-12.

economic realities and regulatory demands, and more directly from the perceived changes in principles of public international law, conflict of laws thinking and state practice that followed this evolution."[139]

Most extraterritoriality disputes in securities cases involve alleged violations of the Securities Exchange Act's (SEA) antifraud provisions that prohibit any person from using the means and instrumentalities of interstate commerce to effect fraudulent securities transactions.[140] In the securities context, the effects test is based on the presumption that Congress must have intended to protect the U.S. marketplace from foreign misconduct or from misconduct originating abroad.[141] In addition, securities cases have also applied the "conduct" test.[142]

The conduct test is a subjective theory of territoriality that broadens the basis for extraterritoriality.[143] Applying this test, conduct would be actionable under the SEA regardless of where the effect took place.[144] The conduct test allows actions to be brought wherever conduct in the United States facilitated the sales in question. This test has been applied at the circuit level, most often where U.S. instrumentalities of commerce were utilized, even if the stock was not listed in the United States and was not sold in the United States.[145]

C. *Implied Congressional Intent and the Role of the Effects Test in the Extraterritorial Application of U.S. Criminal Law*

A longstanding principle of U.S. constitutional jurisprudence is that the government has the authority to criminalize certain

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139. Gary Born, *A Reappraisal of the Extraterritorial Reach of U.S. Law*, 24 LAW & POL'Y INT'L BUS. 1, 31 (1992).

140. Turley, *supra* note 76, at 614.

141. *See, e.g.*, RESTATEMENT (THIRD) OF THE FOREIGN RELATIONS LAW OF THE UNITED STATES § 416 (1987). The Second Circuit has held that where "extraterritorial application of the Act is necessary to protect American investors," the presumption against extraterritoriality does not represent a "Congressional intent to preclude application of the Exchange Act to transactions regarding stocks traded in the United States which are effected outside the United States." Schoenbaum v. Firstbrook, 405 F.2d 200, 206 (2d Cir. 1968).

142. Turley, *supra* note 76, at 614.

143. RESTATEMENT (SECOND) OF THE FOREIGN RELATIONS LAW OF THE UNITED STATES §§ 17, 18 (1965); Turley, *supra* note 76, at 615-16.

144. Turley, *supra* note 76, at 616.

145. IIT v. Vencap, Ltd., 519 F.2d 1001, 1018 (2d Cir. 1975); *see also* Leasco Data Processing Equip. Corp. v. Maxwell, 468 F.2d 1326, 1337-39 (2d Cir. 1972).

activities of its subjects even beyond its borders.[146] Congress' intent to apply a criminal law to U.S. citizens abroad out to be plain on the face of the statute. The U.S. Supreme Court has made no exception to the presumption against extraterritoriality for criminal acts. Therefore, a clearly expressed congressional intent should be required for extraterritorial application.

In reality, the circuits have displayed a willingness to find extraterritorial application even where neither the statute relied upon nor the legislative history gave any indication of a congressional intent for extraterritorial application.[147] These cases seem to rely upon a combination of two of the bases for extraterritorial jurisdiction found in international law: the nationality[148] basis and the effects doctrine.[149]

In *United States v. Baker*,[150] the Fifth Circuit upheld the conviction of a defendant who was found in possession of a controlled substance. The defendant was caught at sea, beyond the territorial waters of the United States, presumably on his way to the United States.[151] The court relied on the reasoning that "the power to control efforts to introduce illicit drugs into the United States from the high seas and foreign nations is a necessary incident to Congress' efforts to eradicate all drug trafficking."[152] The court completely ignored the presumption against extraterritoriality. Instead, it essentially relied upon a presumption in favor of extraterritoriality. The Court reasoned that "absent an express intention on the face of the statute to [reach extraterritorially], the exercise of that power may be inferred from the nature of the offense and Congress' other

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146. H. Lowell Brown, *The Extraterritorial Reach of the U.S. Government's Campaign Against International Bribery*, 22 HASTINGS INT'L & COMP. L. REV. 407, 417 (1999).

> It is conceded that the legislation of every country is territorial; that beyond its own territory, it can only affect its own subjects or citizens. . . . The rights of war may be exercised on the high seas, because is carried on upon the high seas; but the pacific rights of sovereignty must be exercised within the territory of the sovereign.

Rose v. Himely, 8 U.S. (4 Cranch) 241, 279 (1808).

147. *See, e.g.*, United States v. Baker, 609 F.2d 134, 136 (5th Cir. 1980) (construing a law against distribution and possession of construed substances to apply where the defendant was found at sea, beyond the territorial limits of U.S. waters); United States v. Thomas, 893 F.2d 1066, 1068 (5th Cir. 1990) (construing the Federal Child Pornography Act to apply extraterritorially).

148. *Thomas*, 893 F.2d at 1068-69.

149. *Baker*, 609 F.2d at 136-37.

150. *Id.* at 134.

151. While the defendant was outside of the three-mile territorial jurisdiction of the United States, it was within the "customs waters" of the United States. *Id.* at 135. The court treated the question as one of extraterritorial application, and ignored any possible "customs waters" distinction. *Id.*

152. *Id.* at 137.

legislative efforts to eliminate the type of crime involved."[153] This strongly resembles an application of the effects test,[154] though it was not couched in the same language. The court's chief concern was apparently that the defendant would have effectuated the harm Congress wished to regulate if given the opportunity.[155] Given the particular circumstances of this case, it appeared certain that the territory of the United States would have been affected by the defendant's actions.

In *United States v. Thomas*, the Ninth Circuit followed a line of reasoning similar to the Fifth Circuit's in *Baker*.[156] The court first examined the type of crime involved, and it concluded that the congressional intent to eliminate the proscribed activity could realistically be served only by extraterritorial application of the statute.[157] The court found that through its statutes, Congress had set up a scheme to eradicate the sexual exploitation of children.[158] That scheme involved prohibiting the transportation, mailing, and receipt of child pornography.[159] By "[p]unishing the creation of child pornography outside the United States that is actually, is intended to be, or may be reasonably expected to be transported in interstate or foreign commerce," the executive branch and courts could more effectively accomplish Congress' ultimate intent.[160] Here, the court's reasoning reached into territory beyond that of Hand's original effects test. Hand required both an intention to cause a harm in the United States and an actual effect in the United States. The *Thomas* court's reasoning applied to antitrust law would allow for the prosecution of a corporation that conspired to commit antitrust violations in the U.S. market, but had not yet accomplished the effect on the U.S. marketplace; Hand had rejected just this result in dicta in *Alcoa*.

The First Circuit used an effects test analysis to provide support for extraterritorial criminal jurisdiction under the Sherman Antitrust

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153. *Id.* at 136.

154. This use of the effects test is contrary to Turley's hypothesized market/non-market distinction.

155. *Baker*, 609 F.2d at 136-37.

156. United States v. Thomas, 893 F.2d 1066, 1066 (5th Cir. 1990).

157. *Id.* Interestingly, the Mann Act that makes it a felony to travel across state lines for sexually immoral purposes was amended in 1994 to specifically apply to those who travel outside of the United States to engage in sexual activities that are illegal inside the United States. Eric Thomas Berkman, *Responses to the International Child Sex Tourism Trade*, 19 B.C. INT'L & COMP. L. REV. 397, 415 (1996). This seems to indicate either that Congress did not intend for the courts to view similar criminal statutes as having an extraterritorial reach lacking specific authorization, or that Congress approved of the extraterritorial application but was unwilling to assume that courts would apply the same reasoning in the future.

158. *Thomas*, 893 F.2d at 1068. *See also* 18 U.S.C. §§ 2241-2257.

159. *Thomas*, 893 F.2d at 1068.

160. *Id.* at 1068-69.

Act.[161] The court analogized from a U.S. Supreme Court decision regarding a state's "authority for applying a state's criminal statute to conduct occurring entirely outside the state's borders."[162] "Acts done outside a jurisdiction, but intended to produce and producing detrimental effects within it, justify a State in punishing the cause of the harm as if he had been present at the effect."[163] The First Circuit said that "it is not much of a stretch to apply this same principle internationally, especially in a shrinking world."[164]

The First Circuit has rejected any distinction between criminal and civil extraterritoriality.[165] The court has held there is no difference in the strength of the presumption against extraterritoriality where criminal rather than civil liability is in question.[166]

D. *Exception for Crimes and Frauds Against the U.S. Government*

The Second Circuit has held that the presumption against extraterritoriality is probably inoperative in cases involving crimes against the U.S. government.[167] A statute prohibiting crimes against the U.S. government "may be applied even in the absence of 'clear evidence' that Congress so intended."[168] This reasoning is logically connected to that of the effects test. Here, it is simply assumed that a fraud against the U.S. government necessarily has an effect within U.S. territory; thus, the harm requirement of the effects test is satisfied.[169] The principle of automatic extraterritoriality for crimes against the U.S. government is derived from the Supreme Court decision *United States v. Bowman*.[170] *Bowman* dealt with a fraud committed by a U.S. citizen against the U.S. government while abroad.[171] The Court recognized an important difference between criminal statutes passed to maintain order within a given

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161. United States v. Nippon Paper Indus. Co., 109 F.3d 1, 6 (1st Cir. 1997).

162. *Id.*

163. Strassheim v. Daily, 221 U.S. 280, 285 (1911).

164. *Nippon Paper*, 109 F.3d at 6 (citing Chua Han Mow v. United States, 730 F.2d 1308, 1311-12 (9th Cir. 1984) (applying the *Strassheim* principle to conduct in Malaysia involving drugs intended for distribution in the United States), *cert denied*, 470 U.S. 1031 (1985)); *see also* United States v. Hayes, 653 F.2d 8, 11 (1st Cir. 1981).

165. *Nippon Paper*, 109 F.3d at 6.

166. *Id.*

167. United States v. Gatlin, 216 F.3d 207, 211 n.5 (2d Cir. 2000).

168. *Id.*

169. One could ask in what way harm to the U.S. government is different from the harm suffered by a U.S. citizen or a U.S. corporation abroad. Why is the harm suffered by the U.S. government acting abroad automatically connected to the U.S. government at home, while U.S. citizens are treated differently under labor law depending on where in the world they stand?

170. United States v. Bowman, 260 U.S. 94, 97-98 (1922).

171. *Id.* at 94.

community, such as the nation at large,[172] and those designed to address a particular harm, irrespective of where the action causing the harm occurs.[173] The Court emphasized the right of the government "to defend itself against obstruction, or fraud wherever perpetrated, especially if committed by its own citizens."[174] In language similar to that of the effects test, the Court found an implied intent on the part of Congress: "Congress has not thought it necessary to make specific provision in the law that the locus shall include the high seas and foreign countries, but allows it to be inferred from the nature of the offense."[175] The courts have continued to infer such an intent.[176] Now, false statements made to the U.S.

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172. *Id.* at 97-98.

173. *Id.*

> The necessary locus, when not specially defined, depends upon the purpose of Congress as evidenced by the description and nature of the crime and upon the territorial limitations upon the power and jurisdiction of a government to punish crime under the law of nations. Crimes against private individuals or their property, like assaults, murder, burglary, larceny, robbery, arson, embezzlement and fraud of all kinds, which affect the peace and good order of the community, must of course be committed within the territorial jurisdiction of the government where it may properly exercise it. If punishment of them is to be extended to include those committed outside of the strict territorial jurisdiction, it is natural for Congress to say so in the statute, and failure to do so will negative the purpose of Congress in this regard. We have an example of this in the attempted application of the prohibitions of the Anti-Trust Law to acts done by citizens of the United States against other such citizens in a foreign country. American Banana Co. v. United Fruit Co., 213 U.S. 347 (1909). That was a civil case, but as the statute is criminal as well as civil, it presents an analogy. But the same rule of interpretation should not be applied to criminal statutes which are, as a class, not logically dependent on their locality for the Government's jurisdiction, but are enacted because of the right of the Government to defend itself against obstruction, or fraud wherever perpetrated, especially if committed by its own citizens, officers or agents. Some such offenses can only be committed within the territorial jurisdiction of the Government because of the local acts required to constitute them. Others are such that to limit their locus to the strictly territorial jurisdiction would be greatly to curtail the scope and usefulness of the statute and leave open a large immunity for frauds as easily committed by citizens on the high seas and in foreign countries as at home. In such cases, Congress has not thought it necessary to make specific provision in the law that the locus shall include the high seas and foreign countries, but allows it to be inferred from the nature of the offense.

Id.

174. *Id.*

175. *Id.*

176. *See, e.g.*, United States v. Walczak, 783 F.2d 852 (9th Cir. 1986), dicussed *infra* note 177.

government, even if they are made outside the borders of the United States, are punishable under U.S. law.[177]

E. *Does the Presumption Against Extraterritoriality Survive the* Chevron *Deference Approach?*

The U.S. Supreme Court has never directly addressed the relationship between the presumption against extraterritoriality and the deference standard established in *Chevron U.S.A. v. Natural Resources Defense Council.*[178] In *Foley Bros.*, which predated the creation of the *Chevron* test, the Court examined an administrative interpretation of the law as evidence of congressional intent.[179] An employee of a U.S. government contractor operating in Iran and Iraq brought suit under the U.S. Eight Hour Law[180] claiming that he was improperly not paid for overtime work. In support of extraterritorial application of the law, the plaintiff pointed to an executive order that suspended the law with respect to laborers employed by the government at Atlantic military bases leased from Great Britain.[181] Arguably, the executive order would have been issued only if the executive branch understood Congress to have meant the statute to apply extraterritorially.

The Court concluded, however, that the order might have been issued on the assumption that the bases were sufficiently under the control of the government that the Eight Hour Law would apply

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177. *Walczak*, 783 F.2d at 854. In this case, the court did not apply the presumption against extraterritoriality. The court neither examined the statutory language for a suggestion of extraterritoriality, nor looked to the legislative history of the statute in question. Instead, it relied upon the assumption made in Bowman that Congress would not feel it necessary to explicitly apply such a statute abroad. The court cited Bowman for the proposition "that some offenses are such that to limit their *locus* to the strictly territorial jurisdiction would be greatly to curtail the scope and usefulness of the statute and leave open a large immunity for frauds as easily committed on the high seas and in foreign countries." *Id.*

178. Curtis A. Bradley, Chevron *Deference and Foreign Affairs*, 86 VA. L. REV. 649, 691 (2000). The doctrine of court deference to agency interpretations originated in Chevron U.S.A. Inc. v. Natural Res. Ref. Council, Inc., 467 U.S. 837 (1984). Jeana L. Goosman, Christensen v. Harris Country*: When Rejecting* Chevron *Deference The Supreme Court Correctly Clarified an Unclear Issue*, 34 CREIGHTON L. REV. 753 (2001).

179. Foley Bros. v. Filardo, 336 U.S. 281, 288-90 (1949).

180. The law provided that

> [e]very contract made to which the United States . . . is a party . . . shall contain a provision that no laborer or mechanic doing any part of the work contemplated by the contract, in the employ of the contractor or any subcontractor . . . shall be required or permitted to work more than eight hours in any one calendar day upon such work.

Id. at 282 (emphasis added). The law further required that any work beyond the eight-hour limit should be compensated at a rate one-and-one-half times the basic rate of pay. *Id.* at 283.

181. *Id.* at 288.

under a separate theory of territoriality found in the Court's decision in *Vermilya-Brown Co. v. Connell*.[182] This level of ambiguity was sufficient for the Court to find that no clear congressional authorization had been granted.[183] The Court more favorably viewed conclusions by the Attorney General and the Comptroller General that the law should not be applied to foreign employees of U.S. corporations abroad.[184] The Court concluded that because the statute did not differentiate between foreign laborers and U.S.-citizen laborers, and the Attorney General and Comptroller General both thought that foreign laborers were not included under the statute, that the law could not apply to one group but not the other on foreign soil.[185]

The U.S. Supreme Court found the presumption against extraterritoriality effective in *Aramco* despite the EEOC's conclusion that the Civil Rights Act of 1964 should have been given an extraterritorial application in the case of U.S. citizen employees employed by U.S. corporations.[186] The Court, however, avoided potential conflict with *Chevron* deference by concluding that "Congress, in enacting Title VII, did not confer upon the EEOC authority to promulgate rules or regulations."[187] Because the EEOC lacks rule-making authority, it is not entitled to the *Chevron* level of deference. Therefore, *Chevron* deference would not apply and the level of deference actually afforded to the EEOC's intepretation of Title VII would "depend upon the thoroughness of evidence of its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control."[188] Petitioners argued that the Court ought to defer to longstanding EEOC guidelines interpreting the statute as protecting U.S. citizens employed abroad.[189] The majority found, however, that the EEOC's interpretation had changed since the statute was first enacted.[190] While this lack of consistency did not lead the majority to "wholly

182. *Id.*; *see also* Vermilya-Brown Co. v. Connell, 335 U.S. 377 (1948).

183. *Id.*

184. *Id.*

185. *Id.* at 288-89.

186. *See generally* Equal Employment Opportunity Comm'n v. Arabian Am. Oil Co. (Aramco), 499 U.S. 244, 244 (1991) (holding that Title VII of the Civil Rights Act of 1964 does not apply extraterritorially in regulating employment practices).

187. *Id.* at 257.

188. *Id.* at 257 (quoting Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944)). The court found that EEOC's interpretation "does not fare well under these standards." *Id.* The EEOC's position contradicted its earlier position that the statute was limited to domestic protection, and provided no explanation for its change in judgment. *Id.*

189. Gibney & Emerick, *supra* note 72, at 131.

190. *Aramco*, 499 U.S. at 257-58.

discount" the EEOC's position, the Court did find that it left the EEOC's interpretation with too little weight "to overcome the presumption against extraterritorial application."[191] Given these circumstances, it is unclear whether the Court would have reached a different conclusion had it afforded the EEOC *Chevron* deference, or given the EEOC's conclusions greater weight under the *Skidmore* standard.[192]

In a concurrence, Justice Scalia stated that he would have accorded *Chevron* deference to the EEOC regarding its interpretation of Title VII.[193] In his *Chevron* analysis, however, Justice Scalia would have incorporated the presumption against extraterritoriality as a factor in examining the reasonableness of the agency's interpretation of its authorizing statute.[194] Scalia stated that the need for Congress to clearly express its intent to overcome the presumption against extraterritoriality "would create a higher burden for the agency in demonstrating the validity of its position."[195] In fact, this would nullify the deference in a *Chevron* deference analysis. Without a "clearly expressed" congressional intent in favor of extraterritoriality, the agency could never reasonably conclude that the law applied extraterritorially. This would essentially substitute a requirement of clear congressional authorization for the reasonable interpretation of the agency. Thus, presumably, the Court would have the power to make the final determination of whether congressional intent was "clearly expressed." Under Scalia's analysis, *Chevron* deference would be completely undermined, leaving the *Chevron* deference approach operative in name only.

The dissent in *Aramco* was unclear as to the level of deference it would afford the EEOC in its interpretation of the statute.[196] The dissent stated that "there is no reason not to give effect to the considered and consistently expressed views" of the relevant agencies.[197] However, it neither exclusively relied on the agencies' interpretations, nor cited *Chevron* in discussing the weight of the agencies' interpretations.[198]

There has been mixed circuit court authority addressing *Chevron* deference and extraterritoriality.[199] In two decisions predating *Aramco*, both involving independent government agencies, the D.C. Circuit held that the presumption against extraterritoriality

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191. *Id.*
192. Bradley, *supra* note 178, at 692.
193. *Aramco*, 499 U.S. at 259 (Scalia, J., concurring).
194. *Id.*
195. *Id.*
196. *Id.* at 260-78
197. *Id.* at 278.
198. *Id.* at 260-78.
199. Bradley, *supra* note 178, at 692.

superseded *Chevron* deference.[200] The Second Circuit, however, more recently found that *Chevron* deference did apply to the SEC's extraterritorial application of a statute.[201]

The U.S. Supreme Court has said that the presumption against extraterritoriality is designed to spur Congress to address issues of extraterritoriality more directly.[202] The principle reason for this appears to be the Court's belief that Congress is institutionally better situated than the judiciary to determine whether and to what extent U.S. law should apply abroad.[203] It has also been suggested that the presumption against extraterritoriality should override *Chevron* deference because "extraterritorial application calls for extremely sensitive judgments involving international relations; such judgments must be made via the ordinary lawmaking process (in which the President of course participates). The executive may not make this decision on its own."[204] The U.S. Supreme Court has observed that Congress is "able to calibrate its provisions in a way that we cannot."[205] The Court may avoid issues that it feels ill equipped to resolve, or that too closely resemble policy-making.[206] Additionally, the Court has expressed concern at the prospect of "running interference in such a delicate field of international relations."[207] The Court does not necessarily prefer congressional interpretation to executive interpretation; it primarily wishes to remove certain issues from determination by the courts.[208] In this respect, the Court has no reason not to give an agency interpretation of extraterritoriality deference if it would do so were the issue not one of extraterritoriality.

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200. *See* Commodity Futures Trading Comm'n v. Nahas, 738 F.2d 487, 495 (D.C. Cir. 1984); Fed. Trade Comm'n v. Companie de Saint Gobain-Pont-a-Mousson, 636 F.2d 1300, 1322-23 (D.C. Cir. 1980).

201. *See* Europe & Overseas Commodity Traders, S.A. v. Banque Paribas London, 147 F.3d 118, 123 & n.3 (2d Cir. 1998), *cert. denied*, 199 S.Ct. 1029 (1999).

202. Curtis A Bradley, *Territorial Intellectual Property Rights in an Age of Globalism*, 37 VA. J. INT'L L. 505, 550-55 (1997).

203. Bradley, *supra* note 178, at 693.

204. Cass R. Sunstein, *Nondelegation Canons*, 67 U. CHI. L. REV. 315, 333 (2000).

205. Equal Employment Opportunity Comm'n v. Arabian Am. Oil Co. (Aramco), 499 U.S. 244, 259 (1991).

206. Bradley, *supra* note 178, at 694.

207. Benz v. Compania Naviera Hidalgo, S.A., 353 U.S. 138, 147 (1957).

208. Bradley, *supra* note 178, at 694.

IV. THE FDA'S POWER TO REGULATE U.S. DRUG RESEARCH ABROAD IS LIMITED

A. *The Food, Drug, and Cosmetic Act Does Not Exhibit a "Clearly Expressed" Congressional Intent for Extraterritorial Application*

The Federal Food, Drug, and Cosmetic Act (FDCA) includes the same "boilerplate language" of interstate commerce as the ADEA. The "Prohibited Acts" section of the statute[209] refers to the "introduction or delivery for introduction into interstate commerce of any article in violation of section . . . 21 USCS 355 (New Drug Application)." The term "interstate commerce" is defined as "commerce between any State or Territory and any place outside thereof," while "State" means "any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico."[210]

The Section of the FDCA that grants rulemaking and enforcement authority to the FDA does not express clearly whether Congress desired the FDA to have an extraterritorial reach in its regulatory powers.[211] It does suggest that the FDA be afforded some degree of ability to act internationally. The mission of the FDA is to

> (1) promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner;
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> (2) with respect to such products, protect the public health by ensuring that—
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> (A) foods are safe, wholesome, sanitary, and properly labeled;
>
> (B) human and veterinary drugs are safe and effective; . . . .
>
> (3) *participate through appropriate processes with representative of other countries* to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements; and
>
> (4) as determined to be appropriate by the Secretary, carry out paragraphs (1) through (3) in consultation with experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products.[212]

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209. 21 U.S.C. § 331 (1997).
210. 21 U.S.C. § 321(a) & (b) (1997).
211. *See generally* 21 U.S.C. § 393 (2001).
212. 21 U.S.C. § 393 (1997) (emphasis added).

This language does not establish whether the FDA's regulatory authority should extend abroad. While it says that the FDA should "participate through appropriate processes" with foreign governments, this probably does not rise to the level of a "clearly expressed" intent to enforce the FDCA extraterritorially, or to produce regulations that would apply extraterritorially.[213] Even under a very narrow reading of the statute, however, it is difficult to escape the conclusion that the FDA possesses some capacity for action beyond the borders of the United States. The FDA is clearly authorized to work with its counterpart agencies in other countries to bring drugs to market faster. Still, this is not a "clearly expressed" congressional intent to allow the FDA to exercise its regulatory powers abroad.

The FDA's past treatment of foreign research data does not support extraterritorial application. The FDA's inconsistent treatment of foreign research data is similar to the EEOC's inconsistent treatment of the Civil Rights Act as discussed in *Aramco*.[214] In 1962, the FDA first told the pharmaceutical industry that data from foreign clinical studies would be acceptable; however, at that time the data could be used only as a supplemental demonstration of the drug's safety and efficacy.[215] Foreign clinical studies could not serve as primary evidence of a drug's safety and efficacy until 1975.[216] At that time, the data became acceptable only in unusual cases.[217] In 1984, in response to pressure from the pharmaceutical industry and foreign governments, and in recognition of rising scientific standards abroad, the FDA finally elevated foreign research data to a status similar to that of domestic data.[218] This evolution reflects a FDA policy shift, not an agency interpretation of congressional intent. It seems unlikely that the current FDA

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213. The FDA has, however, expressed an interest in using international inspections to foster "effective international agreements." *US FDA Looks to Leveraging*, *supra* note 71. The FDA also hopes to "leverage the energies of collaborators such as states." *Id.* This seems to fall within the FDA's mandate from Congress, but how the FDA would go about executing such strategies is very unclear.

214. *See* Equal Employment Opportunity Comm'n v. Arabian Am. Oil Co. (Aramco), 499 U.S. 244, 257-58 (1991).

215. John J. Gorski, *An FDA-EEC Perspective on the International Acceptance of Foreign Clinical Data*, 21 CAL. W. INT'L L.J. 329, 333 (1991). Foreign research data could not directly support the approval of a new drug.

216. *Id.*

217. *Id.* The data was only acceptable if the drug in question was a major advancement, for an uncommon disease, or resulted in a strikingly favorable benefit-risk ratio. *Id.*

218. Julie Relihan, *Expediting FDA Approval of AIDS Drugs: An International Approach*, 13 B.U. INT'L L.J. 229, 251 (1995). The FDA hoped that avoiding unnecessary repetition of clinical studies would reduce the length of the drug approval process. Gorski, *supra* note 215, at 332.

interpretation would be afforded *Chevron* deference under these circumstances.

A general application of the presumption against extraterritoriality found in *Aramco* would likely weigh against allowing the FDA to have an extraterritorial reach. Nothing in the FDA's authorizing statute expresses a clear congressional intent in favor of extraterritoriality. In fact, there is nothing in the statute beyond the standard boilerplate language required for Commerce Clause authorization that easily lends to an interpretation favoring extraterritorial application. It is the same language that has been found insufficient in employment and environmental cases. Without a "clearly expressed" congressional intent to extend the FDA's rule-making authority abroad, the presumption is not overcome.

B. *Under Congress's Statutory Scheme the FDA Probably Has the Power to Accept Foreign Research Data*

The statutory scheme of the FDA provides a basis for extraterritorial application of FDA regulations. In the FDA's authorizing statute, Congress's expressed intent is to protect U.S. consumers of drugs.[219] Congress mandates that the FDA is to ensure the safety and efficacy of drugs sold in the United States, while allowing safe and effective drugs to be brought to market as quickly as possible.[220] The FDA can best do this by accepting foreign data, and ensuring its accuracy. By accepting foreign research data, the FDA can shorten the time required to bring new drugs to market; U.S. consumers benefit through earlier access to useful drugs. The benefit derived from allowing foreign testing is that the ready availability, and lower cost, of foreign test subjects allows drug companies to seek approval with less unnecessary delay, and with less duplication of costs.[221] Merely accepting research data from studies conducted abroad is probably not an extraterritorial reach by the FDA.[222]

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219. 21 U.S.C. § 393 (containing repeated references to "promoting" and "protecting" "public health").

220. The FDA is noted for having a regulatory culture that "emphasizes the agency's needs for useful findings on efficacy and safety which will enable it to make regulatory decisions that are factually supportable and otherwise credible." Michael Baram, *Perspectives on Medical Error: Reactions to the IOM Report*, 27 AM. J.L. & MED. 253, 259 (2001).

221. Dominquez-Urban, *supra* note 29, at 266.

222. Under this rationale, however, it is hard to argue that foreign research should have different, lower procedural requirements than experiments conducted in the United States. Any regulations that function to ensure reliable data should apply equally regardless of the location of the study. The exception would be those requirements that go toward ensuring test subject safety.

The FDA's decision to allow foreign research data could also be considered to run counter to the FDA's mission of ensuring safety and reliability. Foreign research has proven far more difficult to monitor than domestic research.[223] This increases the likelihood that unreliable data could be used to support new drug approval, thus threatening the health of U.S. consumers. "Until the FDA began accepting foreign data to support applications for approval of new pharmaceutical products, there was little likelihood of harm to consumers from unsafe and ineffective drugs."[224] If a court were to determine that the FDA was incorrect to balance these factors in favor of accepting foreign research data under their Congressional authorization, the decision to allow drug testing abroad could fail under a *Chevron* approach, thus making the remaining question of the FDA's power to then regulate that testing moot.

C. *If the FDA Can Accept Foreign Research Data, Then it Can Take Steps to Ensure the Efficacy of the Tests and the Reliability of the Data*

A promising argument for extraterritoriality springs from *Bowman*. Assuming that the FDA can accept foreign research data, further problems with drug testing abroad can generally be split into two categories: (1) concerns over the reliability of data and experimental rigorousness and (2) concerns for the human rights of human test subjects. Under *Bowman*, a strong argument can be made that the FDA has implicit authorization from Congress to regulate testing because of its responsibility to ensure the validity of the results of experimentation. *Bowman* specifically involved a fraud perpetrated against a corporation entirely held by the U.S. government.[225] The U.S. Supreme Court relied heavily on the government's implicit interest in protecting itself against fraud or obstruction.[226] Improprieties in drug testing, amounting to misrepresentations of test data to the FDA, would fall under the same category. A failure to allow the FDA to take steps, including bringing regulatory or criminal actions against drug companies to help to ensure the validity of experimental data, would render the statute essentially null for whatever companies have the resources to test abroad.

The effects test also supports allowing the FDA to regulate abroad for the purpose of ensuring reliable research data. The

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223. *See infra* notes 29-47.
224. Dominguez-Urban, *supra* note 29, at 266.
225. *See* United States v. Bowman, 260 U.S. 94 (1922).
226. *Id.*

relationship between potential bad acts committed abroad such as falsification of drug research data obtained abroad with a harm to U.S. citizens is probably more clearly cognizable than in antitrust or securities law, and almost certainly clearer than in labor or environmental law. If flawed foreign research data were used to support a new drug application, U.S. consumers could certainly be harmed by ineffective or even dangerous drugs. *Bowman*'s effectiveness, however, is limited to the problem of reliability of data and experimental procedures; it does not provide a basis for protecting the rights of human test subjects abroad.

D. *The FDA Probably Lacks the Authority to Regulate the Treatment of Human Subjects in Foreign Clinical Drug Trials*

Even assuming that the FDA has the authority to accept foreign research data, the FDA probably lacks the authority to protect human test subjects abroad. Under the FDCA, an applicant seeking to introduce a new drug into interstate commerce must provide the Secretary of Health and Human Services with a full description of the design and size of the clinical trials that will be used.[227] By itself this is not the same as authorizing the FDA to prescribe the methodology to be employed by researchers, particularly where the safety of human research subjects is concerned. The FDA's regulations for testing conducted by, or in conjunction with, federal departments and agencies specifically differentiate between procedures used to protect human subjects in the United States and procedures used in foreign countries.[228] Given this discrepancy,[229] it seems difficult to argue that the protection of human subjects is a necessary part of ensuring valid experimental data. Under the FDA's regulations, protecting human subjects instead seems to be a more supplemental government interest.

For testing conducted neither through a federal agency nor under an IND, the FDA regulations exercise jurisdiction over

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227. 21 U.S.C. § 355(b)(4)(B) (1997).

228. 45 C.F.R. § 46.101(h) (2001). The FDA regulations also prescribe different levels of scrutiny and care depending on whether government funds are used to support an experiment abroad.

229. The regulations for foreign drug testing provide a lower level of protection to human subjects in foreign drug tests than in domestic tests. An example of this is the use of placebo-comparison drug trials on HIV patients in Africa. The use of placebos in trials would be considered a substandard level of care in the United States. However, such practice still conforms with the FDA's foreign clinical trial requirements. *See* Robert Mittendorf II, *Primum Non Nocere: Implications for the Globalization of Biomedical Research Trials*, 25 FLETCHER F. WORLD AFF. 239, 245 (2001) (discussing allegations made by advocates for Public Citizen that AZT trials in Africa were unethical because they failed to conform to the U.S. guidelines for its domestic tests).

experimentation when the sponsor of a new drug application submits the results of the foreign clinical studies in support of the new drug application.[230] The regulatory control requires disclosure of, or access to, many pieces of information that go to the efficacy of the study and the reliability of the study results.[231] These requirements include information related to the researcher or investigator, research facilities, protocol, and individual patient records.[232] These requirements all go to ensuring the safety and efficacy of the drug that may eventually be marketed to the U.S. public. Requirements pertaining to the safety of the human test subjects have no such relationship.

There is no effects test basis for regulating the safety of human test subjects. The health of U.S. consumers will not be affected by a lack of consent by a patient in a developing-country hospital. The U.S. marketplace suffers no harm if the potential side effects of a drug are not explained to research subjects.

The FDA lacks clear congressional authorization for the promulgation of regulations ensuring the health and safety of human test subjects abroad. Furthermore, none of the traditional exceptions to the presumption against extraterritoriality apply to such regulations. Unless the courts are willing to allow the FDA great deference under *Chevron*, the FDA regulations protecting human research subjects are invalid. There does not seem to be any support in the FDCA for the proposition that the FDA's regulations have been a reasonable interpretation of the statute. Thus, FDA lacks the authority to protect the health and safety of human test subjects abroad.

V. INTERNATIONAL MECHANISMS PROTECTING HUMAN RESEARCH SUBJECTS OF MEDICAL TESTING ARE NEEDED

A. *The Difficulties of Regulating Transnational Corporations in the Developing World*

Developing countries have demonstrated limited capacities and interest in conducting and monitoring pharmaceutical research in their territories.[233] Indeed, while most industrialized nations have at

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230. 21 C.F.R. § 312.120 (2002).
231. *Id.* § 312.120(b).
232. *Id.*
233. *See generally* International Summit Conference on Bioethics, Towards an International Ethic for Research with Human Beings (1987), at 69 (noting that the lack of research on diseases common to the tropics can only be corrected by expanding the

least some ethical review standards or mechanisms, many developing countries lack any such protections.[234] Generally, developed countries have provided very little assistance in protecting the rights of human subjects in developing countries; presently, national regulations have been given little extraterritorial effect,[235] and there are no international guidelines that are widely accepted, let alone enforced.[236] Furthermore, there are no international treaties governing experimentation on humans.[237]

Higher regulatory standards in developed countries serve as incentives to pharmaceutical corporations to relocate their testing to developing countries where they face less regulatory pressures and decreased exposure to product liability.[238] Companies are able to conduct substantial amounts of research without being required to obtain any regulatory approval and are able to persuade individual physicians to conduct clinical trials on new and untested products in situations where even the physician's institution is unaware.[239] Of course, the riskiest experiments are among the first to be sent abroad. They are able to flee the burdensome regulations of the United States to jurisdictions that allow them to do as they please. If the host country enforces laws the U.S. company dislikes, the company may simply move on to a more hospitable environment.

Transnational corporations place special burdens on the law. They are "'de-nationalized' in the sense that they view the world, rather than their home or host states, as their base of operations."[240] Transnational corporations are able to use their multiple facilities in

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research capabilities of developing countries). The United States has itself faced difficulties in protecting human research subjects. *See generally* Katz, *supra* note 52. The FDA regulations do not provide answers to many questions in testing on humans. *See generally* Stuart L. Nightingale, *Challenges in Human Subject Protection*, 50 FOOD & DRUG L.J. 493 (1995). For a summary of the U.S. informed consent regulations, see *id.* at 494-95.

234. Dominguez-Urban, *supra* note 29, at 270. The United States provides human subjects with protections through the FDA. *Id.* The European Union has adopted the Declaration of Helsinki as its code of ethics for research trials. *Id.* Japan, while lagging somewhat behind the European Union and the United States, has promulgated clinical practice standards to "pay due ethical consideration to the rights of persons who undergo clinical tests." Dominguez-Urban, *supra* note 29, at 270; *see also* Soji Kodama, *Pharmaceutical Firms Revising System to Monitor Drugs*, NIKKEI WKLY., Jan. 18, 1992, at 8.

235. No countries attempt to ensure the same level of protection for foreign research subjects as for their own citizens. Dawn Joyce Miller, *Research and Accountability: The Need for Uniform Regulation of International Pharmaceutical Drug Testing*, PACE INT'L L. REV. 197, 211 (2001).

236. Dominguez-Urban, *supra* note 29, at 268.

237. Erwin Deutsch, *Medical Experimentation: International Rules and Practice*, 19 VICTORIA U. WELLINGTON L. REV. 1, 4 (1989).

238. Dominguez-Urban, *supra* note 29, at 271.

239. *Id.*

240. Claudio Grossman & Daniel D. Bradlow, *Are We Being Propelled Towards a People-Centered Transnational Legal Order?*, 9 AM. U. J. INT'L L. & POL'Y 1, 8 (1993).

order to evade state power and the constraints of national regulatory schemes.[241] Moreover, the "absence of clear international standards means that they can also avoid regulation at the international level."[242] Thus, large corporations can operate in a largely unregulated manner.

This unrestrained activity can already be seen in the field of labor law.[243] U.S. corporations acting abroad are not bound by U.S. health and safety regulations. This restraint of U.S. law is generally justified by the idea that these matters should be for the host jurisdiction to decide. If the host country either has little law in the field, or has a legal system unable or unwilling to enforce the law against U.S. corporations, however, no law governs them at all.[244] U.S. corporations are able to employ child labor (even of U.S. citizenship) in overseas operations.[245]

Most developing countries lack regulations concerning the protection of human research subjects.[246] Extraterritorial application and enforcement of U.S. regulatory law could be effective in restraining the activities of U.S.-based corporations.

B. *Unilaterally Using U.S. Law to Protect Human Research Subjects Would Violate the Doctrine of International Comity*

Extension of U.S.-regulatory law could easily upset international comity. "International comity is a doctrine that counsels voluntary forbearance when a sovereign which has a legitimate claim to jurisdiction concludes that a second sovereign also has a legitimate claim to jurisdiction under principles of international law."[247] Contemporary conceptions of comity situate it somewhere between a

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241. Ratner, *supra* note 27, at 463 (discussing the ability of corporations to use their international presence to dodge local human rights regulations). *See also* Grossman & Bradlow, *supra* note 240, at 8.

242. Grossman & Bradlow, *supra* note 240, at 9. Transnational corporations "have grown beyond the control of national governments and operate in a legal and moral vacuum." Robert J. Fowler, *International Environmental Standards for Transnational Corporations*, 25 ENVTL. L. 1, 2 (1995).

243. Gibney & Emerick, *supra* note 72, at 124-25.

244. *Id.* at 139.

245. *Id.* at 123.

246. John Daniels, *U.S. Funded AIDS Research in Haiti: Does Geography Dictate How Closely the United States Government Scrutinizes Human Research Testing?*, 11 ALB. L.J. SCI. & TECH. 203, 213 (2000).

247. United States v. Nippon Paper Indus. Co., 109 F.3d 1, 8 (1997) (citing Harold G. Maier, *Extraterritorial Jurisdiction at a Crossroads: An Intersection Between Public and Private International Law*, 76 AM. J. INT'L L. 280, 281 n.1 (1982)). The doctrine of international comity is captured in the *Restatement (Third) of U.S. Foreign Relations Law*. The *Restatement* lists eight factors that should be weighed in deciding whether extraterritoriality is appropriate. RESTATEMENT (THIRD) OF THE FOREIGN RELATIONS LAW OF THE UNITED STATES § 403(2).

mere courtesy and an absolute obligation, usually "closer to the courtesy end of the spectrum."[248] U.S. courts have weighed international comity as a factor in determining whether to apply U.S. law abroad without a clear congressional intent.[249] In *Hartford Fire*,[250] the U.S. Supreme Court recognized comity as limiting U.S. jurisdiction only if compliance with U.S. law would violate foreign law.[251] The doctrine does not have the force of law to limit Congress's power to legislate extraterritorially.

Some commentators have argued that the courts have been too concerned with issues of comity. The courts have used "some vague notion that differences in law necessarily translate into conflicts of law."[252] At the same time, the Supreme Court has said that no conflict exists "where a person subject to regulation by two states can comply with the laws of both."[253] A primary motivation of *Aramco*, however, was to avoid "international discord and unintentional infringements on the sovereignty of other nations."[254] The status of

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248. Edward T. Swaine, *The Local Law of Global Antitrust*, 43 WM. & MARY L. REV. 627, 687 (2001).

> Comity, in the legal sense, is neither a matter of absolute obligation, on the one hand, nor of mere courtesy and good will, upon the other. But it is the recognition which one nation allows within its territory 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 who are under the protection of its laws.

Hilton v. Guyot, 159 U.S. 113, 163-64 (1895) (providing the classic U.S. Supreme Court statement of the nature of the doctrine).

249. Timberlane Lumber Co. v. Bank of Am., 549 F.2d 597 (9th Cir. 1976). The court recognized the usefulness of a balancing test, given that "it is evident that at some point the interests of the United States are too weak and the foreign harmony incentive for restraint too strong to justify an extraterritorial assertion of jurisdiction." *Id.* at 609. "The assertion of jurisdiction by the United States over behavior properly subject to the jurisdiction of a foreign country is unprecedented in the absence of significant policy concerns which outweigh the interests of any affected foreign State regarding such behavior." NYC Bar Report, *infra* note 279.

250. Hartford Fire Ins. Co. v. California, 509 U.S. 764 (1992).

251. *Id.* The U.S. Supreme Court held that "effects jurisdiction under the Sherman Act should be truncated only where foreign law compelled a defendant's antitrust violation." See Swaine, *supra* note 248, at 632-33.

252. Gibney & Emerick, *supra* note 72, at 134.

253. *Hartford Fire*, 509 U.S. at 799 (citing RESTATEMENT (THIRD) FOREIGN RELATIONS LAW § 403, cmt. e). Differences between the laws of nations are not necessarily conflicts. Gibney & Emerick, *supra* note 72, at 143-44. A discrepancy between the prevailing norms in a country and the dictates of U.S. law is not the same as an actual difference between what the two nations' laws mandate. *Id.* If two nations' laws—one local the other extraterritorial—conflicted, conflict could be avoided if the regulated actor simply followed the more stringent of the two standards. *Id.* This contradicts the older standard, wherein if "foreign regulation appropriately applies to the case before the court, the action will usually be dismissed." Maier, *supra* note 247, at 290.

254. Gardner, *supra* note 114, at 567.

international comity under U.S. law appears to remain unsettled, as the *Hartford Fire* ruling was apparently limited to antitrust law, where extraterritorial jurisdiction has long been recognized.

1. U.S. Law Versus the Power of Developing Countries to Legislate for Themselves

Under basic principles of international law, countries hosting drug testing should have jurisdiction over experiments conducted in their territory.[255] Developing countries should be free to set their own policies regarding research on humans. Extraterritorial application of U.S. regulations would essentially rob developing countries of any flexibility in formulating their own policy and regulations. Already, developing countries chafe at U.S. policies that restrict their access to drugs.[256] Other governments have often viewed extraterritorial application of U.S. law as a sign of U.S. arrogance or even as interference in their territorial affairs.[257]

Developing nations' governments may wish to promote experimentation within their borders.

> Research brings with it many benefits. First, clinical drug trials may present the only available treatment for a particular disease. Second, free medical treatment, increased monitoring, and the attention of specialists often accompany research. Third. . ., drugs do not have the same effect for all populations. If a drug is never tested in one country, scientists may fail to discover that it would have an effect on its population, and may dismiss it as ineffective.[258]

Also, some commentators have suggested that exporting the doctrine of informed consent to developing countries, many of which have more communitarian outlooks than developed countries and which lack the same concept of "self" or "personhood," amounts to "ethical imperialism"—an imposition of Western values on non-

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255. In fact, nations have long recognized an obligation to protect their populations from obvious risks and hazards to their health. Jonathan Wike, *The Marlboro Man in Asia: U.S. Tobacco and Human Rights*, 29 VAND. J. TRANSNAT'L L. 329, 359 (1996).

256. "Condemnation of restrictive United States policies is evident from frequent public demonstrations that express concern about the United States impeding developing countries from gaining access to essential drugs." Park, *supra* note 45, at 148.

257. *The Activities of American Multinational Corporations Abroad: Hearings Before the Subcomm. on Int'l Economic Policy of the Comm. on Int'l Relations*, 94th Cong. 24 (1975) (statement of Philip A. Loomis, Jr.) (cited in Brown, *supra* note 146, at n.9).

258. Dominguez-Urban, *supra* note 29, at 275.

Western cultures.[259] For this reason, the right of free consent has been difficult to implement in some developing countries because those countries do not generally share the concept of individual rights held by the West.[260] The notion of individual consent may be foreign to the culture where the trials are taking place.[261] Also, low local levels of education can make it difficult to determine whether actual consent has been obtained from an individual, as opposed to procedural.[262] Procedural consent, in general, can be the only standard for determining consent. The right of free consent is subjectively evaluated and impractical for large scientific studies.[263]

U.S. regulatory schemes may also be inappropriate because, in the opinion of some, the West may place too much emphasis on the formality of obtaining a signature on a consent form, which may become a substitute for dialogue with the patient.[264] This can be particularly significant where the pool of potential subjects has a high rate of illiteracy and a low level of education.[265]

2. The Anti-Democratic Force of Extraterritorial Application of U.S. Law

The extraterritorial application of U.S. laws is anti-democratic. Extraterritorial application of laws amounts to a "perversion of democratic governance."[266] Extraterritoriality violates the principle that government ought to rest on the consent of the governed.[267] Those in foreign countries who may bear the ultimate burden of U.S. regulation are powerless to change the statutes or regulations.[268] It is difficult, if not impossible, for foreigners (either in the form of foreign governments or individual foreigners) to influence the U.S. political process; they are ineligible to vote in U.S. elections and are limited in their ability to make monetary contributions to

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259. *See generally* M.P. Préziosi et al., *Practical Experiences in Obtaining Informed Consent for a Vaccine Trial in Rural Africa*, 336 NEW ENG. J. MED. 317 (1997); Dominguez-Urban, *supra* note 29, at 279.

260. Fidler, *supra* note 45, at 337.

261. *Id.* The WHO-CIOMS guidelines allow consent by the community leader to substitute for individual consent. George J. Annas, *The Changing Landscape of Human Experimentation: Nuremberg, Helsinki, and Beyond*, 2 HEALTH MATRIX 119 (1992).

262. Fidler, *supra* note 45, at 338.

263. *Id.*

264. Dominguez-Urban, *supra* note 29, at 281.

265. *Id.* at 271-72.

266. Gibney & Emerick, *supra* note 72, at 133.

267. *Id.*

268. Mark P. Gibney, *The Extraterritorial Application of U.S. Law: The Perversion of Democratic Governance, the Reversal of Institutional Roles, and the Imperative of Establishing Normative Principles*, 19 B.C. INT'L & COMP. L. REV. 297, 312-13 (1996).

participants in the political system.[269] Also, foreigners face potentially insurmountable obstacles of logistics and judicial jurisdiction should they attempt to challenge a provision of U.S. law through the courts.[270] It would be difficult for a foreign entity to gain standing in order to challenge a U.S. statute being applied to them, and it would be nearly impossible to challenge the inapplicability of a statute.

It should be noted that several of the arguments against U.S. extraterritorial application that work from the view that it is anti-democratic and anti-imperialistic would not apply in the realm of drug testing. First, the United States is often criticized because "protection of the law has generally not followed enforcement of the law."[271] Here, particularly in the realm of human rights, protection of the law and enforcement of the law would be one and the same. The goal of the law's enforcement would be for the protection (albeit to the extent that it is judged appropriate by the United States) of those in foreign countries. Second, the United States has been criticized for giving itself one set of standards to follow, while those who live in other countries may be constrained by a different set of standards, but still under U.S. law.[272] The exact purpose here would be to afford foreigners the same level of protection from (predominantly U.S.) drug companies that U.S. citizens enjoy. Third, U.S. extraterritoriality has been accused of treating similarly situated individuals unequally.[273] Currently, the FDA's application is triggered by the location of the experiment and the experiment sponsor's intention to introduce the experimental results in seeking FDA approval, not by the citizenship of the participants in the study.[274] There are no special FDA provisions for U.S. citizens participating in experiments abroad, nor for foreigners experimented on in the United States. FDA extraterritorial application would further equalize the relationship between U.S. citizens and foreigners; they would be treated equally regardless of where they participated in an experiment.

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269. *Id.* at 313.
270. *Id.* at 313.
271. *Id.* at 308.
272. *Id.*
273. *Id.* at 316. This can be seen in the application of U.S. labor laws. Congress was forced to specifically authorize extraterritorial application of the laws. However, now the laws protect U.S. citizens from being discriminated against by U.S. multinational corporations on the basis of age, race color, religion, sex, or national origin. U.S. multinational corporations are not prevented from discriminating against foreigners on such grounds. *Id.*
274. *Id.*

3. Potential Conflict of U.S. Law with Other Developed-Country Regulatory Practices

A multiplicity of extraterritorial regulatory regimes could easily come into conflict.[275] Many other developed countries have their own regulatory regimes with their own approaches to research on human subjects and informed consent.[276] Not only would FDA extraterritorial application give rise to potential conflicts with local foreign law, but it may also conflict with laws of other countries where the drug sponsor seeks approval. For example, while the United States expects that new drug trials on human subjects will include the use of a controlled, placebo test group, French researchers view placebo controlled studies as "cruel and inhumane" because the patients receiving the placebo have "no chance of surviving."[277]

"Extraterritorial application of U.S. law . . . has often been viewed by other governments as a sign of U.S. arrogance or even as interference in their territorial affairs."[278] Generally, governments have been reluctant to attempt to reach their regulatory criminal law beyond their own territory.[279] This reluctance "stems from concepts of sovereignty and the territorial supremacy of States."[280]

Another problem with U.S. extraterritorial application is that it would apply to experimentation in all foreign countries.[281] The law is unable to differentiate between the European Union, which is economically and politically well-situated to protect its citizens to whatever extent it (and they) desire, and countries like Nigeria where transient and corrupt regimes may be too easily influenced by the wishes of drug companies and who may not be interested in affording their citizens even basic human rights. This problem would be somewhat negated by current FDA regulations that allow local

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275. For a general description of this situation in antitrust law, see generally Swaine, *supra* note 248. "Numerous antitrust regimes impose inconsistent requirements and substantial compliance costs, especially for the growing number of mergers requiring approval in multiple jurisdictions." *Id.* at 630.

276. For example, the individual countries of the European Union have their own individual regulatory regimes, and the European Union has adopted the European Convention on Biomedicine setting out rules of consent within the European Union. Dawn Joyce Miller, *Research and Accountability: The Need for Uniform Regulation of International Pharmaceutical Drug Testing*, 13 PACE INT'L L. REV. 197, 206 (2001).

277. Anne E. Wells, *Regulating Experimental AIDS Drugs: A Comparison of the United States and France*, 13 LOY. L.A. INT'L & COMP. L. REV. 393, 403 (1990). Unlike the Europeans, the FDA continues to do placebo-controlled trials even in symptomatic conditions. *Foreign Trials Require Sponsors*, *supra* note 65.

278. Brown, *supra* note 146, at 435.

279. The Association of the Bar of the City of New York, Ad Hoc Committee on Foreign Payments, Report on Questionable Foreign Payments by Corporations: The Problem and Approaches to a Solution (1977) (cited in Brown, *supra* note 146, at 437) [hereinafter NYC Bar Report].

280. *Id.*

281. Gibney, *infra* note 268, at 317.

country guidelines to replace U.S. guidelines if they "offer greater protection . . . of the subject."[282] Difficulties would arise should the European Union not appreciate the United States setting itself up in a position to decide which set of standards provides more protections. Drug companies could easily be caught between the two regulatory regimes should each jurisdiction believe its is the more protective.

C. *The Role of International Law and the Rights of Human Test Subjects*

1. The Status of Research on Humans Under International Law

The use of human subjects in pharmaceutical research has long been recognized as a human-rights issue.[283] In recent years, however, little attention has been paid to addressing human-rights issues arising from research on human subjects.[284]

It has been argued that some examples of experimentation in developing countries have actually been violations of international law.[285] The rules for clinical trials and research arguably have international legal status through treaty or custom.[286] For example, it has been argued that the Nuremberg Code is itself an international legal document.[287] The fundamental rule of the Nuremberg Code is "the right not to be subjected to medical or scientific experimentation without free consent."[288] This principle has appeared in human rights treaties, including the International Covenant on Civil and Political Rights, to which the United States is a signatory.[289] Additionally, it has been argued that the principles consistently found in the Nuremberg Code, the Declaration of Helsinki, and the Council of International Organizations of Medical Sciences (CIOMS)

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282. 21 C.F.R. § 312.120(c)(2).

283. Dominguez-Urban, *supra* note 29, at 258.

284. Kevin M. King, *A Proposal for the Effective International Regulation of Biomedical Research Involving Human Subjects*, 34 STAN. J. INT'L L. 163, 166 (1998).

285. Fidler, *supra* note 45, at 303-04.

286. *Id.* at 325.

287. *Id.* at 325; Robert F. Drinan, *The Nuremberg Principles in International Law*, *in* GEORGE J. ANNAS & MICHAEL A. GRODIN, THE NAZI DOCTORS AND THE NUREMBERG CODE 174, 176 (1995). The problem now is "how to get these principles, which are universally accepted, implemented and enforced throughout the world." Drinan, *supra*, at 176.

288. Fidler, *supra* note 45, at 325.

289. U.N. Office of the High Commissioner for Human Rights, *International Covenant on Civil and Political Rights*, art. 7 (Mar. 23, 1976), *available at* http://www.unhchr.ch/html/menu3/b/a_ccpr.htm [hereinafter U.N. *Int'l Covenant*]. "[N]o one shall be subjected wihout his free consent to medical or scientific experimentation." *Id.*

Guidelines have "become customary international law binding on all states except persistent objectors."[290] It is far from clear, however, that the standards mandating free consent to experimentation have become sufficiently widely recognized to be established as international law. The Code is "seen by many as a product of and reaction to Nazi terror . . . no longer useful for today's researchers."[291]

The current regulatory scheme could lead to the odd result of a U.S. pharmaceutical company being prosecuted in U.S. court for not paying subjects an adequate amount for their "inconvenience and time spent," or for paying an amount "so large . . . as to induce prospective subjects to participate in the research against their better judgment."[292] This provision is among the Ethical Guidelines for Research Involving Human Subjects issued by the Pan American Health Organization and is followed by various Central and South American countries. It appears to be a requirement beyond those of the Helskinki Declaration, and therefore, U.S. companies testing in jurisdictions with such a law would be subject to regulation by the United States for violations of that standard.

The U.N. International Covenant on Civil and Political Rights forbids experimentation on any person "without his or her free consent."[293] This clause, however, has not been used to support any human-rights action. Without any specific definition of consent or enforcement mechanism, the right guaranteed by the Covenant is unenforceable and can easily be ignored. Thus, while informed consent has some status under international law,[294] it is nevertheless currently unenforceable.

2. The Lack of Status of Corporate Entities Under International Law

Corporations are not currently treated as legal entities under international human rights law.[295] Thus, most testing performed on

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290. Fidler, *supra* note 45, at 326. "To become a tule of customary international law, a principle must be supported by (1) general and consistent state practice; and (2) evidence that the general and consistent state practice is followed out of a sense of legal obligation." *Id.*

291. Richard W. Garnett, *Why Informed Consent? Human Experimentation and the Ethics of Autonomy*, 36 CATH. LAW. 455, 471-72 (1996).

292. *See* Helsinki Guidelines, *supra* note 17.

293. U.N. *Int'l Covenant*, *supra* note 289. The United States is a signatory of this document. The Covenant is among the set of documents generally recognized as defining international human rights. Barbara A. Frey, *The Legal and Ethical Responsibilities of Transnational Corporations in the Protection of International Human Rights*, 6 MINN. J. GLOBAL TRADE 154, 160-61 (1997).

294. *Id.*

295. *See generally* Ratner, *supra* note 27 (arguing that corporations should be treated like states under international law). "Norms associated with violations other than genocide, war crimes, piracy, and slavery are binding only upon states and persons acting under color of state law." Brad J. Kieserman, Comment, *Profits and*

humans is currently beyond the reach of international law, since most research is conducted without the participation of a government.[296] The Nuremberg Trials, however, did show the "willingness of key legal actors to contemplate corporate responsibility at the international level."[297] A movement in favor of recognizing corporations as having status for the purposes of international human rights law has recently begun.[298] In 1990, the U.N. Commission on Transnational Corporations completed a U.N. Code of Conduct on Transnational Corporations, which was an attempt to set forth standards of host government behavior toward transnational corporations.[299] The final draft of the Code stated that corporations must respect human rights.[300] The Code was, however, never enacted, and the Commission itself was eventually consolidated into another agency.[301] The United States has occasionally attempted to force corporations to comply with international human rights law, but generally, only on a case-by-case basis.[302]

Commentators have suggested that international regulatory institutions should be created to deal with the special problems posed by transnational corporations. Such institutions would benefit from being an economy of scale; a single institution could ensure that corporations comply with human rights standards, whereas many national governments would have to have redundant regulatory bodies to accomplish the same goal.[303] Also, this would avoid the

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Principles: Promoting Multinational Corporate Responsibility by Amending the Alien Tort Claims Act, 48 CATH. U. L. REV. 881, 905 (1999).

296. See King, *supra* note 284, at 178. Government participation is necessary to label conduct as "torture or cruel, inhuman, or degrading treatment." *Id.*

297. Ratner, *supra* note 27, at 477. In these cases individuals were on trial, but the courts routinely spoke in terms of corporate responsibilities and obligations. *Id.*

298. Erin Elizabeth Macek, *Scratching the Corporate Back: Why Corporations Have No Incentive to Define Human Rights*, 11 MINN. J. GLOBAL TRADE 101, 124 (2002) (calling for the United Nations to promulgate human rights standards that companies would be held to, and that would have legal effect). Barbara A. Frey, *The Legal and Ethical Responsibilities of Transnational Corporations in the Protection of International Human Rights*, 6 MINN. J. GLOBAL TRADE 154, 158 (1997) (citing Report of the Fourth World Conference on Women, Beijing Declaration, Annex I, at 8, U.N. Doc. A/Conf.177/20 (1995)).

299. Frey, *supra* note 298, at 166-67.

300. *Id.*

301. *Id.*

302. *Id.* at 169-70. For example, the Anti-Apartheid Act prohibited U.S. companies from doing business directly with South Africa. The United States has frequently used embargos to pressure states accused of violating human rights.

303. Macek, *supra* note 298, at 120. Also, such institutions could use levels of specialization that would improve their efficiency compared with national governments.

problem of forcing corporations or nations to take on a competitive risk others in the marketplace might be unwilling to adopt.[304]

D. *Nations Must Work Together to Formulate Protections for Human Research Subjects*

The need for regulation of testing on human subjects in the developing world urgently needs to be addressed. Unilateral extraterritorial regulatory action by the United States or the European Union would be the fastest way to address the problem. This would, however, amount to legal imperialism; the developed countries would be dictating policy to the developing world. Further, such action would be difficult and costly. The FDA currently conducts almost no monitoring of corporate activity in the developing world. The United States would incur great cost by unilaterally positioning itself as a worldwide regulatory body. Developing countries and the European Union would likely resent such an action because it would remove their flexibility in formulating policy. The alternative, disallowing use of foreign research data, is even less palatable because it would greatly increase the time required to bring drugs to market. Developing nations would be denied the opportunity to obtain what can be free medical treatment and infrastructure from the experiments that do have a reasonable chance at success.

Developed and developing nations need to work together to compose a set of enforceable rules to govern testing on human subjects. An international body, including both developed and developing nations, would be the best vehicle for creating a workable set of international rules. As an organization, the U.N. Educational, Scientific, and Cultural Organization (UNESCO) is well positioned to create a set of international rules governing research on humans.[305] UNESCO alone, however, probably would not be able to enforce any rules or guidelines it might formulate. It would still need to rely on

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304. *Id.* For example, it would be difficult for a developing country to adopt tougher informed consent standards for fear that it would drive drug companies away, and lose the positive externalities that result from drug testing.

305. "UNESCO, the premier international organization in the fields of science, culture, communications and education, has the legal authority to negotiate and sponsor the codification and implementation of international instruments advancing technology, public health and human rights." Allyn L. Taylor, *Globalization and Biotechnology: UNESCO and an International Strategy to Advance Human Rights and Public Health*, 25 AM. J.L. & MED. 479, 481 (1999). For a set of proposed guidelines, see King, *supra* note 284. The Pan American Health Organization, a regional office of the World Health Organization, has published its own set of guidelines. Pan American Health Organization, Division of Health and Human Development, *DHHD Ethical Guidelines for Research Involving Human Subjects*, *at* http://www.paho.org/English/HDP/HDR/RPG/RGP_ethics_guide-2002.pdf.

the enforcement mechanisms of states, primarily in the developed world. Alternatively, the United Nations could create an international body to enforce the regulations. At least one commentator has already called for a "permanent Nuremberg"[306]—a permanent sitting tribunal that would enforce human rights. If the meaning of consent were better developed under international law, and corporations were treated as subject to international law, such a body could be used to provide protection from unethical corporate action.

Another potentially useful model is the Organisation for Economic Cooperation and Development's (OECD) regulation of transparency of international economic activity. The OECD does not itself enforce laws. Instead, it has created a set of guidelines with which its Member States are to comply. The OECD Convention requires states to criminalize certain activities.[307] An independent international organization similar to the OECD could be created to regulate worldwide testing on humans. It could formulate a set of guidelines with input from both the developed and developing nations that would prescribe procedures to ensure protection of human rights, as well as the validity of data. Member States of such an organization could agree only to accept research data from experiments conducted in other Member States. Such an organization would be a very useful tool in moving toward harmonization of international drug testing standards. The FDA clearly has congressional authorization to work with such an organization. The FDCA grants the FDA the power to work with representatives of other nations to facilitate the drug approval process. Participation in an international organization would be a valid extraterritorial activity for the FDA.

VI. CONCLUSION

In the coming years, international drug research will only continue to grow in frequency and importance and to effect more people in the developing world. Under current U.S. law, it appears that the FDA is unable to provide protection for these people through extraterritorial regulation of the behavior of drug companies. Allowing the FDA to regulate extraterritorially, either through court approval or congressional action, may provide the best short-term solution to protecting human research subjects. This is not, however,

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306. Drinan, *supra* note 287, at 176-77. Such a tribunal would probably be similar in nature to the new U.N. War Crimes Tribunal.

307. Ratner, *supra* note 27, at 535.

the best available approach. The United States should cooperate with other nations from the developed and developing world to create an international regulatory scheme that accounts for the interests of the differently situated nations. The rights of human subjects of drug research are clearly a matter for international law. Cross-border research will test the international community's dedication to human rights.

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