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## Closing the Constant Garden: The Regulation and Responsibility of U.S. Pharmaceutical Companies Doing Research on Human Subjects in Developing Nations

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# CLOSING THE CONSTANT GARDEN: THE REGULATION AND RESPONSIBILITY OF U.S. PHARMACEUTICAL COMPANIES DOING RESEARCH ON HUMAN SUBJECTS IN DEVELOPING NATIONS

## I. INTRODUCTION

In Lampang, Thailand, a U.S. army doctor observed transmission rates between HIV-infected mothers and their infants without providing readily accessible medication that would likely have prevented the HIV transmission.<sup>1</sup> In Buenos Aires, Argentina, a man being treated for unstable angina died after being given an experimental medication provided by a U.S.-based pharmaceutical company.<sup>2</sup> It was later discovered that his signature on the treatment consent form had been forged, that he did not have unstable angina, and that the doctor who enrolled him in the study received \$2,700 for doing so.<sup>3</sup> Meanwhile, in Tuotuo, China, an isolated, impoverished, community where villagers live in reed huts, Harvard researchers promised free medical care to residents—but only if they were willing to donate their blood for genetic research.<sup>4</sup> Subsequently, it was alleged that even though the blood was collected, in addition to millions of dollars in grant money based on the blood collection, the medical care was never provided.<sup>5</sup> In Parnu, Estonia, a young man who could not resist the opportunity for a free trip to Switzerland, including travel, housing and a large stipend, agreed to test a drug that he believed was a vitamin.<sup>6</sup> Once in Switzerland, he and 177 other Estonians were given consent forms that they could not read;

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1. See Mary Pat Flaherty & Doug Struck, *The Body Hunters; Perils of Placebos, Life by Luck of the Draw; In Third World Drug Tests, Some Subjects Go Untreated*, WASH. POST, Dec. 22, 2000 at A1 (discussing ethical issues in various research projects related to transmission, vaccination and treatment of HIV and AIDS performed in Thailand).

2. See Karen DeYoung & Deborah Nelson, *The Body Hunters: Testing's El Dorado; Latin America is Ripe for Trials, and Fraud; Frantic Pace Could Overwhelm Controls*, WASH. POST, Dec. 21, 2000, at A1.

3. *Id.*

4. John Pomfret & Deborah Nelson, *The Body Hunters: Harvesting China's Blood; An Isolated Region's Genetic Mother Lode; Harvard-Led Study Mined DNA Riches; Some Say Donors' Promises Were Broken*, WASH. POST, Dec. 20, 2000, at A1.

5. *Id.*

6. Sharon LaFraniere, Mary Pat Flaherty & Joe Stevens, *The Body Hunters: Failure of Consent; The Dilemma: Submit or Suffer; 'Uninformed Consent' Is Rising Ethic of the Drug Test Boom*, WASH. POST, Dec. 19, 2000, at A1.

moreover, they were never informed of the true nature of the clinical trials in which they were to participate.<sup>7</sup> In 1996, Kano, Nigeria was ravished by an outbreak of meningitis.<sup>8</sup> A team from a large U.S.-based pharmaceutical company was dispatched to provide medical care to the victims and to test an antibiotic on Nigerian children. The team left two weeks later, leaving in their wake eleven dead children and numerous others suffering from long-term complications.<sup>9</sup> What is the responsibility of U.S. courts when the U.S. government or U.S.-based corporations engage in unethical medical research abroad? What responsibility does the U.S. legislature have in attempting to prevent unethical medical research? This Note addresses remedies currently available to victims of unethical international research and discusses recommendations for future changes in this area of law.<sup>10</sup>

## II. BACKGROUND AND HISTORY

### A. *The Impact of Nuremberg*

The development of international law with respect to medical experimentation has its origins in the Nuremberg Trials.<sup>11</sup> At Nuremberg, Nazi physicians and scientists who engaged in human medical experimentation were prosecuted for war crimes and crimes against

7. *Id.* It was also alleged that the clinic staff was incompetent, that patients were forced to draw their own blood, and that study results were contaminated because patients, many of whom had substance abuse problems, exchanged urine samples. *Id.* The Swiss research was performed by Van Tx Research, Ltd., a Swiss company that contracted to do research for some of the largest U.S. pharmaceutical companies. *Id.*

8. Joe Stephens, *The Body Hunters: Exporting Human Experiments; 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.

9. *Id.* Two hundred children were enrolled in the study having, at most, signed consent forms that they were unable to read and without being told that they could receive standard medical treatments free of charge from other medical teams within the facility. *Id.*

10. For an overview of the scope of the problem of clinical trials in underdeveloped countries, see Marcia Angell, *The Body Hunters*, THE NEW YORK REVIEW, Oct. 6, 2005, at 23 (book review) (“Probably close to half of all clinical trials are now conducted in the third world, although there is no way to know for sure.”). Although ethical guidelines for clinical trials in the United States are beyond the scope of this Note, for a good discussion of U.S. pharmaceutical research, development and marketing of drugs, see Marcia Angell, *THE TRUTH ABOUT DRUG COMPANIES, HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT* (2004).

11. For an extensive discussion of the Nuremberg Trials and the resulting Nuremberg Code, see *THE NAZI DOCTORS AND THE NUREMBERG CODE: HUMAN RIGHTS IN HUMAN EXPERIMENTATION* (George J. Annas & Michael A. Grodin eds., 1992). “The Nuremberg Code set the general agenda for all future ethical and legal questions pertaining to the conduct of human experimentation.” *Id.* at 6. Furthermore, “all contemporary debate on human experimentation is grounded in Nuremberg.” *Id.* at 3.

humanity.<sup>12</sup> Out of these trials, the Nuremberg Code was developed to “formulate a universal natural law standard for human experimentation.”<sup>13</sup> The Nuremberg Code’s principles “set the framework for United States federal regulations as well as . . . international guidelines.”<sup>14</sup>

### B. *The Declaration of Helsinki*

After the atrocities of World War II, the World Medical Association (WMA) was formed.<sup>15</sup> In 1949, the WMA adopted the Declaration of Geneva to serve as a pledge for physicians regarding their duty to their patients.<sup>16</sup> In 1964, the WMA adopted the Declaration of Helsinki in order to specifically address ethical principles for research involving human subjects.<sup>17</sup>

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12. *See id.* at 3.

13. *Id.* The Nuremberg Code provides, *inter alia*: (1) subjects of medical experimentation must provide voluntary, informed consent; (2) the experiment must yield socially useful results that would not have been obtainable by other means; (3) the experiment should be conducted to minimize risk to the subject; and (4) the experiment must be terminated if the researcher believes that it may cause harm to the subject. The Nuremberg Code, *reprinted in* TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW No. 10, Vol. 2, 181–82 (Government Printing Office 1949), *available at* [http://www.pnl.gov/hs/documents/nuremberg\\_code.pdf](http://www.pnl.gov/hs/documents/nuremberg_code.pdf).

14. Micheal A. Grodin, *Historical Origins of the Nuremberg Code*, in *THE NAZI DOCTORS AND THE NUREMBERG CODE: HUMAN RIGHTS IN HUMAN EXPERIMENTATION* 121, 139 (George J. Annas & Micheal A. Grodin eds., 1992).

15. *See* The World Medical Association, WMA History, Background and Preliminary Organization, <http://www.wma.net/e/history/background.htm> (last visited Nov. 6, 2005).

16. The Declaration of Geneva was adopted at the 3rd General Assembly of the WMA and is also known as the International Code of Medical Ethics. *See* WORLD MEDICAL ASSOCIATION, INTERNATIONAL CODE OF MEDICAL ETHICS (1948), *available at* <http://www.wma.net/e/policy/c8.htm> (last visited Nov. 6, 2005). In relevant part, the Declaration proclaims: “The health of my patient will be my first consideration . . . . I will not permit considerations of age, disease or disability, creed, ethnic origin, gender, nationality, political affiliation, race, sexual orientation, or social standing to intervene between my duty and my patient.” *Id.*

17. WORLD MEDICAL ASSOCIATION, THE DECLARATION OF HELSINKI (1964), *available at* <http://www.wma.net/e/policy/pdf/17c.pdf>. The Declaration of Helsinki is “a statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects.” *Id.* art. A(1). The Declaration of Helsinki states that “[i]n medical research on human subjects, considerations related to the well-being of the human subjects should take precedence over the interests of science and society.” *Id.* art. A(5). Furthermore,

[m]edical research is subject to ethical standards that promote respect for all human beings and protect their health and rights. Some research populations are vulnerable and need special protection. The particular needs of the economically and medically disadvantaged must be recognized. Special attention is also required for those who cannot give or refuse consent for themselves, for those who may be subject to giving consent under duress, for those who will not benefit personally from the research and for those for whom the research is combined with care.

*Id.* art. A(8). Additionally, “[r]esearch investigators should be aware of the ethical, legal and regulatory requirements for research on human subjects in their own countries as well as applicable

### C. *The Council for International Organizations of Medical Sciences*

The Council for International Organization of Medical Sciences (CIOMS) publishes international human subjects ethical guidelines in collaboration with the World Health Organization (WHO).<sup>18</sup> These guidelines are based on principles established by the Nuremberg Code and the Declaration of Helsinki. CIOMS offers twenty-one guidelines for research on human subjects which broadly cover: (1) ethical review; (2) informed consent; (3) populations with limited resources; (4) choice of control method; (5) vulnerable groups; (6) women as research participants; (6) confidentiality; (7) compensation; (8) ethical and scientific review of research; and (9) the obligation to provide healthcare services.<sup>19</sup> The CIOMS guidelines provide the most rigorous guidelines for international human subject research to date.<sup>20</sup>

### D. *The International Covenant on Civil and Political Rights*

The United Nations addressed the subject of human experimentation in the International Covenant on Civil and Political Rights (ICCPR), which states that “[n]o one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation.”<sup>21</sup> The

international requirements.” *Id.* art. A(9). Other relevant provisions include that: (1) only qualified persons should perform the research; (2) research should be proceeded by risk/benefit analysis; (3) research risks should be minimized and managed; (4) research should only be conducted if the importance of the research outweighs potential burdens to subjects; (5) research should only be conducted on populations that will benefit from it; (6) in most circumstances, subjects must give voluntary, informed consent; (7) publishers have ethical obligations as well as researchers; (8) experimental treatments should be tested against a control group of the best known, established medical treatment; (9) at the conclusion of the study, all participants should be given access to the best proven treatment; (10) refusal to participate in the study should not interfere with the medical care rendered; and (11) experimental treatments may be used on patients who have failed treatment under established methods if (a) the patient consents, (b) the treatment offers hope of being life-saving, and (c) where possible, the treatment is the subject of research. *Id.* arts. B–C.

18. COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES (CIOMS), INTERNATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS 7 (2002) [hereinafter CIOMS ETHICAL GUIDELINES].

19. *Id.* at 523–82.

20. Finnuala Kelleher, *The Pharmaceutical Industry’s Responsibility for Protecting Human Subjects of Clinical Trials in Developing Nations*, 38 COLUM. J.L. & SOC. PROBS. 67, 74 (2004).

21. International Covenant on Civil and Political Rights [hereinafter ICCPR], G.A. Res. 2200A (XXI), 21 U.N. GAOR Supp. (No. 16) at 52, U.N. Doc. A/6316 (Dec. 20, 1966), 999 U.N.T.S. 171, opened for signature Dec. 20, 1966, available at <http://documents.un.org/simple.asp> (search “A/6316” in symbol field). See also The Universal Declaration of Human Rights, art. 5, G.A. Res. 217A, at 73, U.N. GAOR, 3d Sess. 1st plen. mtg., U.N. Doc A/810 (Dec. 12, 1948), available at <http://documents.un.org> (select “welcome”, then select “simple search”, then type “A/810” in the “Symbol” field) (“No

United Nations' formulation of informed consent is significant because it equates un-consented medical experimentation to torture and cruel, inhuman, and degrading treatment.<sup>22</sup> The ICCPR, however, has been criticized for its "weak implementation provisions"<sup>23</sup> and has yet to be applied to any human subject experimentation cases.<sup>24</sup>

### *E. U.S. Law and Policy*

Within the United States, the federal government imposes regulations on pharmaceutical research vis-à-vis the Food and Drug Administration (FDA) pursuant to the Food Drug and Cosmetic Act of 1962 (FDCA).<sup>25</sup> The National Research Act of 1974 (NRA) governs human subjects research.<sup>26</sup> The NRA established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (NCPHS).<sup>27</sup> Although the FDCA and the NRA do not directly apply to

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one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment."); American Convention on Human Rights, Nov. 22, 1969, art. 5(2), 1144 U.N.T.S. 123, 146 (1978) ("No one shall be subjected to torture or to cruel, inhuman, or degrading punishment or treatment."); see African [Banjul] Charter on Human and Peoples' Rights, June 27, 1981, art. 5, Org. of African Unity Doc. CAB/LEG/67/3/Rev. 5 (1981), reprinted in 21 I.L.M. 59, 60 (1982), <http://www.africa-union.org/root/au/Documents/Treaties/Text/Banjul%20Charter.pdf> ("Every individual shall have the right to respect of the dignity inherent in being a human being and to the recognition of his legal status. All forms of exploitation and degradation of man particularly slavery, slave trade, torture, cruel, inhuman or degrading punishment and treatment shall be prohibited.").

22. See Kevin M. King, *A Proposal for the Effective International Regulation of Biomedical Research Involving Human Subjects*, 34 STAN. J. INT'L L. 163, 173 (1998) (proposing ICCPR as the "best option for the creation of an enforceable legal regime governing human experimentation" despite acknowledging enforcement difficulties). See also Benjamin Mason Meier, *International Protection of Persons Undergoing Medical Experimentation: Protecting the Right of Informed Consent*, 20 BERKELEY J. INT'L L. 513, 550 (2002) ("A treaty-based solution would offer the best hope of unifying disparate national legislation and solidifying weak international ethics codes.").

23. M. Cheriff Bassiouni et al., *An Appraisal of Human Experimentation in International Law and Practice: The Need for International Regulation of Human Experimentation*, 72 J. CRIM. L. & CRIMINOLOGY 1597, 1657 (1981).

24. See also Meier, *supra* note 22, at 534.

25. 21 U.S.C. §§ 301–399. Pursuant to this Act, the Food and Drug Administration (FDA) has promulgated specific guidelines for human subjects research, which are found in 21 C.F.R. part 50. The Department of Health and Human Services (DHHS) promulgates regulations known as "The Common Rule" for protection of human subjects and establishment of Institutional Review Boards under 45 C.F.R. part 46. Furthermore, contracts sponsored by the U.S. Agency for International Development (USAID) are subject to 48 C.F.R. § 752.7012, which adopts the Common Federal Policy for the Protection of Human Subjects.

26. Pub. L. No. 93-348, 88 Stat. 342. The National Research Act (NRA) was enacted in response to the Tuskegee syphilis experiments and sets forth guidelines for establishing IRBs to approve and monitor human subjects research. The application of the Food Drug and Cosmetic Act (FDCA) and the NRA to research conducted in the U.S. is beyond the scope of this Note.

27. NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE

research conducted outside the United States, they have some indirect implications for international research. Research involving devices the FDA regulates must comply with both the FDA and Department of Health and Human Services (DHHS) regulations, including Institutional Review Board (IRB) and informed consent procedures.<sup>28</sup> Additionally, DHHS has issued regulations for the protection of human subjects in federally funded research. But, the human subjects protection policy of foreign countries where the research is conducted may replace DHHS policy if such protection is determined to be equal or greater than DHHS policy.<sup>29</sup>

### 1. *The Belmont Report*

In 1979, the NCPHS published the Belmont Report, which established basic ethical guidelines for performing biomedical and behavioral research.<sup>30</sup> The Belmont Report establishes three basic principles of ethical human subjects research: respect for persons,<sup>31</sup> beneficence,<sup>32</sup> and justice.<sup>33</sup> Application of these research principles involves informed

PROTECTION OF HUMAN SUBJECTS OF RESEARCH (1979) [hereinafter BELMONT REPORT], available at <http://medicine.wustl.edu/~hsc/ethics/belmontreport.pdf> (“One of the charges to the Commission was to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects, and to develop guidelines, which should be followed to assure that such research is conducted in accordance with those principles.”). Furthermore, the Belmont Report is “the outgrowth of an intensive four-day period of discussion that [was] held in February 1976 at the Smithsonian Institution’s Belmont Conference Center, supplemented by monthly deliberations of the Commission that were held over a period of nearly four years.” *Id.*

28. Food and Drug Administration, INFORMATION SHEETS: GUIDELINES FOR INSTITUTIONAL REVIEW BOARDS AND CLINICAL INVESTIGATORS, *Appendix E*, 97–98 (1998), available at <http://www.fda.gov/oc/ohrt/irbs/default.htm>.

29. 45 C.F.R. part 46 subpart A, 56 Fed. Reg. 28,003 (1991). Notably, the DHHS has enacted more rigorous protection regulations for pediatric research. *See* Additional Protections for Children Involved as Subjects in Research, 48 Fed. Reg. 9818 (1991). *See also* OFFICE OF INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES, OEI-01-00-00190, THE GLOBALIZATION OF CLINICAL TRIALS (2001) [hereinafter OIG GLOBALIZATION REPORT] (discussing the limitations of the applicability of U.S. law and regulation to research done by U.S. companies and citizens in foreign jurisdictions).

30. BELMONT REPORT, *supra* note 27. It is important to note that “the Belmont Report does not make specific recommendations for administrative action by the Secretary of Health, Education and Welfare. Rather, the Commission recommended that the Belmont Report be adopted in its entirety, as a statement of the Department’s policy.” *Id.*

31. *Id.* “Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection.” *Id.* According to the report, respect for persons entails consideration of a person’s “opinions and choices” as well as assuring that research be voluntary and informed. *Id.*

32. *Id.* “Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm; and (2) maximize possible benefits, and minimize possible harms.” *Id.*

33. *Id.* “An injustice occurs, when some benefit to which a person is entitled is denied without

consent,<sup>34</sup> assessment of risks and benefits,<sup>35</sup> and selection of subjects,<sup>36</sup> respectively.

## 2. *The National Bioethics Advisory Commission*

Following the publication of the Belmont Report, there was little change or development in U.S. policy regarding ethics or regulation of human subjects research. After several highly-publicized cases and the *Washington Post*'s publication of "The Body Hunters" series,<sup>37</sup> there was renewed interest in human subjects biomedical research. In April 2001, the National Bioethics Advisory Commission<sup>38</sup> (NBAC) published a report

good reason, or when some burden is unduly imposed." *Id.* The Commission cites the Nazi medical experiments and the Tuskegee syphilis study as examples of injustice. *Id.* The principle of justice is embodied within the selection of subjects:

[T]he selection of research subjects needs to be scrutinized in order to determine whether some classes . . . are being systematically selected, simply because of their easy availability, their compromised position, or their manipulability . . . . [J]ustice demands both that [publicly funded research] not provide advantages only to those who can afford them, and that such research not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent application of the research.

*Id.*

34. The principle of respect for persons is embodied in informed consent. *Id.* Informed consent entails: (1) the provision of information such that a reasonable person could adequately decide whether they wish to participate in the study; (2) comprehension of the information provided; and (3) voluntariness of consent when granted. *Id.*

35. The principle of beneficence is addressed through an assessment of risks and benefits. *Id.* "The assessment of risks and benefits requires a careful array of relevant data, including, in some cases, alternative ways of obtaining the benefits sought in the research." *Id.* Relevant factors for consideration in this analysis are: (1) the nature and scope of the risks and benefits and (2) the systematic assessment of risks and benefits. *Id.*

36. Selection of subjects implicates the principle of justice and contains two relevant inquiries: individual selection of subjects and social selection of subjects. *Id.* "Individual justice in the selection of subjects would require that the researcher exhibit fairness" by not only selecting individuals likely to give a result favorable to the outcome of the study. *Id.* "Social justice requires that [a] distinction be drawn between classes of subjects that ought, and ought not, to participate in any particular kind of research, based on the ability of members of that class to bear burdens, and on the appropriateness of placing further burdens on already burdened persons." *Id.* The Belmont Report makes no reference to international populations in developing nations when discussing social justice, but instead lists as examples "racial minorities, the economically disadvantaged, the very sick and the institutionalized." *Id.*

37. See *supra* notes 1–9 (discussing articles in this series). See also Joe Stephens, *Panel Suggests Rules for Foreign Drug Tests*, WASH. POST, May, 1, 2001 at A21 ("The report also follows an 11-month *Washington Post* investigation into ethical issues surrounding medical research conducted in the developing world.").

38. The NBAC was established in 1944 pursuant to 42 U.S.C. § 300v to, *inter alia*, undertake studies of the ethical and legal implications of the requirements for informed consent to participation in research projects and to otherwise undergo medical procedures . . . [and] current procedures and mechanisms designed to safeguard the privacy of human subjects of behavioral and biomedical research . . . and such other matters relating to

entitled *Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries* (hereinafter NBAC Report).<sup>39</sup> The NBAC Report made twenty-two recommendations regarding “essential ethical requirements for the ethical conduct of clinical trails.”<sup>40</sup>

The NBAC recommended that the United States refrain from sponsoring research that does not comply with certain minimal ethical standards and suggested that the FDA should not accept data obtained through unethical research.<sup>41</sup> The NBAC further recommended that clinical trials in developing countries: (1) respond to the health needs of the population;<sup>42</sup> (2) be designed to provide an established, effective treatment as a control group;<sup>43</sup> and (3) be designed and implemented with input from local community members.<sup>44</sup> Furthermore, informed consent must be obtained<sup>45</sup> in a “culturally appropriate way.”<sup>46</sup>

medicine or biomedical or behavioral research as the President may designate for study by the Commission.

*Id.*

39. NATIONAL BIOETHICS ADVISORY COMMISSION (NBAC), *ETHICAL AND POLICY ISSUES IN INTERNATIONAL RESEARCH: CLINICAL TRIALS IN DEVELOPING COUNTRIES* (2001) [hereinafter NBAC *ETHICAL AND POLICY ISSUES*]. The report was commissioned in response to (1) public concerns regarding “the protection of the rights and welfare of human participants” in international research “conducted or sponsored by U.S. interests” and (2) “the changing landscape of international research” as a result of the increasing status and sophistication of scientists from developing countries who are better able to collaborate with U.S. researchers. *Id.* at 3. The NBAC recommendations may be divided into substantive and procedural recommendations. *Id.* at 5. This Note is primarily concerned with the substantive recommendations of the report. Procedural recommendations beyond the scope of this Note are not discussed. The British corollary of the NBAC published the Nuffield Report in response to similar concerns. See Alice Page, *Ethical Issues in International Biomedical Research: An Overview*, 37 J. HEALTH L. 629, 630 (2004).

40. NBAC *ETHICAL AND POLICY ISSUES*, *supra* note 39, at ii. In doing so, the NBAC extends the principles of the Belmont Report to human subjects research involving populations in developing nations. *Id.*

41. *Id.* at 6. Among these are:

- a) prior review of research by an ethics review committee(s);
- b) minimization of risk to participants;
- c) risks of harm that are reasonable in relation to potential benefits;
- d) adequate care of and compensation to participants for injuries directly sustained during research;
- e) individual consent from all competent adult participants in research;
- f) equal regard for all participants; and
- g) equitable distribution of the burdens and benefits of research.

*Id.*

42. *Id.* at 8. This includes making post clinical trial access to the study treatment available to the population. *Id.* at 12.

43. *Id.* at 28.

44. *Id.* at 30–31.

45. *Id.* at 38.

46. *Id.* at 40. Procedurally, an ethics review committee should review the informed consent protocols as part of the clinical trial approval process. *Id.* To ensure culturally appropriate consent mechanisms, “[r]esearchers should consult with community representatives.” *Id.* Culturally appropriate informed consent may include consent from community leaders or representatives, which should be obtained without coercion to potential subjects. *Id.* at 43–44. Furthermore, in some cultures,

Additionally, the NBAC recommended that “[r]esearchers and sponsors of clinical trials should make good faith efforts . . . to secure, at the trial’s conclusion, continued access for all participants to needed experimental interventions that have been proven effective . . . .”<sup>47</sup> The NBAC also recommended that researchers make effective treatments available to the general population of a host country, whenever pre-negotiating with the host country is possible.<sup>48</sup> The NBAC recommended procedures to ensure the protection of the host country’s citizens by generally stating that the U.S. government should only sponsor trials that both a U.S. IRB<sup>49</sup> and a host country ethics review committee have approved.<sup>50</sup>

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informed consent may entail supplemental consent given by the subject’s husband. *Id.* at 45. If culturally appropriate, ethics review committees may waive the requirement that informed consent be given in writing if the study design indicates how such consent will be given. *Id.* at 50. The NBAC encourages the National Institute of Health, the Centers for Disease Control and Prevention, and other relevant agencies to engage in research to determine culturally appropriate informed consent mechanisms for different cultures. *Id.*

47. *Id.* at 74. The initial research protocol should detail the “duration, extent and financing of such continued access.” *Id.*

48. *Id.* The NBAC recognizes but discounts criticism of pre-negotiated agreements to provide effective treatments in host countries. *Id.* at 67–68. These critiques include: (1) that reaching such an agreement might prevent or delay the research; (2) that such agreements may be “substantively, procedurally, and logistically” problematic; (3) that making such prior agreements is not standard in international research; (4) that the researchers may be unable to influence the host countries’ existing health policy to make provision of the treatment realistic; (5) that such agreements create a double standard for provision of treatments to host countries when such a requirement is not necessary in the United States; and (6) that such obligations may be breached. For detailed discussion and response to these critiques, see NBAC ETHICAL AND POLICY ISSUES, *supra* note 39, at 67–72.

49. IRBs are established pursuant to 42 U.S.C. § 289 (2000), which provides that

each entity which applies for a grant, contract, or cooperative agreement under this chapter for any project or program which involves the conduct of biomedical or behavioral research involving human subjects submit in or with its application for such grant, contract, or cooperative agreement assurances satisfactory to the Secretary that it has established (in accordance with regulations which the Secretary shall prescribe) a board (to be known as an “Institutional Review Board”) to review biomedical and behavioral research involving human subjects conducted at or supported by such entity in order to protect the rights of the human subjects of such research.

50. NBAC ETHICAL AND POLICY ISSUES, *supra* note 39, at 83, 84. The NBAC recommends that the IRB requirement be waived when it has been determined that the host country ethics review board complies with the substantive ethical provisions discussed in note 32, *supra*.

### III. CASE STUDIES

#### A. Pfizer's Nigerian Antibiotic Research

In 1996, a severe outbreak of bacterial meningitis occurred in northern Nigeria,<sup>51</sup> a country already devastated by the ongoing effects of cholera and measles.<sup>52</sup> Meanwhile, in the United States, Pfizer had developed a new antibiotic known as Trovan<sup>53</sup> and was starting clinical trials.<sup>54</sup> Since animal studies indicated that Trovan caused complications in children, including bone and joint deformities and liver damage, Pfizer could not test Trovan on children in the United States.<sup>55</sup> Scott Hopkins, a physician working for Pfizer, learned of Kano's meningitis outbreak.<sup>56</sup> Seeing this outbreak as an opportunity for extensive pediatric testing, Hopkins proposed to send a six member team to Kano<sup>57</sup> in order to test orally-administered Trovan on Nigerian children.<sup>58</sup> In order to export Trovan to Nigeria, Pfizer obtained FDA approval, which was based upon the Kano government's and a Nigerian hospital's ethics committee's approval.<sup>59</sup>

The Pfizer team arrived in Nigeria and set up operations at Kano's Infectious Disease Hospital (IDH).<sup>60</sup> Over a two week period, Pfizer

51. Stephens, *supra* note 8, at A1. By the end of the epidemic 15,800 Africans died from meningitis. *Id.* See also Abdullahi v. Pfizer, 2002 WL 31082956, \*1 (S.D.N.Y. 2002) (*Abdullahi I*).

52. Stephens, *supra* note 8, at A1.

53. Trovan is the brand name for the compound Trovaflozacin Mesylate. *Abdullahi I*, 2002 WL 31082956, at \*1.

54. Stephens, *supra* note 8, at A1.

55. *Id.* Trovan belongs to a class of antibiotics known as quinolones which have been known to cause joint damage, including arthropathy and chondrodysplasia, in juvenile canines and rats. *Trovan*, in PHYSICIANS DESK REFERENCE 2645, 2650 (58th ed. 2004). Animal studies with Trovan yielded similar results. *Id.*

56. Stephens, *supra* note 8, at A1.

57. Nigeria has neither a formal review process for human subjects research nor widespread guidelines for ethical human subjects research other than those provided by the Declaration of Helsinki. Remigius Nwabueze, *Ethical Review of Research Involving Human Subjects in Nigeria: Legal and Policy Issues*, 14 IND. INT'L & COMP. L. REV. 87, 110 (2003).

58. *Id.* Hopkins pitched the Kano clinical trial to Pfizer as a humanitarian effort; however, another Pfizer representative called this characterization "a little bit disingenuous." *Id.* Trovan had an estimated sales value of \$1 billion per year and conducting clinical trials in developing nations was relatively inexpensive compared to conducting trials in developed, highly regulated nations. *Id.*

59. *Abdullahi I*, 2002 WL 31082956, at \*1. It was later alleged that the ethics committee approval letter did not exist at the time of the FDA's approval but was later written, and backdated, in response to an FDA audit. *Id.* In fact, Sadiq Wali, medical director of the Kano hospital, later reported that no such IDH committee existed at the time of the Trovan trial and alleged that the letter must have been forged. Joe Stephens, *Doctors Say Drug Trial's Approval Was Backdated*, WASH. POST, Jan. 16, 2001 at A1.

60. *Abdullahi I*, 2002 WL 31082956, at \*1; see also Stephens, *supra* note 8, at A1. Pfizer's medical team was one of several others at IDH, including Doctors Without Borders. *Id.* All other medical teams provided established treatment regimens. *Id.*

treated 198 pediatric meningitis patients with either a full dose of oral Trovan or a partial dose of injected ceftriaxone.<sup>61</sup> Pfizer never informed the subjects that they were part of a clinical trial or that free, established, effective treatment was being provided by other medical groups at the same facility.<sup>62</sup> Although Pfizer's protocol called for blood tests upon admission and at fixed treatment intervals, Pfizer did not perform the necessary blood tests on all of the patients.<sup>63</sup> Furthermore, it was alleged that Pfizer did not change treatment protocols for patients who failed to respond to the experimental treatment with Trovan.<sup>64</sup>

After only two weeks, Pfizer left Nigeria and directed the research subjects to follow up with the other clinicians at the IDH.<sup>65</sup> At the end of the Kano-Trovan clinical trial, it was alleged that eleven children died, five in the Trovan group and six in the control ceftriaxone group.<sup>66</sup> Approximately sixty children reported arthralgias and other disease sequelae after receiving Trovan.<sup>67</sup>

Following the Kano clinical trials, Pfizer applied to the FDA for approval of pediatric use of Trovan in the United States.<sup>68</sup> When the FDA noted discrepancies during an audit of the Nigeria documents,<sup>69</sup> Pfizer withdrew its application to use the drug for "epidemic meningitis."<sup>70</sup> In February of 1998, Pfizer began marketing Trovan in the United States,<sup>71</sup>

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61. *Id.* Pfizer alleges that the under dosing of the ceftriaxone control group resulted from an attempt to reduce the pain of the injections that were given mainly intramuscularly by inexperienced hospital staff. *Id.* Hoffman-Laroche, the maker of ceftriaxone, alleges that such low dosing may have skewed the study results in favor of Trovan and could have resulted in unnecessary deaths for some children. *Id.*

62. *Id.*

63. *Id.* Pfizer again alleged that the tests were not completed due to staff shortages and staff inexperience. *Id.*

64. *See id.* (reporting that at least two patients died while taking the oral Trovan, including a ten year old girl who worsened over three days without being switched to the ceftriaxone control group).

65. *Id.* Children who still needed treatment were transferred to another hospital. *Id.*

66. *Abdullahi I*, 2002 WL 31082956, at \*2. Doctors Without Borders estimated the mortality rate in Kano to be about 20% overall. Stephens, *supra* note 8, at A1.

67. *Id.* Joint symptoms may also be a complication of bacterial meningitis. Gerard Merenstein, David Kaplan & Adam Rosenberg, HANDBOOK OF PEDIATRICS 334-39 (18th ed. 1997). The Nigerian families also allege other side effects of treatment including brain damage, paralysis, and seizures. *See* Brief and Special Appendix for Plaintiffs-Appellants-Cross Appellees at 9, *Abdullahi v. Pfizer, F. App'x* 48 (2003) (Nos. 02-9223).

68. Stephens, *supra* note 8, at A1.

69. *Id.* Discrepancies included disparate recording of white blood cell counts, contradictory statements about where lab work had been performed, and an inability to determine who had actually recorded data. *Id.*

70. *Id.* In fact, Trovan was never approved for use in children in the United States. Furthermore, when the European Union approved Trovan, it specifically stated that the antibiotic should not be given to children. *Id.*

71. *Id.* Trovan's approval for use in adults was based on clinical trials in 13,000 people in 27

but shortly thereafter, complaints of liver disease and liver failure surfaced among Trovan users; these complaints lead to severe restrictions of Trovan's use in the United States.<sup>72</sup>

## B. Trovan Clinical Trial Litigation

### 1. Abdullahi v. Pfizer in District Court

On July 31, 2001, thirty Nigerian families whose children were involved in the Kano–Trovan clinical trials filed a lawsuit in federal district court for the Southern District of New York alleging that Pfizer exposed them to “cruel, inhuman and degrading treatment.”<sup>73</sup> As the basis of their action, plaintiffs claimed that Pfizer failed to obtain informed consent, that Pfizer did not inform them that they would be part of a clinical trial, that they had the right to refuse experimental treatment, and that other medical teams within the same facility could have provided safe, effective treatment at no cost.<sup>74</sup>

Plaintiffs sought relief under the Alien Tort Statute<sup>75</sup> (ATS) which provides that “[t]he district courts shall have original jurisdiction of any civil action by an alien for a tort only, committed in violation of the law of nations or a treaty of the United States.”<sup>76</sup> The plaintiffs pointed to violations of ICCPR Article 7,<sup>77</sup> the Nuremberg Code,<sup>78</sup> the Declaration of Helsinki,<sup>79</sup> and “other norms of international law” in order to establish

different countries. *Id.*

72. *Id.* Trovan's use in the European Union has been completely suspended. *Id.* See also *Abdullahi I*, 2002 WL 31082956, at \*2.

73. Joe Stephens, *Suit Accuses Pfizer of Rights Violations*, WASH. POST, Aug. 30, 2001, at A9 (internal quotations omitted).

74. *Abdullahi I*, 2002 WL 31082956, at \*2. Doctors Without Borders offered treatment with chloramphenicol at the same facility. *Id.*

75. 28 U.S.C. § 1350 (1988) [hereinafter ATS]. Although the ATS usually applies to state actors, it may be applicable to private actors if their conduct is particularly egregious. See *Kadic v. Karadzic*, 70 F.3d 232, 239–40 (2d Cir. 1995) (“Individuals may be held liable for offenses against international law, such as piracy, war crimes, and genocide.”) (citing Restatement (Third) of Foreign Relations Laws of the U.S. (1986)). Here, plaintiffs do not allege such conduct but rather allege that “Pfizer acted as a *de facto* state actor because it conducted the Trovan study with the assistance of the Nigerian government and government employees from IDH and Aminu Teaching Hospital.” *Abdullahi I*, 2002 WL 31082956, at \*5. Analyzing the relationship under a joint participation theory, the district court found that Pfizer was in fact a joint participant with the Nigerian government. *Id.* at \*5–6.

76. 28 U.S.C. § 1350. To bring a cause of action under the ATS, plaintiffs must adequately plead a breach of international law. See *Kadic*, 70 F.3d, at 238.

77. CIOMS ETHICAL GUIDELINES, *supra* note 18.

78. The Nuremberg Code, *supra* note 13.

79. WMA, THE DECLARATION OF HELSINKI, *supra* note 17.

federal court jurisdiction under the ATS.<sup>80</sup> Although the district court conceded that the plaintiffs may have had a colorable claim under the ATS,<sup>81</sup> it dismissed the action on the basis of *forum non conveniens* concluding that Nigeria would be a more appropriate forum for the litigation.<sup>82</sup>

## 2. Zango v. Pfizer

One of the district court's primary reasons for dismissing the *Abdullahi* action was that Pfizer was already facing a lawsuit in Nigeria based on the Kano clinical trials.<sup>83</sup> In the Nigerian case styled *Zango v. Pfizer Int'l, Inc.*,<sup>84</sup> the plaintiffs sued both Pfizer and Nigerian government officials in order to obtain an emergency injunction to limit Pfizer's Trovan clinical trials.<sup>85</sup> The injunction was denied.<sup>86</sup> The plaintiffs then sought damages from Pfizer and the government officials.<sup>87</sup> When the defendant government officials failed to appear in court and made procedural errors in their filings, the plaintiffs dropped their suit against them but continued to pursue the action against Pfizer.<sup>88</sup>

Upon dismissal of the suit against the government, the three hundred-fifty *Zango* plaintiffs proceeded with their action against Pfizer, but they eventually dismissed that lawsuit as well.<sup>89</sup> The plaintiffs averred that they dismissed the suit because of undue delays in the litigation, citing removal of the judge initially assigned to the case, fourteen adjournments, a second judge stepping down from the case for personal reasons, and no

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80. *Abdullahi I*, 2002 WL 31082956, at \*4.

81. "Non-self executing agreements like ICCPR may evidence the binding principles of international law . . . . Thus, while plaintiff's need not rely on ICCPR to provide a private right of action, they may look to that treaty to allege that Pfizer's conduct violated well established, universally recognized norms of international law." *Id.* (internal citations and quotations marks omitted).

82. *Id.* at \*12. The district court found *forum non conveniens* based on the following considerations: (1) Nigeria provided an adequate alternative forum; (2) Pfizer was already defending a lawsuit in Nigeria based on the same conduct; (3) the presumption that a plaintiff's choice of forum is convenient is weaker when the plaintiff is foreign; (4) Nigerian courts should be able to apply international law as effectively as U.S. courts; (5) Nigeria has a strong interest in the litigation; and (6) most of the documents and witnesses necessary for trial are located in Nigeria. *Id.* at \*6-12.

83. *Id.* at \*12.

84. Case No. FHC/K/CS/204/2001(Nigeria).

85. Reply Brief for Plaintiffs-Appellants-Cross Appellees at 11, *Abdullahi v. Pfizer*, 77 F. App'x 48 (2003) (Nos. 02-9223, 02-9303).

86. *Id.*

87. *Id.* at 12.

88. *Id.* at 11.

89. *Id.* at 13. Note that the fact that there were three hundred-fifty *Zango* plaintiffs in addition to the *Abdullahi* and *Adamu* plaintiffs, *infra* note 115, contradicts accounts that there were two hundred children treated, *supra* note 54.

replacement judge being assigned to the case.<sup>90</sup> The *Abdullahi* plaintiffs allege that the second judge in the *Zango* proceedings recused himself because of undue pressure from Pfizer.<sup>91</sup> The *Zango* proceedings were dismissed on October 17, 2002, approximately one month after the U.S. District Court for the Southern District of New York dismissed the *Abdullahi* proceedings for *forum non conveniens*.<sup>92</sup>

### 3. *Abdullahi v. Pfizer in the Appellate Court*

In the United States, the *Abdullahi* plaintiffs appealed the district court's *forum non conveniens* dismissal of their case to the U.S. Court of Appeals for the Second Circuit.<sup>93</sup> Noting that the Nigerian *Zango* proceedings had been dismissed, the Second Circuit vacated the district court's judgment and remanded the case for rehearing on the *forum non conveniens* issue.<sup>94</sup> In remanding the case, the appellate court instructed the district court to reconsider the adequacy of the Nigerian courts as a forum for the *Abdullahi* action in light of the *Zango* dismissal.<sup>95</sup>

### 4. *Abdullahi Rehearing in the District Court*

On remand, the district court primarily addressed the defendant's motion to dismiss. The court determined that none of the sources of law

90. *Abdullahi v. Pfizer*, 2005 WL 1870811, at \*3–5 (S.D.N.Y. 2005) (*Abdullahi III*). There is conflict in the record regarding whether the *Zango* plaintiffs may have contributed to the delay themselves by requesting continuances and pointing out technical deficiencies in the defendant's filings. *Id.*

91. *Id.* at \*6. Plaintiffs also allege that Pfizer bribed other law enforcement officials in Nigeria during the clinical trials. They allege that the Nigerian government halted the trials and that Pfizer employees in Nigeria requested cash from Pfizer headquarters to prevent them from being jailed. *Id.* at \*5. In a letter written by *Abdullahi* plaintiffs' counsel Elaine Kusel, plaintiffs allege that "[t]hese facts provide strong circumstantial evidence that Justice Hobon declined jurisdiction because he was subject to improper or undue pressure, perhaps from Pfizer itself, or from government officials friendly to Pfizer who had been involved with the Trovan tests." *Id.* at \*6 (internal quotations omitted).

92. *Abdullahi v. Pfizer*, 77 F. App'x 48, 52 n.2 (2d Cir. 2003) (*Abdullahi II*). The *Abdullahi* plaintiffs allege that the *Zango* case was dismissed approximately one month prior to the district court's *Abdullahi* decision. *Id.* They rely on the fact that the "Notice of Discontinuance" was dated August 19, 2002; however, the Second Circuit opinion notes that the Notice was not actually filed with the Nigerian court until October 17, 2002. *Id.*

93. *Id.* at 50. Pfizer cross appealed the denial of its motion to dismiss; however, the appellate court did not reach this issue. *Id.* at 53.

94. *Id.*

95. *See id.* at 53. The appellate court declined to decide the *forum non conveniens* issue, citing factual conflicts in the record as to what occurred in the *Zango* proceedings that needed to be resolved by a fact finder. *Id.*

the plaintiffs cited in their original action gave rise to a cause of action under the ATS against Pfizer.<sup>96</sup>

The court first addressed the plaintiffs' claim that the defendant's conduct violated the Nuremberg Code. The district court held that violations of the Nuremberg Code did not give rise to a cause of action under the ATS stating that: (1) the Code did not "give rise to a private right of action;" (2) the United States had not ratified or adopted the Code; and (3) the Code had not been adopted by the international community, including the United Nations and other prominent states.<sup>97</sup>

The court next addressed the plaintiffs' second claim of jurisdiction based on the Declaration of Helsinki and the CIOMS Guidelines.<sup>98</sup> The court found that these guidelines were general policy statements issued by private organizations but not law.<sup>99</sup> Furthermore, the court determined that both the Declaration of Helsinki and the CIOMS Guidelines, as general policy statements, did not dictate specific behavior.<sup>100</sup> In addition, the court found that neither the Declaration of Helsinki nor the CIOMS Guidelines created binding legal obligations.<sup>101</sup> Consequently, the plaintiffs could not assert a cause of action under the ATS based on either policy.<sup>102</sup>

Third, the court addressed the plaintiffs' claim of jurisdiction under the ATS based on Pfizer's alleged violation of ICCPR Article 7<sup>103</sup> for failure to obtain informed consent. While the court conceded that the ICCPR does create customary international law, it refused to recognize the ICCPR

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96. *Abdullahi III*, 2005 WL 1870811, at \*11.

97. *Id.* at \*10.

98. *See generally* CIOMS ETHICAL GUIDELINES, *supra* note 18. CIOMS published these guidelines in collaboration with the World Health Organization. The guidelines cover ethical review, informed consent, vulnerable groups, and women as research participants. These guidelines incorporate many of the general principles contained in the guidelines discussed above.

99. *Abdullahi III*, 2005 WL 1870811, at \*12. The court relies on *Flores v. S. Peru Copper Corp.*, 414 F.3d 233, 262 (2d Cir. 2003) (stating that a "mere general statement of policy . . . is unlikely to give rise to obligations in any strict sense"), and *United States v. Yousef*, 327 F.3d 56, 102–03 (2d Cir. 2003):

In a system governed by the rule of law, no private person-or group of men and women such as compromise the body of international scholars-creates the law. Accordingly, instead of relying primarily on the works of scholars for a statement of the customary international law, we look primarily to the formal lawmaking and official actions of States and only secondarily to the works of scholars as evidence of the established practice of States.

100. *Abdullahi III*, 2005 WL 1870811, at \*12. *See Flores*, 414 F.3d at \*254 ("[I]n order to state a claim under the [ATS], we have required that a plaintiff allege a violation of a clear and unambiguous rule of customary international law.").

101. *Abdullahi III*, 2005 WL 1870811, at \*12.

102. *Id.*

103. ICCPR, *supra* note 21.

articles as binding obligations on federal courts.<sup>104</sup> In reaching its conclusion, the court relied on the fact that the United States ratified the ICCPR as a non self-executing treaty.<sup>105</sup>

Finally, the court turned to the plaintiffs' claim that jurisdiction under ATS was proper based on the defendant's alleged violations of the Universal Declaration of Human Rights (Declaration of Human Rights).<sup>106</sup> The court held that the Declaration of Human Rights is not binding but is merely "aspirational" by asserting that, "this Court will not judicially forge broad aspirational language into customary international law."<sup>107</sup> The court found no private right of action under any of the sources of international law plaintiffs cited and thus declined to assert jurisdiction under the ATS.<sup>108</sup> Based on these findings, the district court granted the defendant's motion to dismiss.<sup>109</sup>

The court next addressed the *forum non conveniens* issue. The court affirmed its previous ruling that Nigeria provided an adequate alternative forum for the plaintiffs' claim.<sup>110</sup> Based on its assessment of the *Zango* record,<sup>111</sup> the court determined that there was insufficient evidence to indicate that the Nigerian courts were not an adequate forum.<sup>112</sup> The court stated that the temporary delay in the *Zango* proceedings was not enough to render the forum inadequate, noting that it was the *Zango* plaintiffs who had voluntarily dismissed the suit.<sup>113</sup> Although the court ultimately dismissed the action based on the defendant's motion to dismiss, it

104. *Abdullahi III*, 2005 WL 1870811, at \*13. See *Sosa v. Alvarez-Machain*, 542 U.S. 692, 735 (2004) ("[A]lthough the [ICCPR] does bind the United States as a matter of international law, the United States ratified the covenant on the express understanding that it was not self-executing and so did not itself create obligations enforceable in the federal courts.").

105. *Abdullahi III*, 2005 WL 1870811, at \*13. See *Sosa*, 542 U.S. at 728 ("[T]he Senate has expressly declined to give the federal courts the task of interpreting and applying international human rights law, as when its ratification of the [ICCPR] declared that the substantive provision of the document were not self-executing.").

106. WMA, THE DECLARATION OF HELSINKI, *supra* note 17.

107. *Abdullahi III*, 2005 WL 1870811, at \*13.

108. *Id.* at \*14.

109. *Id.* at \*18.

110. See *id.*

111. The court notes that it was unable to obtain a transcript of the *Zango* proceedings and therefore bases its conclusions on affidavits of the party's experts. *Id.* at \*3.

112. See *id.* at \*16. "Most of Plaintiffs' submissions are 'of little use' because 'they largely consist[] of broad, conclusory assertions as to the relative corruptability or incorruptability of the [Nigerian] courts, with scant reference to specifics.'" *Id.* (quoting *Aguinda v. Texaco, Inc.*, 142 F. Supp. 2d 534, 544 (S.D.N.Y. 2001)).

113. *Id.* at \*17. "An alternative forum will be held inadequate only in those rare circumstances where it is so clearly unsatisfactory that it is no remedy at all." *Id.* at \*18 (internal quotation marks omitted).

specifically stated “[e]ven if this Court had subject matter jurisdiction, it would dismiss the action on *forum non conveniens* grounds . . . .”<sup>114</sup>

#### 5. Adamu v. Pfizer

A second group of plaintiffs brought suit in the U.S. District Court for the Southern District of New York based on Pfizer’s Trovan trials in Kano.<sup>115</sup> In addition to the claims alleged in *Abdullahi*, the plaintiffs claimed breach of the Connecticut Unfair Trade Practices Act (CUTPA) and the Connecticut Products Liability Act (CPLA).<sup>116</sup> The district court dismissed the plaintiffs’ claims under the ATS for substantially the same reasons enumerated in *Abdullahi*<sup>117</sup> and dismissed the claims under the Connecticut statutes after determining that Nigerian, rather than Connecticut law, governed the action.<sup>118</sup> In reaching its holding, the court applied principles of conflict of laws and reasoned that Nigeria had the greater interest in seeing its laws applied.<sup>119</sup>

### IV. ANALYSIS

The final section of this Note analyzes the likelihood of any remedy for plaintiffs in cases similar to *Abdullahi* under the ATS as it is currently interpreted by U.S. federal courts. It then discusses the inadequacy of

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114. *Id.* at \*18. The court conditioned its dismissal on the defendant’s (1) “consent[] to suit and acceptance of process in any suit plaintiffs file in Nigeria . . . .”; (2) waiver of any applicable statute of limitations in Nigeria; (3) payments for transportation of any documents or witnesses necessary for the action in Nigeria; and (4) waiver of any claim of res judicata or collateral estoppel in the U.S. District Court should Nigeria decline to accept jurisdiction of the case. *Id.* Also, note the inherent inconsistency between the district court’s rehearing opinion and its initial decision. *See supra* text accompanying note 81.

115. *See Adamu v. Pfizer*, 399 F. Supp. 2d 495 (S.D.N.Y. 2005). This case was originally filed in the District of Connecticut, but was transferred to the Southern District of New York. *Id.* at 497.

116. *Id.* at 497.

117. *Id.* at 503. These reasons are enumerated in notes 90–100, *supra*.

118. *Id.* at 503.

119. *Id.* *See also* Restatement (Second), Conflict of Laws § 145(1) (“The rights and liabilities of parties with respect to an issue in tort are determined by the local law of the state which, with respect to that issue, has the most significant relationship to the occurrence and the parties under the principles stated in § 6.”); Restatement (Second), Conflict of Laws § 6:

(1) A court, subject to constitutional restrictions will follow a statutory directive of its own state on choice of law. (2) When there is no such directive, the factors relevant to the choice of applicable rule of law include (a) the needs of interstate and international systems, (b) the relevant policies of the forum, (c) the relevant policies of other interested states in the determination of the particular issue, (d) the protection of justified expectations, (e) the basic policies underlying the particular field of law, (f) certainty, predictability, and uniformity of result, and (g) ease in determination and application of the law to be applied.

available remedies in light of U.S. tort policy and how the lack of proper remedies may reinforce cultural norms. Next, the Note examines how the doctrine of *forum non conveniens* further deters foreign plaintiffs' efforts and the inadequacy of international enforcement mechanisms in addressing their claims. Finally, the Note recommends solutions to reasonably regulating U.S. companies' pharmaceutical testing in developing nations.

### A. *The Alien Tort Statute Decisions*

The *Abdullahi* and *Adamu* cases may have a profound impact on the ATS being available as a remedy for damages U.S. companies cause in international human subjects research. These decisions severely limit the scope of what can be considered "international law," especially in regard to ethical human subjects research behavior. However, the ATS should not be considered only in this context.

The Second Circuit has held that customary international law encompasses "those rules that States universally *abide by*, or accede to, out of a sense of *legal obligation* and *mutual concern*."<sup>120</sup> In *Flores v. S. Peru Copper Corp.*, the Second Circuit explicitly excluded the ICCPR, on which the *Abdullahi* plaintiffs relied, from being customary international law sufficient to bring a claim under the ATS.<sup>121</sup> Furthermore, the *Flores* Court held that even "shocking and egregious" conduct does not necessarily give rise to a violation of customary international law under the ATS.<sup>122</sup>

Principles established by the U.S. Supreme Court for defining international law under the ATS have been set forth in other contexts. In *Sosa v. Alvarez-Machain*,<sup>123</sup> the Court held that a violation of the law of

120. *Flores v. S. Peru Copper Corp.*, 343 F.3d 140, 154 (2d Cir. 2003) (emphasis added). However, the Second Circuit severely limits the applicability of this definition by stating: "[I]n determining what offenses violate customary international law, courts must proceed with extraordinary care and restraint." *Id.*

In *Flores*, representatives of deceased Peruvian miners brought suit against an American mining company alleging violation of plaintiffs' rights to health and a clean environment. *Id.* at 143–44. The *Flores* Court defined customary international law as "those rules that States universally abide by, or accede to, out of a sense of legal obligation and mutual concern." *Id.* at 154. The Court furthermore held that "[i]n determining whether a particular rule is part of customary international law . . . courts must look to concrete evidence of the customs and practices of States." *Id.* at 156.

121. *Id.* at 163–64. The Second Circuit's rationale was twofold: (1) the ICCPR is not a self-executing treaty and (2) none of its provisions are specifically definite enough to define a standard under international law. *Id.*

122. *Id.* at 159.

123. 542 U.S. 692 (2004). In *Sosa*, the plaintiff, a Mexican citizen, alleged that he was abducted

nations must “rest on a norm of international character accepted by the civilized world and defined with specificity comparable to the features of the 18th-century paradigms we have recognized.”<sup>124</sup> In addition, courts must be “particularly wary of impinging on the discretion of the Legislative and Executive Branches in managing foreign affairs.”<sup>125</sup>

Furthermore, the Court declared that the Declaration of Human Rights “[d]oes not of its own force impose obligations as a matter of international law.”<sup>126</sup> The Court has likewise rejected attempts to use the ICCPR as a basis for establishing customary international law. The Court stated that although the ICCPR “[d]oes bind the United States as a matter of international law, the United States ratified the [ICCPR] on the express understanding that it was not self-executing and so did not itself create obligations enforceable in the federal courts.”<sup>127</sup>

What has become clear post-*Sosa* is that it will be difficult for plaintiffs like those in *Abdullahi* to prevail under the ATS<sup>128</sup> because *Sosa* expressly limits the ATS to providing subject-matter jurisdiction and explicitly states that the ATS itself does not provide a separate cause of action.<sup>129</sup>

Plaintiffs who seek to assert a cause of action must find a source of international law, custom, or norm. The *Abdullahi* and *Adamu* plaintiffs asserted claims based on international treaties, policies, and customs regarding human rights as applied to medical care and treatment.<sup>130</sup> No source was sufficient to bring a claim under the ATS.<sup>131</sup> These plaintiffs

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by the U.S. Drug Enforcement Agency (DEA) to stand trial in the U.S. *Id.* at 695. He brought suit against another Mexican citizen whom he alleged had aided the DEA in his abduction under the ATS. *Id.* The U.S. District Court for the Central District of California and the U.S. Court of Appeals for the Ninth Circuit granted the plaintiff’s claim under the ATS, holding that the statute gave both subject-matter jurisdiction and a cause of action. *Id.* at 699. The U.S. Supreme Court reversed its holding that the ATS provided only jurisdiction. *Id.* at 723. Significantly, *Sosa* was decided after *Abdullahi I* and *II*, but before *Abdullahi III* and *Adamu*.

124. *Id.* at 725.

125. *Id.* at 727.

126. *Id.* at 735.

127. *Id.* See also *id.* at 728 (noting that “the Senate expressly declined to give the federal courts the task of interpreting and applying international human rights law, as when its ratification of the [ICCPR] declared that the substantive provisions of the document were not self-executing”).

128. See Sandra Coliver, Jennie Green & Paul Hoffman, *Holding Human Rights Violators Accountable by Using International Law in U.S. Courts: Advocacy Efforts and Complementary Strategies*, 19 EMORY INT’L L. REV. 169, 212 (2005) (“*Abdullahi* may signify a new trend in ATS cases in which courts will entertain product liability-like causes of actions. It remains to be seen whether such cases will survive after *Sosa*.”).

129. *Sosa*, 542 U.S. at 725.

130. See *supra* text accompanying notes 97–107.

131. ATS claims have survived for allegations of slavery; forced labor; genocide; crimes against humanity; cruel, inhuman and degrading treatment; forced exile; arbitrary detention; freedom of association; and right to life. See Coliver et al., *supra* note 128, at 216. The authors postulate that pre-

essentially had no cause of action in U.S. courts for the alleged wrongs committed by a U.S. pharmaceutical corporation.

### B. U.S. Tort Policy

The basic functions of the U.S. tort system are: (1) corrective justice; (2) optimal deterrence; (3) loss distribution; and (4) redress of social grievances.<sup>132</sup> Disallowance of claims, like those of the Nigerian plaintiffs, under the ATS undermines these functions. It provides no justice for those who have been wronged. Lack of redress for these groups of victims fails to deter corporate entities from engaging in unethical research in underdeveloped countries when that research is economically beneficial to them.<sup>133</sup> Furthermore, when loss occurs as a result of unethical research, it distributes the loss to those least able to bear it, while potential intentional tortfeasors may benefit from such a loss. Researchers should not be allowed to “[e]xploit and take advantage of the abundant research subjects, poverty and disease, low level of regulation, and comparatively cheaper cost of clinical trials in developing countries . . .”<sup>134</sup> without bearing some of the resultant loss. The victim of unethical research will not receive any compensation for his or her loss. And finally, this result fails to redress social grievances caused by large, impersonal corporations.<sup>135</sup>

### C. Cultural Norms

Failing to compensate victims of harmful, unethical medical research reinforces the notion that the persons affected are inferior and thus, not deserving of redress.<sup>136</sup> Attorney Jay Dyckman argues that “postcolonial

*Sosa* causes of action will remain viable while post-*Sosa* causes will bear a heavier burden of production. *Id.* at 217. The authors further speculate that causes involving physical violence will be the most successful. *Id.*

132. KENNETH ABRAHAM, *THE FORMS AND FUNCTIONS OF TORT LAW* 14–20 (2d ed. 2002).

133. See Colloquy, *International Challenges for the Pharmaceutical/Biotech Industries in the 21st Century*, 24 LOY. L.A. ENT. L. REV. 1, 24–25 (2004) (commenting on, *inter alia*, pharmaceutical research in developing countries, Mr. Mauer, lecturer in public policy at the University of California, Berkeley, states: “The reason that these standards are so high is because the assumption is the pharmaceutical researchers are cheating. Because you have huge economic advantages to cheat on your studies to make them look good . . . . And I think litigation does drive some honesty. It can obviously go to the extreme, but it does drive one to, if one is doing bad things, at least, to cover it up better.”).

134. Remigius Nwabueze, *Ethical Review of Research Involving Human Subjects in Nigeria: Legal and Policy Issues*, 14 IND. INT’L & COMP. L. REV. 87, 88 (2003).

135. See ABRAHAM, *supra* note 132, at 19.

136. See generally Jay Dyckman, *The Myth of Informed Consent: An Analysis of the Doctrine of Informed Consent and Its (Mis)application in HIV Experiments On Pregnant Women in Developing*

media images [portraying Africans] as diseased, dismembered, deformed, and deceased” cause them to be viewed as merely fungible bodies, subject to the rules of property.<sup>137</sup> Imposing liability on researchers who take such a callous perspective of human life, as evidenced by unethical medical research procedures, forces the researchers to take the research subject’s humanity into consideration when designing and implementing a study.

#### *D. The Forum Non Conveniens Doctrine*

Additionally, the *Abdullahi* court’s *forum non conveniens* analysis fails to consider the practical difficulties that the *Abdullahi* plaintiffs faced by bringing suit in Nigeria.<sup>138</sup> Although Nigeria, as a member of the World Medical Association, is subject to the Declaration of Helsinki, currently it has no formal ethics regulatory process.<sup>139</sup> The Nigerian “Constitution has made provisions to insulate the judiciary from legislative and executive political influences and to ensure impartial determination of cases . . . [however,] implementation must be left to human imperfections and vagaries.”<sup>140</sup> Although the Nigerian Constitution seeks to prevent influence through fixed salary and term of service provisions, politically unpopular judges can and have been removed from office.<sup>141</sup> Furthermore, fixed salaries can be adjusted for inflation, at times giving rise to implications of corruption.<sup>142</sup> Additionally, the judicial appointment process may be used to apply political pressure to the Nigerian judiciary.<sup>143</sup> The combination of political influences on the judiciary and lack of ethical regulatory control over medical experimentation may thwart the effective prosecution of human subject research ethics violators

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*Countries*, 9 COLUM. J. GENDER & L. 91, 120 (1999) (hypothesizing that apathy regarding medical experimentation in African nations stems from images of dismembered African war and famine victims, which leads to the notion that “these bodies are irrelevant”).

137. *Id.* According to Dyckman, such thinking (“that certain groups are not worthy of medicine or bodily integrity because of the social or political construction of their bodies as inferior”) gave rise to the Holocaust. *Id.* at 119.

138. See generally Elliot J. Schrage, *Judging Corporate Accountability in the Global Economy*, 42 COLUM. J. TRANSN’L L. 153, 168 (2003) (“[T]he United States should support effective analysis by U.S. courts in scrutinizing practices of foreign judiciaries to determine their independence and in examining whether local justice can be fairly and effectively administered.”).

139. See Nwabueze, *supra* note 134, at 102–03.

140. Major Nannguhan Madza, *The Judicial System of Nigeria*, ARMY LAW. 20, 26 (1987).

141. *Id.*

142. *Id.*

143. *Id.*

in developing countries worldwide.<sup>144</sup> The *Zango* case illustrates this result.

### *E. International Efforts*

The International Conference on Harmonization (ICH) was established to create international ethical guidelines for biomedical research.<sup>145</sup> The guidelines promulgated by ICH are, like many other ethical guidelines, voluntary.<sup>146</sup> Although published in the Federal Register, they lack the force of law in the United States and abroad.<sup>147</sup> Therefore, the ICH guidelines are insufficient to protect human research subjects in developing nations.

International cooperation, however, may lead to developed countries dominating policy origination.<sup>148</sup> Such a scenario would be costly to developed nations in terms of development and enforcement dollars and could lead nations who are not part of the policy process to resent the development process.<sup>149</sup> Principles of cultural relativism<sup>150</sup> dictate that all cultures involved must be accounted for in any broad policy decisions in order for such policies to be truly ethical.

Additionally, enforcement of international policy necessitates the establishment of a suitable forum. Either a United Nations enforcement council or an independent “permanent Nuremberg” tribunal could be established, and such a council would have to recognize corporations as entities in order to prosecute them.<sup>151</sup>

144. See OIG GLOBALIZATION REPORT, *supra* note 29. See also Meier, *supra* note 22, at 532 (“African nations vie to minimize regulation on the conduct of medical research. They fear that legislation, and resulting lawsuits, could have a chilling effect on beneficial research efforts.”).

145. OIG GLOBALIZATION REPORT, *supra* note 29, at 3. Countries party to this conference include the United States, Japan, and the European Union. *Id.*

146. *Id.*

147. *Id.*

148. William Dubois, *New Drug Research, the Extraterritorial Application of FDA Regulations and the Need for International Cooperation*, 36 VAND. J. TRANSNAT'L L. 161, 205 (2003) (proposing “unilateral extraterritorial action by the United States or European Union”).

149. *Id.*

150. Cultural Relativism is “[a]nthropological perspective that withholds condemnation of ‘cultural practices’ of communities not ones’s own.” Leti Volpp, *(Mis)Identifying Culture: Asian Women and the “Cultural Defense”*, 17 HARV. WOMEN’S L.J. 57, 83 (1994).

151. See Dubois, *supra* note 148, at 206–07. “Corporations are not currently treated as legal entities under international human rights law.” *Id.* at 203.

### *F. Proposed Legislative Solution*

Given the difficulties with international cooperation, a voluntary plaintiffs' forum in the United States, under the ATS, for example, would be the ideal enforcement mechanism for accepted international ethical guidelines. Because circuit courts and the Supreme Court have limited the scope of what constitutes international law under the ATS, it may be necessary for Congress to give legislative guidance regarding what was intended to be considered international law under the ATS.<sup>152</sup> Congress could choose to recognize ICCPR or the Nuremberg Code, two widely accepted standards in international law, to create a right of action under the ATS. By doing so, Congress could limit the effect of the ATS to situations where it felt judicial interference was necessary; therefore courts would not be faced with the issue of whether to interfere in foreign policy, a concern expressed in *Sosa*.<sup>153</sup>

Indeed, the DHHS and FDA regulations on the protection of human subjects in research make it clear that, according to U.S. policy, human subjects research done abroad should comport with domestic regulations. The difficulty is that such regulations only reach federally-funded research and research on drugs and devices regulated by the FDA. *Abdullahi* and its companion cases illustrate that even when drugs and devices are monitored by the FDA, FDA and DHHS guidelines are sometimes disregarded without repercussions in the drug approval process. A legislative solution strengthens the established U.S. position on the protection of human subjects in privately-funded research done abroad.

## V. CONCLUSION

Despite the overwhelming number of ethical guidelines for international medical research, especially as relating to developing countries, and a large body of scholarly literature on the subject,<sup>154</sup> there is little in the way of enforcement mechanisms outside of the host country. As previously discussed, developing countries may lack the infrastructure and regulatory ability to oversee medical research studies. Furthermore,

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152. See Virginia Monken Gomez, *The Sosa Standard: What Does it Mean for Future ATS Litigation*, 33 PEPP. L. REV. 469, 500 (2006) ("Unless Congress takes additional action, however, the scope of [the U.S. judiciary's] role under the auspices of the ATS is a narrow one [post-*Sosa*].").

153. See *supra* text accompanying note 125.

154. Indeed, not only are there many ethical guidelines on the subject, review of these guidelines reveals that the basic tenets of such guidelines are strikingly similar and not in dispute. See generally Page, *supra* note 39.

political pressures and the healthcare needs of the target population may influence governmental and judicial decision-making.

Ethical guidelines promulgated by ICH and the NBAC, as well as the WHO-CIOMS Guidelines and the Declaration of Helsinki, are all voluntary. International treaties such as ICCPR are not binding on countries that are not party to them. Furthermore, U.S. federal courts seem reluctant to acknowledge these documents as sources of cognizable international law for purposes of bringing a claim under the ATS. The *Zango*, *Adamu*, and *Abdullahi* cases illustrate the enforcement difficulties with such voluntary and treaty ethical guidelines.

While many corporations engaged in human subjects biomedical research will comply with such guidelines, there are huge financial incentives for not complying.<sup>155</sup> Furthermore, cultural views and images which may arguably commoditize or disembodify persons in developing countries reinforce notions that persons in developing nations are expendable.

Enforcement mechanisms are necessary outside of the host country in order to ensure that research is conducted ethically. Multinational regulation and enforcement is problematic because of the difficulty, expense, and cultural implications of policy development and enforcement mechanisms. Moreover, under international human rights law, corporate entities might fall outside the ambit of such a scheme.

Because of U.S. judicial reluctance to enforce the norms of ethical international biomedical human subject research, legislative intervention may be necessary to protect vulnerable populations. The legislature could remedy the impact of *Sosa* and similar circuit court decisions on claims brought under the ATS statute by clarifying what constitutes an acceptable form of international law under the ATS. In the context of international human subjects research, this could be accomplished either by acknowledging ICCPR as international law applicable to the United States or by acknowledging voluntary ethical guidelines as norms.<sup>156</sup> A legislative remedy of the ATS ensures that U.S. biomedical research corporations will be responsible for their actions and thus fulfill the basic functions of the U.S. tort system. Furthermore, this would not lead to

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155. See OIG GLOBALIZATION REPORT, *supra* note 29, at 13–14.

156. In fact, U.S. courts have incorporated international law in domestic cases involving biomedical human subject research. See, e.g., *Grimes v. Kennedy Krieger Inst., Inc.* 782 A.2d 807, 835 (Md. 2001) (applying the Nuremberg Code in a case of non-therapeutic experimentation absent informed consent stating that “the Nuremberg Code . . . was the result of legal thought and legal principles, as opposed to medical or scientific principles, and thus should be the preferred standard for assessing the legality of scientific research on human subjects”).

resentment by underdeveloped nations because their citizens would be able to choose whether or not to take advantage of this remedy.<sup>157</sup> In the age of globalization, “[b]arring the courthouse door is not a feasible strategy.”<sup>158</sup> We cannot allow U.S. pharmaceutical corporations to do overseas with impunity what they would not be permitted to do within our own borders.

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157. Schrage, *supra* note 138, at 164 (“The Alien Tort Statute should be an effective tool to support development of the rule of law. The threat of civil liability in the United States encourages improvements in the administration of justice and meaningful relief for victims of abuse in developing countries, since such relief would reduce the likelihood that U.S. courts will accept jurisdiction in the first place.”).

158. *Id.* (arguing that the sustained growth of the U.S. economy stems in part from the global confidence in the U.S. judiciary).

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