"Geographical Morality" Revisited: International Relations, International Law, and the Controversy over Placebo-Controlled HIV Clinical Trials in Developing Countries

David P. Fidler

Indiana University Maurer School of Law, dfidler@indiana.edu

Follow this and additional works at: http://www.repository.law.indiana.edu/facpub

Part of the Health Law and Policy Commons, International Law Commons, and the International Public Health Commons

Recommended Citation

Fidler, David P., "Geographical Morality" Revisited: International Relations, International Law, and the Controversy over Placebo-Controlled HIV Clinical Trials in Developing Countries" (2001). Articles by Maurer Faculty. Paper 434.
http://www.repository.law.indiana.edu/facpub/434

This Article is brought to you for free and open access by the Faculty Scholarship at Digital Repository @ Maurer Law. It has been accepted for inclusion in Articles by Maurer Faculty by an authorized administrator of Digital Repository @ Maurer Law. For more information, please contact wattn@indiana.edu.
"Geographical Morality" Revisited: International Relations, International Law, and the Controversy over Placebo-Controlled HIV Clinical Trials in Developing Countries

David P. Fidler*

I. INTRODUCTION

Since the early 1980s, the human immunodeficiency virus (HIV) and the acquired immunodeficiency syndrome (AIDS) have wreaked enormous damage on humanity.\(^1\) Table 1 below provides a statistical summary of the enormous scale of the HIV/AIDS pandemic in the period from 1998 to 2000. No abatement of the horror of HIV/AIDS is on the horizon.\(^2\) HIV/AIDS initially gained attention as an epidemic in developed countries, but today 95% of existing cases are located in developing countries.\(^3\) Sub-Saharan Africa has been the most severely affected region in the world,\(^4\) but

---

* Professor of Law, Indiana University School of Law—Bloomington; M.Phil., University of Oxford, 1988; J.D., Harvard Law School, 1991; B.C.L., University of Oxford, 1991. I would like to thank Leslie E. Schafer for her research assistance during the preparation of this Article. I owe Mary Ann Torres a debt of gratitude in connection with this Article. I also thank my colleagues Roger Dworkin and Susan Williams for sharing their thoughts with me on aspects of this analysis.


2. See id. (arguing that "unless action against the epidemic is scaled up drastically, the damage already done will seem minor compared with what lies ahead").


experts fear the further spread of HIV/AIDS in the huge populations of India and China.\(^5\)


<table>
<thead>
<tr>
<th>Category</th>
<th>1998</th>
<th>1999</th>
<th>2000</th>
</tr>
</thead>
<tbody>
<tr>
<td>New HIV infections</td>
<td>5.8 million</td>
<td>5.4 million</td>
<td>5.3 million</td>
</tr>
<tr>
<td>People living with HIV/AIDS</td>
<td>33.4 million</td>
<td>34.3 million</td>
<td>36.1 million</td>
</tr>
<tr>
<td>Deaths from AIDS</td>
<td>2.5 million</td>
<td>2.8 million</td>
<td>3.0 million</td>
</tr>
<tr>
<td>Total AIDS deaths since beginning of pandemic</td>
<td>13.9 million</td>
<td>18.8 million</td>
<td>21.8 million</td>
</tr>
</tbody>
</table>

Although HIV/AIDS is gaining prominence on the agendas of international organizations\(^7\) and the great powers of the international system,\(^8\) the developing-country context of the pandemic creates significant problems in international relations.\(^9\) One of the most acrimonious conflicts concerns the

\(^5\) See generally UNAIDS, REPORT ON THE GLOBAL HIV/AIDS EPIDEMIC: JUNE 2000, supra note 1, at 12 ("China and India between them account for around 36% of the world's population. With such huge populations, even low HIV prevalence rates mean that huge numbers of people live with the virus.").

\(^6\) The data used to construct this table were taken from UNAIDS, AIDS EPIDEMIC UPDATE: DECEMBER 1998, supra note 3, at 1; UNAIDS, REPORT ON THE GLOBAL HIV/AIDS EPIDEMIC: JUNE 2000, supra note 1, at 6; UNAIDS, AIDS EPIDEMIC UPDATE: DECEMBER 2000, supra note 4, at 3.


\(^9\) For many, HIV/AIDS has become not only a global health problem, but also an economic development crisis because of the socio-economic impact HIV/AIDS is having in developing countries, especially those in sub-Saharan Africa. In February 2001, the UN Secretary-General argued that [a]cquired immunodeficiency syndrome (AIDS) has become a major development crisis. . . . In the hardest hit regions, AIDS is now reversing decades of development . . . . By eventually impairing economic growth, the epidemic has an impact on investment, trade and national security, leading to
lack of affordable access to effective HIV therapies in developing countries. Antiretroviral therapies, such as zidovudine (AZT) and protease inhibitors, have allowed persons with HIV living in developed countries to avoid acquiring AIDS and live longer lives, but the therapies are expensive even in affluent countries and have been unaffordable to most individuals suffering from HIV/AIDS in developing countries.

Three strategies have emerged to address the problem that HIV therapies are not affordable in developing countries. The first involves Western pharmaceutical companies reducing prices on HIV therapies to help make developing-country access more realistic. The second strategy is for governments in developing countries to use compulsory licenses to allow cheaper production of HIV therapies in their jurisdictions. The third strategy is to develop HIV vaccines and new HIV therapies and therapy regimens that are less expensive and easier to implement than existing treatments. This third strategy is still more widespread and extreme poverty. In short, AIDS has become a major challenge for human security.

Report of the Secretary-General, supra note 7, at 4, 6.

10. See UNAIDS, REPORT ON THE GLOBAL HIV/AIDS EPIDEMIC: JUNE 2000, supra note 1, at 99 (noting that the cost of drugs is one underlying reason for the poor access in developing countries).


12 Hope, ECONOMIST, June 29, 1996, at 84 (noting that new HIV therapy regimens cost between $10,000 and $12,000 annually and arguing that "[a]t this price it will be of precious little use to more than 90% of those people infected with the virus—the ones who live in poor countries").

13 UNAIDS, REPORT ON THE GLOBAL HIV/AIDS EPIDEMIC: JUNE 2000, supra note 1, at 100 (discussing price reductions for antiretroviral drugs for use in developing countries); UNAIDS, ACCELERATING ACCESS TO HIV CARE. SUPPORT AND TREATMENT NEWS BULLETIN NUMBER 2, FEB. 20, 2001, http://www.unaids.org/acc_access/acc_care_support/news_bulletin2.html (visited Mar. 15, 2001) (noting that tiered pricing of HIV-related medicines where pharmaceutical companies make such medicines available to developing countries at highly reduced prices constitutes one strategy to increase access, and reporting on agreements reached between Rwanda, Senegal, and Uganda to buy HIV therapies at significantly reduced prices from pharmaceutical companies).

14. UNAIDS, REPORT ON THE GLOBAL HIV/AIDS EPIDEMIC: JUNE 2000, supra note 1, at 102-03 (discussing compulsory licensing in connection with HIV/AIDS drugs); Tina Rosenberg, LOOK AT BRAZIL, N.Y. TIMES, Jan. 28, 2001 (magazine), at F26 (reporting on Brazil's successful use of compulsory licensing in producing cheap generic HIV therapies and distributing them freely and widely to Brazilians living with HIV); Donald G. McNeil, Jr., INDIAN COMPANY OFFERS TO SUPPLY AIDS DRUGS AT LOW COST IN AFRICA, N.Y. TIMES, FEB. 7, 2001, at A1 (reporting on Indian pharmaceutical company's offer to sell HIV therapies at a price far below that offered by Western pharmaceutical companies); Press Release, Médecins Sans Frontières, AIDS TRIPLE THERAPY FOR LESS THAN $1 A DAY—MSF CHALLENGES PHARMACEUTICAL INDUSTRY TO MATCH GENERIC PRICES, FEB. 7, 2001, http://www.accessmed.msf.org (visited Mar. 15, 2001) (encouraging developing countries to "take full advantage of their rights to produce or import generic AIDS drugs under the [World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)]").

15 On therapies, see Peter Lurie & Sidney M. Wolfe, UNETHICAL TRIALS OF INTERVENTIONS TO REDUCE PERINATAL TRANSMISSION OF THE HUMAN IMMUNODEFICIENCY VIRUS IN DEVELOPING COUNTRIES, 337 NEW ENG. J. MED. 853, 853 (1997) (noting the need for less expensive HIV therapies in both developing and developed countries). On vaccines, see INTERNATIONAL AIDS VACCINE INITIATIVE, THE WORLD NEEDS AN AIDS VACCINE, http://WWW.IAVI.ORG/VACCINE_Z_WORLD.HTML (visited Mar. 3, 2001): Prevention programs—including education, condom and clean needle distribution and peer counseling—have slowed the spread of HIV, but have not stopped it. Treatment advances have yielded
strategy requires researchers to conduct clinical trials to test the efficacy of vaccines, new drugs, or new drug regimens. Developing countries have been and will continue to be an attractive venue for such clinical trial research.

Each of these strategies has proven controversial. The reduction of prices by Western pharmaceutical companies has not significantly improved access to HIV therapies in developing countries. The attempted use of compulsory licenses by governments in developing countries sparked conflict between such governments, Western pharmaceutical companies, and the United States. The conduct of HIV/AIDS clinical trial research in developing countries is more readily available, side effects and increased rates of viral resistance have raised concerns about their long-term use. *Only an AIDS vaccine can end the HIV/AIDS pandemic.*

16. UNAIDS, *REPORT ON THE GLOBAL HIV/AIDS EPIDEMIC: JUNE 2000, supra* note 1, at 103 (noting that "pharmaceutical companies have not yet decreased their prices enough to make their products affordable to the majority of people in developing countries"). In May 2000, five major pharmaceutical companies signed a Joint Statement of Intent with the United Nations pledging to sell HIV therapies at lower cost to developing countries. Michael Waldolz, *Into Africa: Makers of AIDS Drugs Agree to Slash Prices for Developing World, WALL ST. J.,* May 11, 2000 at A1. The drug prices under this agreement would still not be affordable for most populations in Africa. *Id.* In April 2001, UN Secretary-General Kofi Annan announced a new agreement with six major pharmaceutical companies under which the companies agreed to continue cutting the prices of HIV/AIDS drugs for developing nations. *Companies Promise More AIDS-Related Drug Price Cuts For Poor, REUTERS MEDICAL NEWS, Apr. 5, 2001,* http://www.medscape.com/ reuters/prof/20010405/06120010405publ006.html (visited Apr. 20, 2001). Under the new agreement, the pharmaceutical companies will offer HIV/AIDS drugs to the least developed countries as a group and continue to reduce prices for other developing countries on a country-by-country basis. *Id. See also* Press Release, UNAIDS, Statement by the UN Secretary-General After Meeting the Leaders of Six Leading Research-Based Pharmaceutical Companies (Apr. 5, 2001), http://www.unaids.org/whatsnew/press/eng/pressarc01/lSgstate_050401.html (visited Apr. 22, 2001). Pricing of HIV/AIDS drugs also featured prominently at an April 2001 conference of experts jointly sponsored by the World Trade Organization (WTO) and the World Health Organization (WHO) on access to essential drugs at which consensus emerged for "differential pricing" as a means of achieving greater access for developing countries. *See* Press Release, WTO, Experts: Affordable Medicines for Poor Countries Feasible, WTO Doc. Press/220 (Apr. 11, 2001), http://www.wto.org/english/news/el_press/01/elpr220_e.htm (visited Apr. 22, 2001). The lawsuit by thirty-nine pharmaceutical companies against South Africa in South African courts challenging legislation that contains the power to use compulsory licensing and parallel importing to increase access to essential drugs has, however, caused intense and acrimonious controversy in the area of increasing access to HIV/AIDS drugs. *See, e.g.,* Press Release, Médecins Sans Frontières/Oxfam, 39 Drug Companies versus South Africa: People Die for Lack of Affordable Drugs as Inhumane Industry Ignores Reality (Mar. 5, 2001), http://www.accessmed-msf.org/msf/accessmed/accessmed2.nsf/46c19fd02103f27e1c256871005db296/ff3addbbaed1d35d41256a050039eb90?OpenDocument (visited Apr. 22, 2001) (calling the lawsuit by the pharmaceutical companies "one of the most stark acts of corporate inhumanity"). On April 19, 2001, the thirty-nine pharmaceutical companies dropped their lawsuit against South Africa. Non-governmental organizations that had been criticizing the pharmaceutical companies claimed that global public opinion had forced the companies to drop the suit. *See* Press Release, Médecins Sans Frontières/Oxfam/Treatment Action Group, Drug Companies in South Africa Capitulate Under Barrage of Public Pressure: Powerful Precedent Set for Other Developing Countries (Apr. 19, 2001), http://www.accessmed-msf.org/msf/accessmed/accessmed2.nsf/46c19fd02103f27e1c256871005db296/dbf999938e5bc118c1256a33004467f890?OpenDocument (visited Apr. 22, 2001) ("In response to resounding global denunciation of their lawsuit, 39 drug companies today unconditionally dropped the path they pursued for three years against the South African government. The end of the lawsuit clears the path for the 1997 Medicines Act to go into force, allowing importation of affordable medicines and increased use of quality generic drugs.").

17. The United States has been engaged in a series of disputes with developing countries over increasing access to drugs through compulsory licensing and parallel importing. Details of the disputes can
oping countries by researchers from developed countries has brought forth charges of unethical behavior on the part of, and exploitation by, Western researchers.\textsuperscript{18} This Article focuses on these provocative ethical charges.

Part II describes the HIV clinical trials that triggered one of the most acrimonious controversies in the history of clinical research ethics.\textsuperscript{19} The clinical trials in question sought to ascertain whether a short-course regimen of AZT would reduce perinatal, or mother-to-child, transmission of HIV.\textsuperscript{20} Previous research showed that a longer-course AZT regimen reduced perinatal HIV transmission rates, but such a long-course AZT treatment was unaffordable and impractical to implement in most developing countries.\textsuperscript{21} Western researchers, funded by developed-country governments, designed the perinatal HIV transmission clinical trials to test the short-course AZT regimen against a placebo, which meant that some of the research subjects received the short course of AZT while the rest received no therapy at all.\textsuperscript{22} Critics attacked the use of the placebo in the clinical trials as unethical.\textsuperscript{23} A significant feature of the criticism was the accusation that the researchers and their sponsoring governments adopted an ethical "double standard": the use of the placebo in such a clinical trial would never have been allowed in a developed country because of ethical principles.\textsuperscript{24}

Critics of the placebo-controlled clinical trials often employ the language of human rights to attack the ethics of the trials.\textsuperscript{25} The use of human rights concepts and arguments brings international law into the debate. The controversy has, to date, not involved much input from international lawyers.\textsuperscript{26}

\textsuperscript{18} See Lurie & Wolfe, supra note 15, at 853 (articulating the most famous accusation that certain HIV clinical trials were unethical).

\textsuperscript{19} See Douglas P. Lackey, \textit{Clinical Trials in Developing Countries: A Review of the Moral Issues}, 68 \textit{MOUNT SINAI J. MED.} 4, 4 (2001) (noting that Lurie and Wolfe's accusations in the \textit{New England Journal of Medicine} in September 1997 "exploded like a bombshell over the medical ethics community. Not since Henry Beecher's assault in 1966 on the ethics of clinical research scientists had such accusations been hurled about on those cream-colored pages" (footnote omitted)).

\textsuperscript{20} See infra Part II.A.

\textsuperscript{21} See id.

\textsuperscript{22} See id.

\textsuperscript{23} See infra Part II.B.

\textsuperscript{24} See id.


\textsuperscript{26} Lawyers have been a part of the discourse. George J. Annas, who is a professor of health law, has been prominent in the debate. See Annas & Grodin, supra note 25, at 560. In addition, Global Lawyers and Physicians, a non-governmental organization that promotes the health-related provisions of the Universal Declaration of Human Rights, joined Public Citizen in attacking the placebo-controlled trials. Id. This controversy has not, however, attracted much attention in the mainstream community of inter-
This Article analyzes the ethical controversy over the placebo-controlled trials through the lens of international law, adding a new dimension to the developing discourse on this important global issue.

Two central ethical questions emerge from the controversy over the placebo-controlled clinical trials. The first question is whether ethical research practices (1) require an international standard of care that applies universally to all countries and peoples; or (2) allow clinical trial design and implementation to take into account the local standards of care. The second question is whether clinical trials conducted in developing countries involve exploitation when the fruits of such trials are unlikely to benefit the people in those countries in the short- or long-term. Critics of the placebo-controlled trials have argued that the trials were unethical because they violated the human rights of pregnant women who participated in the trials and the children born to them. A deeper human rights claim is implicit in these arguments because international ethical guidelines, such as the Nuremberg Code, the Declaration of Helsinki, and the Guidelines of the Council for International Organizations of Medical Sciences (“CIOMS Guidelines”) rest on a foundation of respect for fundamental human rights.

national law. For an exception, see Jonathan Todres, Can Research Subjects of Clinical Trials in Developing Countries Sue Physician-Investigators for Human Rights Violations?, 16 N.Y.L. SCH. J. HUM. RTS. 737 (2000) (analyzing whether the research subjects of the placebo-controlled clinical trials can sue the researchers in U.S. courts under the Alien Tort Claims Act for violations of international law).

27. See Lurie & Wolfe, supra note 15, at 855 (raising the issue of double standards and arguing that “it is time to develop standards of research that preclude the kinds of double standards evident in these trials”).

28. See Annas & Grodin, supra note 25, at 561 (“The central issue involved in doing research with impoverished populations is exploitation.”).

29. Letter from Peter Lurie, Research Associate, Public Citizen; Sidney M. Wolfe, Director, Public Citizen's Health Research Group; George Annas, Professor of Health Law, Boston University School of Public Health, Co-founder, Global Lawyers and Physicians: Working Together for Human Rights [hereinafter Global Lawyers & Physicians]; Michael A. Grodin, Professor of Medical Ethics, Boston University School of Public Health, Co-founder, Global Lawyers & Physicians; and George Silver, Emeritus Professor of Medicine, Yale University School of Medicine, to Donna Shalala, Secretary of the U.S. Department of Health and Human Services (Apr. 22, 1997), http://www.citizen.org/hrg/publications/1415.htm (visited Mar. 15, 2001) [hereinafter Letter to Secretary Shalala] (arguing that because of the placebo-controlled trials “1,504 infants... can be expected to die unnecessarily in these experiments”); Lurie & Wolfe, supra note 15, at 853 (arguing that HIV-positive pregnant women participating in the placebo-controlled trials were denied treatment available to HIV-pregnant women in clinical trials in developed countries); Annas & Grodin, supra note 25, at 560 (stressing the application of the Universal Declaration of Human Rights to HIV-transmission prevention trials in Africa).


32. COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES, INTERNATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS (1993) [hereinafter CIOMS Guidelines].

33. See Jonathan Mann, Medicine and Public Health, Ethics and Human Rights, 27 HASTINGS CENTER REP. 6, 10 (1997) (arguing that "rather than seeing human rights and ethics as conflicting domains, it
These two ethical arguments raise interesting questions for an international lawyer. If the placebo-controlled trials violated human rights, then exactly what rights were violated, and how were they violated? Does international law recognize a human right to receive the best care available anywhere in the world when a person participates in a clinical trial? Does international law require governments sponsoring international clinical trials to make successful drugs and vaccines available at affordable prices in countries in which the clinical research takes place? Answering these questions involves analysis of relevant human rights as they are embedded in international law. While this analysis is legal in orientation, it bears on and informs the ethical debate.

Ethical concerns about exploitation and international versus local standards of behavior are familiar to those who study international relations and international law. In fact, these ethical issues connect with long-standing controversies in international relations and international legal theory. Different approaches to explaining international relations and international law take distinct and sometimes antithetical positions on the role and importance of ethics and law in international politics and economics. While this larger realm may seem distant from ethical arguments about the placebo-controlled trials, it is important because how we view international ethical standards and international law flows from how we perceive the nature of international relations. The relevance of international relations theory can be seen in the arguments of some experts that the furor over the placebo-controlled trials underscores the fundamental injustice of the world political and economic order. Behind the scientific, medical, public health, ethical, and international legal discourses on the placebo-controlled trials are disagreements about how power is distributed, regulated, and exercised in international relations.

This analysis proceeds in three parts. Part III looks at the problem of ethical "double standards" and the exploitation they foster from the perspective of international relations theory. It frames the international relations analysis around Edmund Burke's attack on the concept of "geographical morality"—
the idea that moral standards vary in different geographical regions of the world. Burke confronted the "geographical morality" problem in his efforts to improve British imperial practices in India, but his analysis of this problem sets up broader debates in international relations theory about the role of ethics and international law. The ethical debate about the placebo-controlled trials assumes that ethics are important in the conduct of international relations. An international legal analysis of the placebo-controlled trials likewise assumes that international law is important in international relations. Part III's analysis demonstrates that both of those assumptions are controversial in international relations theory. Understanding these controversies in the study of international relations helps put the ethical and international legal aspects of the debate over the placebo-controlled trials into theoretical perspective.

Part IV analyzes whether the placebo-controlled trials violated international human rights law. The analysis covers both civil and political human rights and economic, social, and cultural rights, and concludes that the placebo-controlled trials did not involve violations of international human rights law. In addition, the analysis suggests that international human rights law does not presently condemn ethical double standards in contexts such as the placebo-controlled trials. Moreover, in the area of economic, social, and cultural rights, the international legal principles work against the establishment of universally applicable standards.

Part V concludes by reflecting on the implications of the analysis in Parts III and IV for the ethical dispute over the placebo-controlled trials. It sketches out three different paths for dealing with the ethical problems created by the placebo-controlled trials and the importance of the international legal analysis for choosing a path to take.

II. THE CONTROVERSY OVER THE PLACEBO-CONTROLLED HIV CLINICAL TRIALS

A. Background Information on the Placebo-Controlled HIV Trials

The clinical trials at the center of the ethical storm that emerged in September 1997 represented attempts by researchers and governments in developed and developing countries to find a more affordable and practical way to administer AZT to pregnant women living with HIV in developing countries in order to reduce perinatal HIV transmission. With millions of HIV-infected women in developing countries giving birth every year, reducing perinatal HIV transmission became an important public health goal in the fight to control the HIV/AIDS pandemic. UNAIDS reported in June 2000

---

36. See infra Part III.A.
37. See infra Part III.B.
38. See UNAIDS, REPORT ON THE GLOBAL HIV/AIDS EPIDEMIC: JUNE 2000, infra note 1, at 81 (reporting that the vast majority of the 3.8 million children who have died of AIDS before their fifteenth
that "[t]he developing world, and especially sub-Saharan Africa, stands to gain even more from large-scale programmes for reducing mother-to-child transmission because women [in developing countries] have more children and have far higher rates of HIV infection."

Prior research demonstrated that an AZT therapy regime known as the "076 regimen" reduced rates of HIV transmission from infected, pregnant women to their infants. The 076 regimen involved treating HIV-infected pregnant women with AZT for up to twenty-six weeks during pregnancy and during labor and childbirth. The 076 regimen also involved providing infants of HIV-positive mothers with AZT for six weeks after birth. While the 076 regimen proved effective in clinical trials in reducing perinatal HIV transmission, the length and intensity of the regimen were beyond the financial and public health capabilities of many developing countries.

HIV/AIDS researchers in the United States and Europe designed clinical trials to take place in developing countries to test the efficacy of less expensive and complex interventions, such as a short-course use of AZT, in reducing perinatal transmission of HIV. In these clinical trials, researchers gave one group of HIV-positive pregnant women a shortened course of AZT that covered the last month of pregnancy and the process of childbirth. The researchers gave a second group of HIV-positive pregnant women placebos or no therapy at all. The results from the women receiving the short-course AZT regimen were evaluated against the control group of women receiving placebos to determine how effective the short-course AZT regimen was in reducing perinatal HIV transmission.

The United States sponsored nine such placebo-controlled clinical trials, and six more were sponsored by France (two studies), Belgium, Denmark, South Africa, and UNAIDS. Côte d'Ivoire, Uganda, Tanzania, South Af-

birthday and of the 1.3 million children who are currently living with HIV "were born to HIV-infected mothers: they acquired the virus in the womb, around the time of childbirth or during breastfeeding").

39 Id.

40. This regimen takes its name from Pediatric AIDS Clinical Trials Group (ACTG) Protocol 076 Study, which was the first clinical trial to show the effectiveness of an AZT regimen in reducing perinatal HIV transmission. See Edward M. Connor et al., Reduction of Maternal-Infant Transmission of Human Immunodeficiency Virus Type 1 with Zidovudine Treatment, 331 NEW ENG. J. MED. 1173 (1994).

41. Id. at 1175 (reporting that the women in the clinical trial testing the 076 regimen received the AZT regimen for a median of eleven weeks, with zero to twenty-six weeks being the range of treatment).

42. Id. at 1174 (reporting that infants were given AZT orally every six hours for six weeks).

43. Id. at 1178 ("Our study indicates that substantial reduction in the rate of maternal-infant transmission of HIV is possible [with the 076 regimen of AZT] with minimal short-term toxicity to mother or child.").

44. See UNAIDS, REPORT ON THE GLOBAL HIV/AIDS PANDEMIC: JUNE 2000, supra note 1, at 81 (noting that "the drug regimens used in high-income countries for reducing HIV transmission to infants are too expensive and complicated to be practical for wide-scale use in poor countries"); Lurie & Wolfe, supra note 15, at 853 (noting that "the potential of the ACTG 076 regimen remains unrealized primarily because of the drug's exorbitant cost in most countries").

45. See Lurie & Wolfe, supra note 15, at 853.

46. Todres, supra note 26, at 738.

47. Id.

48. See Letter to Secretary Shalala, supra note 29.
rica, Malawi, Thailand, Ethiopia, Burkina Faso, Zimbabwe, Kenya, and the
Dominican Republic hosted the placebo-controlled trials.\(^{49}\) Scientists and
physicians from the host countries also participated in the research con-
ducted in the placebo-controlled trials.\(^{50}\) Both the sponsoring and host
countries reviewed the research protocols for the placebo-controlled trials for
scientific validity and conformity with prevailing ethical standards on con-
ducting medical research on human subjects.\(^{51}\)

**B. An Ethical Controversy Erupts Concerning the Placebo-Controlled Trials**

In September 1997, Peter Lurie and Sidney Wolfe of the advocacy group
Public Citizen criticized these placebo-controlled clinical trials as unethical
and exploitative.\(^{52}\) Lurie and Wolfe argued that giving the women in the
control group placebos rather than the 076 regimen was unethical because it
denied these women the standard of care available to clinical trial partici-
pants in developed countries.\(^{53}\) The World Medical Association's Declaration
of Helsinki (1996)—one of the most important documents guiding the
ethics of biomedical research—provided in 1996 that "[i]n any medical
study, every patient—including those of a control group, if any—should be
assured of the best proven diagnostic and therapeutic method."\(^{54}\) In the case
of perinatal transmission of HIV, the 076 regimen of AZT was the best-
proven therapeutic method. Lurie and Wolfe argued that, if the clinical tri-
als in question had taken place in a developed country, the control group
would have received AZT antiretroviral treatment and not placebos since
giving placebos would have, without question, been considered unethical
because it denied the women the best available standard of care.\(^{55}\) The
researchers running the placebo-controlled trials had, in short, created a
double ethical standard for clinical trial research: a higher ethical standard for

---

49. Lurie & Wolfe, supra note 15, at 853.
50. See Harold Varmus & David Satcher, Ethical Complexities of Conducting Research in Developing Coun-
51. See id.
52. Lurie & Wolfe, supra note 15, at 853. One of the editors of the New England Journal of Medicine
supported the accusations of Lurie and Wolfe. See Marcia Angell, The Ethics of Clinical Research in the Third
World, 337 NEW ENG. J. MED. 847 (1997); Marcia Angell et al., AIDS Studies Violate Helsinki Rights
Accord, N.Y. TIMES, Sept. 24, 1997, at A26. Lurie and Wolfe have been the leading critics of the placebo-
controlled trials, and this Article focuses on their sustained campaign to expose the unethical nature of
the trials and to encourage the adoption of a universal standard that would ensure all subjects of medical
research the highest standard of care available. Lurie and Wolfe's efforts triggered an international con-
troversy that is reflected not only in the many other sources cited in this Article but also in the revision of
important international documents on the ethics of scientific research involving human subjects. See infra
text accompanying notes 63–72.
55. Lurie & Wolfe, supra note 15, at 853 (noting that in "two studies being performed in the United
States, the patients in all the study groups have unrestricted access to zidovudine or other antiretroviral
drugs"); Letter to Secretary Shalala, supra note 29 ("In essence, the U.S.-funded researchers are conducting
experiments abroad that would never pass ethical muster in the U.S.").
people in developed countries and a lower ethical standard for people in developing countries.56

The directors of the U.S. National Institutes of Health (NIH) and Centers for Disease Control and Prevention (CDC), Harold Varmus and David Satcher, responded to Lurie and Wolfe's attack by defending the placebo-controlled trials.57 They argued that Lurie and Wolfe offered a simplistic perspective on conducting clinical trials in developing countries because "they have not adequately considered the purpose and complexity of such trials and the needs of the countries involved."58 Varmus and Satcher claimed that "[t]he most compelling reason to use a placebo-controlled study is that it provides definitive answers to questions about the safety and value of an intervention in the setting in which the study is performed, and these answers are the point of the research."59 In other words, the ethics of the placebo-controlled trials has to be evaluated with local conditions in mind, including local standards of therapeutic care. Important to the NIH and CDC directors was the 1994 recommendation by an international panel convened by the World Health Organization that "placebo-controlled trials offer the best option for obtaining rapid and scientifically valid results."60 Varmus and Satcher pointed out both the difficulty and exorbitant cost of the 076 regimen in most developing countries, suggesting that ethical evaluation of the trials has to take into consideration the differences in public health and health care resources between developed and developing countries.61 The directors of the agencies also pointed to the support and approval the placebo-controlled trials received from local physicians, researchers, and government officials in the developing countries involved.62

56 Lurie & Wolfe, supra note 15, at 855 ("Acceptance of a standard of care that does not conform to the standard in the sponsoring country results in a double standard in research."); Letter to Secretary Shalala, supra note 29 ("For your department to maintain a double standard in which it funds studies that on the one hand routinely provide life-saving drugs to Americans, while on the other deny these drugs to thousands of citizens of developing countries, conveys to the international community the impression that the U.S. government places less value on the lives of non-Americans.").


58. Varmus & Satcher, supra note 50, at 1003.

59. Id. at 1004 (emphasis added).


61. Varmus & Satcher, supra note 50, at 1004; see also WHO Panel Recommendations, supra note 60 (stressing the ethical importance of local standards of care in the argument that in the developing world "the choice of placebo for the control group of a randomized trial would be appropriate as there is currently no effective alternative for HIV-infected pregnant women").

62. Varmus & Satcher, supra note 50, at 1005.
The battle between opponents and defenders of the ethics of placebo-controlled trials continued as the World Medical Association and the Council for International Organizations of Medical Sciences (CIOMS) began revisions of their respective guidelines and principles on the ethics of biomedical research. In addition, the controversy over the placebo-controlled trials also affected the drafting by UNAIDS of its Guidance Document on Ethical Considerations in HIV Preventive Vaccine Research, eventually published in May 2000 ("UNAIDS Guidance Document").

In connection with the proposed revisions in March 1999 to the Declaration of Helsinki (1996) by the World Medical Association, Lurie and Wolfe expressed alarm at the draft amendments and attacked, among other proposed modifications, changes to Principle II.3 of the declaration that would add the phrase "that would otherwise be available to him or her" to the duty to give research subjects "the best proven diagnostic and therapeutic method." Lurie and Wolfe referred to this proposed change as an "insidious assault on the rights of participants in research" that will condemn "most residents in developing countries to potentially receiving second-rate medical care when they participate in experiments." They also criticized the proposed draft for greatly expanding the potential use of placebos in clinical trials. Public Citizen complained that similar changes were being considered in revision of the CIOMS Guidelines and the proposed UNAIDS guidance document for HIV vaccine trials. Wolfe argued that "[t]hese changes would formalize double standards based on economics, convenience and efficiency that should be anathema to any physician or patient."

In connection with the drafting of the UNAIDS Guidance Document, Lurie and Wolfe criticized the proposed document in January 1999 for, among other things, proposing the standard of "highest attainable therapeu-

---

63. See Declaration of Helsinki (1996), supra note 31; CIOMS GUIDELINES, supra note 32.
67. Id.
tic method," which opens the door for lower standards of care to be justified by the local conditions in developing countries.\textsuperscript{70} Lurie and Wolfe asserted that the UNAIDS Guidance Document was being used "as a stalking horse for revisions of the CIOMS document and the Declaration of Helsinki."\textsuperscript{71}

The final revised versions of the Declaration of Helsinki and the UNAIDS Guidance Document have not calmed down the ethical storm Lurie and Wolfe created with their accusations. The World Medical Association adopted an amended version of the Declaration of Helsinki in October 2000.\textsuperscript{72} Principle 29 of the Declaration of Helsinki (2000) states that "[t]he benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods."\textsuperscript{73} Principle 30 provides that "[a]t the conclusion of the study, every patient entered in the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study."\textsuperscript{74} Under Principle 29, the placebo-controlled trials Lurie and Wolfe attacked would be unethical because the short-course AZT regimen was tested against placebos, not against the 076 regimen. After earlier drafts of the revised Declaration contained language that would have upheld the ethical basis for the placebo-controlled trials, the World Medical Association moved in the final version toward the universal standard of care principle advocated by Lurie and Wolfe.\textsuperscript{75}

UNAIDS published its final version of its Guidance Document on Ethical Considerations in HIV Preventive Vaccine Research in May 2000.\textsuperscript{76} Guidance Principle 16 of this document addresses the standard of care issue at the heart of the dispute of the placebo-controlled trials.\textsuperscript{77} UNAIDS concluded that "[a]t present, there is no universal consensus regarding the level of care and treatment that should be provided."\textsuperscript{78} UNAIDS argued that its consultations and deliberations produced three different ethical positions. Care and

\textsuperscript{70} Letter to Esparza, \textit{supra} note 68. For a defense of the "highest attainable standard of care" principle, see Levine, \textit{supra} note 35, at 533. Levine has played an important role in revising the Declaration of Helsinki, CIOMS Guidelines, and the UNAIDS Guidance Document. \textit{See} Public Citizen Press Release Aug 1999, \textit{supra} note 68 (asserting that "[a]ll three of these documents have been written primarily by Dr. Levine").

\textsuperscript{71} Letter to Esparza, \textit{supra} note 68.


\textsuperscript{73} \textit{Id.} princ. 29.

\textsuperscript{74} \textit{Id.} princ. 30.

\textsuperscript{75} Lurie and Wolfe noted how the World Medical Association had considered revising the Declaration of Helsinki to allow for an ethical double standard but had ultimately rejected the double standard for a universal standard based on the best proven level of care and treatment. \textit{See} Letter from Peter Lurie \& Sidney M. Wolfe, Public Citizen, to Harold T. Shapiro, Chairman, National Bioethics Advisory Committee (Nov. 13, 2000), \textit{http://www.citizen.org/hrp/publications/1545.htm} (visited Mar. 15, 2001) [hereinafter Letter to Shapiro].

\textsuperscript{76} \textit{UNAIDS, ETHICAL CONSIDERATIONS IN HIV PREVENTIVE VACCINE RESEARCH, supra} note 64.

\textsuperscript{77} \textit{Id.} at 41.

\textsuperscript{78} \textit{Id.}
treatment for those who become infected should be provided (1) at the level of care offered in the country sponsoring the vaccine research; (2) at the level determined by the country hosting the vaccine research; or (3) at the level that is consistent with the care available in the host country.\textsuperscript{79} Guidance Principle 16 takes a procedural approach to setting the standard of care and treatment. It sets the ideal standard as the “best proven therapy” and the minimum standard of “the highest level of care attainable in the host country.”\textsuperscript{80} Guidance Principle 16 then provides that a comprehensive care package should be agreed upon by consensus through a dialogue involving the sponsor country, host country, and community representatives taking into account a number of factors.\textsuperscript{81} UNAIDS’ procedural approach to the standard of care clearly rejects the adoption of a universal standard to be applied in all clinical trials wherever conducted.

The controversy Lurie and Wolfe started has provoked much sound and fury within the scientific, medical, and public health communities.\textsuperscript{82} As the divergent paths taken by the World Medical Association and UNAIDS in their respective positions on the ethical issue at the heart of the placebo-controlled trials dispute reveal, consensus on the proper ethical approach has not been reached. Lurie, Wolfe, and their allies continue to push the universal standard of care position in their evaluation of the work of ethical bodies considering the issue. Lurie and Wolfe have criticized the ongoing work of the U.S. government’s National Bioethics Advisory Commission (NBAC) in the preparation of a report on “Ethical and Policy Issues in International Research.”\textsuperscript{83} They have argued that the NBAC is backing ethical standards of care and treatment lower than those supported by the Declaration of Helsinki (2000).\textsuperscript{84} In addition, Lurie, Wolfe, and five colleagues condemned the NBAC’s November 2000 revision of its September 2000 draft report to drop the requirement of review of U.S. government-funded research in developing countries by a U.S. institutional review board.\textsuperscript{85} “The onus of partici-

\textsuperscript{79}. Id. at 41–42.
\textsuperscript{80}. Id. at 41.
\textsuperscript{81}. Id. The factors are (1) level of care and treatment available in the sponsor country; (2) highest level of care available in the host country; (3) highest level of treatment available in the host country; (4) availability of infrastructure to provide care and treatment in the context of research; and (5) potential duration and sustainability of care and treatment for the trial participant. Id.
\textsuperscript{82}. Levine, supra note 35, at 532 (noting that the debate over the ethical justification for the placebo-controlled trials triggered “the most acrimonious controversy over the ethics of clinical trials in recent memory”); Lackey, supra note 19, at 4 (noting how Lurie and Wolfe’s accusations “exploded like a bombshell over the medical ethics community”).
\textsuperscript{83}. The most recent draft of the National Bioethics Advisory Commission’s report on Ethical and Policy Issues in International Research, dated September 29, 2000, can be found at http://bioethics.gov/toc.html (visited Mar. 15, 2001).
\textsuperscript{84}. Letter to Shapiro, supra note 75 (arguing that the NBAC draft report falls short of the Declaration of Helsinki’s ethical standards on what researchers are required to provide research subjects).
\textsuperscript{85}. Letter from Peter Lurie, Deputy Director, Public Citizen’s Health Research Group; George Annas, Professor of Health Law, Boston University School of Public Health, Co-founder, Global Lawyers & Physicians; Troyen A. Brennan, Chairperson, Human Subjects Committee, Harvard School of Public Health; Arthur Caplan, Director, Center for Bioethics, University of Pennsylvania; Dirceu Greco, Profes-
pant protection in such studies," the letter argued, "could be shifted from the U.S. to the developing world, where the ethical review infrastructure . . . is often grossly inadequate."\(^{86}\) The resulting situation would not, of course, support the adoption of a universal standard of care and treatment for clinical research conducted in developing countries.\(^{87}\) Such an approach signals a move towards an ethical double standard in connection with medical research undertaken in developing countries by researchers from high-income countries. The different approaches taken or considered by the World Medical Association, UNAIDS, CIOMS, and the NBAC suggest that the ethical dispute triggered by Lurie and Wolfe continues to rage nationally and internationally.

## III. The Problem of Geographical Morality in International Relations Theory

### A. Edmund Burke and the Problem of Geographical Morality

The ethical conflict embodied in the placebo-controlled trials raises important questions within the larger context of international relations: How do we morally and legally evaluate the behavior of the citizens of one country that takes place inside the territory of another country when the two countries have different political, economic, cultural, religious, and historical heritages? How do we factor into this evaluation significant inequalities in political and economic power and wealth between the two countries? These questions are old ones in the study of international relations.

One of the earliest and most interesting attempts to come to grips with these questions came from the eighteenth-century British statesman-philosopher Edmund Burke in connection with his efforts to change British imperial policy in India. In the course of his parliamentary career, Burke became a fierce opponent of British imperial behavior in India, symbolized most dramatically in his attempt to impeach Warren Hastings, governor-general of Bengal, for high crimes and misdemeanors for the manner in which Hastings ran the East India Company.\(^{88}\)
The development of the British empire in India confronted Burke and his contemporaries with political, economic, legal, and moral questions generated by contact between a surging European great power and a weaker non-European country. Burke argued that British imperial behavior in India had degenerated into immoral and illegal exploitation of the Indian peoples. Burke believed that Hastings and the other employees of the East India Company had engaged in arbitrary, despotic acts that destroyed indigenous Indian politics, economics, and culture. Hastings argued in his defense that he merely acted as oriental princes behaved in India and that he should be judged according to the local standards of political behavior, not those applicable in Great Britain. Burke rejected Hastings's defense, claiming that Hastings was bound to run the East India Company on British principles and according to the "one, great, immutable, pre-existent law, prior to all devices, and prior to all our contrivances, paramount to our very being itself, by which we are knit and connected in the eternal frame of the universe, out of which we cannot stir." Burke argued that Hastings had formulated:

a plan of Geographical morality, by which the duties of men in public and in private situations are not to be governed by their relations to the Great Governor of the Universe, or by their relations to men, but by climates, degrees of longitude and latitude, parallels not of life but of latitudes. As if, when you have crossed the equinoctial line all virtues die, . . . and commence a new order and system of things.

---


89. Burke served on a parliamentary select committee that investigated between 1781 and 1783 the abuses committed by the British East India Company in India. See Fidler & Welsh, supra note 88, at 22. In the Ninth Report of the Select Committee, which Burke wrote, the Committee comprehensively analyzed "the Principles of Policy, and the Course of Conduct, by which the Natives of all Ranks and Orders have been reduced to their present State of Depression and Misery." Ninth Report of the Select Committee, in V THE WRITINGS AND SPEECHES OF EDMUND BURKE 194, 197 (P.J. Marshall ed., 1981).

90. Speech on Fox's India Bill, in V THE WRITINGS AND SPEECHES OF EDMUND BURKE, supra note 89, at 378, 402 (arguing that "there is nothing before the eyes of the natives but an endless, hopeless prospect of new flights of birds of prey and passage, with appetites continually renewing for a food that is continually wasting").

91. Speech on Opening the Impeachment, in VI THE WRITINGS AND SPEECHES OF EDMUND BURKE 264, 348-49 (P.J. Marshall, ed., 1991) (quoting Hastings defending his actions by stating that "[t]he whole history of Asia is nothing more than precedents to prove the invariable exercise of arbitrary power").

92. Id. at 349-50 ("You have heard his lecture upon arbitrary power . . . . Do your Lordships really think that the nation would bear, that any human creature would bear, to hear an English Governor defend himself upon such principles? . . . Here he has declared his opinion that he is a despotic prince, that he is to use arbitrary power, and of course all his acts are covered with that shield . . . . Will your Lordships ever hear the corrupt practices of mankind made the principles of Government?").

93. Id. at 350.
This Geographical morality we do protest against. . . .

Burke wanted to know exactly what the officers of the East India Company were providing the natives of India:

What are the articles of commerce, or the branches of manufacture which those gentlemen [of the East India Company] have carried hence to enrich India? What are the sciences they beamed out to enlighten it? What are the arts they introduced to cheer and adorn it? What are the religious, what the moral institutions they have taught among that people as a guide to life, or as a consolation when life is to be no more . . .

To Burke, Hastings's arguments were little more than a poor excuse for British exploitation of India. Hastings's position also involved notions of British and European superiority over Indian civilization, which represented a cultural chauvinism that Burke rejected. Burke realized that Hastings's "plan of Geographical morality" would appeal to members of parliament, and he chastised them for not giving proper attention and concern to the poor, unfortunate inhabitants of India who were victims of British exploitation perpetuated through behavior based on a double standard. "[T]he cries of India," argued Burke, "are given to seas and winds, to be blown about, in every breaking up of the monsoon, over a remote and unhearing ocean."

The Burke-Hastings conflict is important because in it we see the basic features of the ethical controversy surrounding the placebo-controlled trials. Critics of these trials argue that the "local standard of care" defense of the trials is unethical and disguises the exploitation of poor countries by powerful countries. Allowing local public health and health care conditions to affect the ethical analysis means that moral judgments are driven by geographical parameters. In other words, the placebo-controlled trials revealed a contemporary "plan of Geographical morality" at work in the world of international clinical trials.

94 Id. at 346.
96. Speech on Opening the Impeachment, supra note 91, at 361 ("I assert that their [the Indians'] morality is equal to ours as regards the morality of Governors, fathers, superiors; and I challenge the world to shew, in any modern European book, more true morality and wisdom than is to be found in the writings of Asiatic men in high trusts, and who have been Counsellors to Princes."); Speech on Fox's India Bill, supra note 90, at 389 ("This multitude of men [the Indians] does not consist of an abject and barbarous populace; much less gangs of savages . . .; but a people for ages civilized and cultivated; cultivated by all the arts of polished life, whilst we were yet in the woods.").
97. Speech on Fox's India Bill, supra note 90, at 381 (Burke attacking his fellow members of parliament for "the total silence of these gentlemen concerning the interest and well-being of the people of India").
98. Id. at 403.
This analogy is not intended to suggest that the U.S. National Institutes of Health, U.S. Centers for Disease Control and Prevention, and the researchers they sponsored acted in arbitrary and despotic ways like the officers of the East India Company. Instead, it highlights the basic features of the placebo-controlled trials controversy, the complexities of which will be examined below. In addition, the "plan of Geographical morality" Burke criticized represents in microcosm a larger controversy in international relations theory about the role of ethics and international law in international politics. This larger controversy is also important in examining the ethical debate over the placebo-controlled trials.

B. Ethics, International Law, and International Relations

The role of ethics and international law in international relations has been the subject of much debate in international relations theory. A simple, but still helpful, approach to this controversy is to look at the importance given to ethics and international law in Martin Wight's three traditions of international theory: realism, rationalism, and revolutionism.100

1. Realism

Realism holds that morality has no place in the relations among states,101 If ethics has a role in human life, that role is at the personal level rather than the political level.102 The anarchical nature and dynamics of the international system force moral considerations to retreat to the private realm, where they become unimportant for explaining the behavior of states in the international system.

If states use the language of ethics in their relations with other states, such language is merely a diplomatic ploy that no statesperson takes seriously.103 Thucydides famously captured this attitude in the Melian Dialogue when the Athenian envoys, who are denied access to speak to the people of Melos, encourage the Melian leaders to drop all pretenses of justice and morality in their discussions with the Athenians.104 E.H. Carr, a twentieth-
The accumula-
tion, maintenance, and exercise of power are what the statesperson seeks.105 As the twentieth-century realist Hans Morgenthau argued, “statesmen think and act in terms of interest defined as power.”106 Similarly, international law is merely another tool in the game of power politics.108 As Jean-Jacques Rousseau grimly put it, “justice and truth must be bent to serve the most powerful; that is the rule.”109 Whether individuals rely on ethical principles in conducting transnational activities is of no concern to the realist, whose analytical focus remains fixed on the state and its behavior in the game of power.

2. Rationalism

Rationalism holds that states can find ways to structure their relations to avoid simply engaging in a perpetual and violent power struggle.110 Rationalists do not deny that the anarchical nature of inter-state relations creates a difficult milieu for co-existence and cooperation, but they believe that states can agree on certain common interests and values that support more orderly and peaceful international relations.111 This position creates more potential for ethical considerations and international law to play a role in international politics.112

105 Carr, supra note 101, at 79-80 (“Theories of international morality are ... the product of dominant nations or groups of nations ... For the past hundred years, ... the English-speaking peoples have formed the dominant group in the world; and current theories of international morality have been designed to perpetuate their supremacy ...”).


108. Scott Burchill, Realism and Neo-Realism, in THEORIES OF INTERNATIONAL RELATIONS 67, 80 (S. Burchill et al. eds., 1996) (noting that in realism “[i]nternational law was regarded sceptically, particu-
larly if states believed that it infringed on their capacity to pursue their national interests”); Wight, supra note 100, at 235 (arguing that under realism “international law operates in the domain of subsidi-
ary importance”).


110 Wight, supra note 100, at 13 (arguing that rationalists “are those who concentrate on, and be-
lieve in the value of, the element of international intercourse in a condition predominantly of interna-
tional anarchy”); Andrew Linklater, Rationalism, in THEORIES OF INTERNATIONAL RELATIONS, supra note 108 at 93, 94 (arguing that “rationalism begins with anarchy but unlike realism it acknowledges that the sense of belonging to the community of humankind has left its civilizing mark upon the state and interna-
tional relations”).

111. Wight, supra note 100, at 39 (characterizing rationalism as believing in the existence of an in-
ternational society that involves the use of international law); Linklater, supra note 110, at 100 (arguing that “rationalism considers the processes by which systems of states are transformed into international societies and focuses upon the normative and institutional expressions of society between states”).

112. See Wight, supra note 100, at 238, 241–44 (discussing rationalist perspectives on international legal obligations and international ethics); Robert H. Jackson, The Political Theory of International Society, in INTERNATIONAL RELATIONS THEORY TODAY 110, 114 (Ken Booth & Steve Smith eds., 1995) (noting the importance of international law to rationalism); Linklater, supra note 110, at 100–04 (noting the importance of questions of justice and morality to rationalism).
In connection with ethics, rationalism exhibits two different strands of thought: pluralism and solidarism.\textsuperscript{113} Pluralism acknowledges that states have different domestic political, economic, and cultural systems but holds that even diverse states can, at the international level, form a society with moral and legal rules.\textsuperscript{114} The morality is, however, a morality of states, not of domestic political systems or individuals.\textsuperscript{115} The diversity within states makes it difficult, if not impossible, to project moral principles applicable domestically to governments and individuals onto states and their political and economic interactions. The basis of inter-state morality is the practices of states in their systemic interactions rather than \textit{a priori} principles or natural law.\textsuperscript{116} Similarly, the rules of international law in a pluralistic vision of international society flow from the patterns of state behavior, not from abstract moral principles. This rationalistic idea can be seen in Article 38(1) of the Statute of the International Court of Justice, which lists the major sources of international law, all of which derive from actual state practice and state consent, and not natural law thinking.\textsuperscript{117}

Solidarism holds that the society of states rests upon a foundation of political, economic, and social like-mindedness within states.\textsuperscript{118} International society and international law are weak under pluralism, and only similitude domestically among states provides a strong foundation for a role for morality and international law in international relations.\textsuperscript{119} Domestic political, economic, and cultural homogeneity means that states share important values, principles, and interests and will be able to use this homogeneity as a basis for more effective cooperation. Solidarism creates the conditions neces-

\textsuperscript{113} Fidler & Welsh, \textit{supra} note 88, at 52 (noting that in the international society tradition of international relations thinking, pluralist and solidarist approaches can be discerned); Linklater, \textit{supra} note 110, at 100 (noting how rationalism distinguishes between pluralistic and solidaristic international societies).

\textsuperscript{114} Fidler & Welsh, \textit{supra} note 88, at 52. For more on pluralism, see Andrew Hurrell, \textit{Vattel: Pluralism and Its Limits, in Classical Theories of International Relations} 233 (Ian Clark & Iver B. Neumann eds., 1996).

\textsuperscript{115} Fidler & Welsh, \textit{supra} note 88, at 52; Linklater, \textit{supra} note 110, at 100 (noting that "[a]ccording to the pluralist perspective . . ., the members of that [international] society are states rather than individuals").

\textsuperscript{116} Wight, \textit{supra} note 100, at 39 (noting that rationalists see international society as a customary society—a society built out of the shared customs and practices of states).

\textsuperscript{117} See Statute of the International Court of Justice, June 26, 1945, art. 38(1), 59 Stat. 1055.

\textsuperscript{118} Fidler & Welsh, \textit{supra} note 88, at 52–53 (discussing the solidaristic perspective).

\textsuperscript{119} Edmund Burke expressed this idea when he wrote that

\begin{quote}
[w]e lay too much weight upon the formality of treaties and compacts . . . . Men are not tied to one another by papers and seals. They are led to associate by resemblances, by conformities, by sympathies. It is with nations as with individuals. Nothing is so strong a tie of amity between nation and nation as correspondence in laws, customs, manners, and habits of life. They have more than the force of treaties in themselves. They are obligations written in the heart.
\end{quote}

sary to facilitate an important international role for ethical and international legal principles for both states and individuals.\(^{120}\)

While solidarism offers a stronger foundation for ethics and international law than pluralism, rationalism's goal is, at best, the approximation of moral standards rather than their complete fulfillment.\(^{121}\) The anarchical environment of international politics makes more than the approximation of ethical principles difficult, even in the case of like-minded states. In addition, pluralism and solidarism can simultaneously exist in the international system as some states will exhibit homogeneity while others do not. Ethical conundrums arise when states and individuals from the solidaristic core engage with states and peoples outside the core.\(^{122}\) Even in situations where the ethical and legal principles of the core are applied to or accepted by the periphery, socio-economic problems in the periphery complicate full application of the core's principles. This problem is at the heart of the controversy over the placebo-controlled trials because the poor economic and health conditions in developing countries complicate the application of ethical standards primarily established by and used in developed countries.

3. Revolutionism

One of the characteristic features of revolutionism as a theory of international relations is the belief in the moral unity of humanity.\(^{123}\) It is, thus, the opposite of realism's amorality.\(^{124}\) The limited state morality of pluralistic rationalism underemphasizes, in revolutionism's view, the underlying moral unity of humankind.\(^{125}\) Pluralistic international law embodies principles of behavior that reinforce divisions in humanity rather than build unity across borders.\(^{126}\) Revolutionism is closest in outlook to solidaristic rationalism,

---

\(^{120}\) Hedley Bull, *The Grotian Conception of International Society*, in *Diplomatic Investigations: Essays in the Theory of International Politics* 52, 64 (Herbert Butterfield & Martin Wight eds., 1966) (arguing that solidarity in international society involves not only states but also assumes "that individual human beings are subjects of international law and members of international society in their own right").

\(^{121}\) WIGHT, supra note 100, at 243 ("Ideals are never realized, but should be striven for; the fundamentals wherein we believe will not be carried out, but it is necessary to affirm them: here is the moral tension within which Rationalist statecraft is conducted"); Linklater, supra note 110, at 101 (stressing how rationalism represents a middle way between the pessimism of realism and the optimism of cosmopolitanism).

\(^{122}\) Fidler & Welsh, supra note 88, at 53 (discussing how solidarism raises questions about intercourse between different cultures).

\(^{123}\) WIGHT, supra note 100, at 40–41 (arguing that a characteristic of revolutionism is its conception of the world as a single society, *a civitas maxima*).

\(^{124}\) Id. at 40 (noting how revolutionism differs from realism in its conception of a unified humanity); Jackson, supra note 112, at 114 (noting that "[r]evolutionism assumes a world society in which states, while present, nevertheless are subject to certain moral obligations to human beings, who in some fundamental respects are prior to them").

\(^{125}\) WIGHT, supra note 100, at 40 (noting how revolutionism differs from rationalism in its conception of a unified humanity); Jackson, supra note 112, at 114 (contrasting rationalism's concern with orderly intercourse between states and revolutionism's concern with the unity of humankind).

\(^{126}\) This sentiment is apparent in Immanuel Kant's description of Grotius, Puffendorf, and Vattel as
but revolutionism is more radical because it postulates a universal moral unity without the cultural and socio-economic boundaries implicit in solidaristic rationalism.

Revolutionism advocates that political action has to be directed toward the achievement of political, economic, and cultural moral unity of humanity.127 This moral unity, in short, becomes the lodestar for national, transnational, and international action. Revolutionism frowns upon compromising moral objectives in the face of difficult political and economic conditions. Different strands of revolutionism take divergent positions on international law. Revolutionism à la Kantian liberalism attempts to harness international law by transforming it into a progressive tool for building perpetual peace.128 Revolutionism à la Marxism has no progressive role for international law because such law represents the very system that has to be destroyed to achieve human unity.129

4. The Three Traditions, the Geographical Morality Problem, and the Placebo-Controlled Trials

Realism, rationalism, and revolutionism take different positions in connection with the problem of "geographical morality." Revolutionism is hostile toward notions of geographical morality in ethics or international law because of its fundamental attachment to the moral unity of humanity. Any plan of geographical morality is an attack on this moral unity and must be opposed.

Pluralistic rationalism opens space for the concept of geographical morality because it recognizes that states often have different political, economic, and cultural systems that are not assimilated in any common ideology or shared moral code. In a pluralistic framework, international law reflects the diversity of states by not requiring governments and individuals to follow rules based on one particular ethical system. Morality is, by definition, geographical under pluralistic rationalism.

Solidaristic pluralism reduces the space for geographical morality because states within the solidaristic core share ethical codes nationally and internationally. Under solidarism, the common ethical principles of the core influence the substance of international law as the states in the solidaristic

---

127. WIGHT, supra note 100, at 41–48 (discussing strands of revolutionism that seek to unify humankind in different ways).
128. See KANT, supra note 126, at 81–86 (explaining the second definitive article of the conditions for perpetual peace, which involves the transformation of the law of nations). For more on Kant's international thinking, see Howard Williams & Ken Booth, Kant: Theorist Beyond Limits, in CLASSICAL THEORIES OF INTERNATIONAL RELATIONS, supra note 114, at 71.
129. See V. KUBÁĽKOVÁ & A.A. CRUCKSHANK, MARXISM AND INTERNATIONAL RELATIONS 17–18 (1985) (listing the essential features of the Marxist tradition, including the proposition that "[t]he substance of international relations . . . is inter-class relations").
core translate shared moral understandings into binding international legal commitments. The problem of geographical morality largely disappears in the moral and legal homogeneity characterizing state relations in the core. Geographical morality remains a problem for solidaristic rationalism in connection with relations between the states in the solidaristic core and states not integrated into the political, economic, and cultural heritage shared by states in the core.

The ethical controversy over the placebo-controlled trials looks like a debate between a perspective that echoes revolutionism and one that is suggestive of solidaristic rationalism. Those critical of the placebo-controlled trials apply a universal ethical framework that insists that a research subject in a clinical trial in a developing country receive exactly the same treatment as one in a developed country. Explicit in this universalist position is the belief in the moral unity of humankind and that this unity should guide action related to the conduct of clinical trials. In other words, human rights are universal; and compromising a poor person’s rights for scientific utility or reasons related to the different socio-economic context of poor countries is ethically illegitimate.

Defenders of the placebo-controlled trials sound like solidaristic rationalists influenced by liberalism. First, the defenders believe in a shared ethical code for conducting clinical trials; the defenders of the placebo-controlled trials have not rejected international ethical codes such as the Nuremberg Code and the Declaration of Helsinki but are interpreting these ethical principles differently from the opponents of the trials. The ethical framework in the Nuremberg Code and the Declaration of Helsinki comes out of liberal political thinking because respect for individual rights is central to the entire framework. Liberalism is the philosophical foundation of solidaristic rationalism in contemporary international relations because liberalism has become the dominant political philosophy in world affairs.

Second, the defenders of the placebo-controlled trials are willing to compromise on the application of the framework in socio-economic contexts radically different from those in the states in the solidaristic core. Echoing rationalism, the defenders of the placebo-controlled trials seek to approximate ethical objectives in activities outside the core rather than dogmatically insisting on the complete fulfillment of every ethical rule applied

130. See Annas & Grodin, supra note 25, at 561 (arguing that human rights are universal and that appeals by Varmus and Satcher to the support of local African researchers for the placebo-controlled trials “implies support for an outdated and dangerous view of cultural relativism”).

131. David P. Fidler, Caught Between Traditions: The Security Council in Philosophical Conundrum, 17 MICH. J. INT’L L. 411, 413 (1996) (“Liberalism refers to a body of thought the core of which is the liberty of the individual . . . . Liberalism posits . . . that international relations is not fundamentally about obtaining power as a shield against anarchy but is about protecting individual liberty at home while fostering individual liberty overseas.”).

132. See, e.g., Francis Fukuyama, The End of History?, THE NATIONAL INTEREST, Summer 1989, at 3 (“The triumph of the West, of the Western idea, is evident . . . in the total exhaustion of viable systematic alternatives to Western liberalism.”).
Geographical morality is not an abandonment of ethics but a practical application of an ethical code in socio-economic conditions alien to the states of the solidaristic core.

While revolutionism and rationalism are relevant perspectives on morality in connection with the placebo-controlled trials controversy, realism appears at first glance unhelpful. A realist would argue, however, that realism's perspective on morality in international relations remains relevant. Realism sees in both defenders and critics of the placebo-controlled trials different excuses for exploitation of the weak by the strong. Defenders of the placebo-controlled trials have difficulty countering the accusation that the therapy tested in the placebo-controlled trials would not have been affordable to people in developing countries. It is most likely that the trials will only provide benefits to developed countries; geographical morality presented as practical ethics in international relations therefore merely disguises an exploitative undertaking. Realists would not be squeamish about engaging in exploitation through clinical trials if such trials produced results that augment the power of the state sponsoring the research by providing it with cheaper HIV drugs.

Critics of the placebo-controlled trials also face a realist charge of exploitation in one of two forms. First, comparing the 076 regimen against a shorter course of AZT would also be exploitation because neither the 076 regimen nor the AZT short course would be affordable in developing countries. Second, refusing for ethical reasons to conduct either 076 regimen/short course AZT equivalency trials or placebo-controlled trials merely represents the exercise of scientific and technological power by rich states over weak states. The ethical discourse merely masks unconvincingly the true nature of the power politics taking place. The North's "ethical conscience" pretends to purity while people in the South continue to die from HIV/AIDS with no therapeutic drugs in sight to relieve individual suffering and societal devastation. Again, realists are unmoved by this suffering and

133. See, e.g., Bayer, supra note 35, at 570 (arguing that the dispute over the placebo-controlled trials is about how to apply agreed-upon principles to different social conditions); David B. Resnik, The Ethics of HIV Research in Developing Nations, 12 BIOETHICS 286 (1998) (arguing that standards of ethical research are universal but not absolute because the application of the standards must take into account factors inherent in particular situations); Robert Baker, A Theory of International Bioethics: The Negotiable and Non-Negotiable, 8 KENNEDY INST. OF ETHICS J. 233 (1998) (arguing that moral universalism collapses under multicultural and postmodernist critiques and that international ethical research standards can be grounded in a rationally negotiated moral order).

134. See, e.g., Annas & Grodin, supra note 25, at 561 (arguing that "[n]either NIH nor CDC (nor the host countries) has a plan that would make the interventions they are studying available in Africa, where more than two thirds of the people in the world reside who are infected with HIV").

135. Id. ("Unless the interventions being tested will actually be made available to the impoverished populations that are being used as research subjects, developed countries are simply exploiting them in order to quickly use the knowledge gained from the clinical trials for the developed countries' own benefit.").

136. Levine, supra note 35, at 533 (arguing that "[f]or several reasons, most of which are economic, the 076 regimen cannot be made available to residents of developing countries on a continuing basis").
devastation unless it factors into the power calculus of international relations. If the North discontinues such placebo-controlled trials, then the reason has to do with national interests of powerful states rather than universal ethical principles.

In sum, four distinct perspectives on the problem of geographical morality can be identified in international relations theory:

*Cynical.* For realism, there is no tactical or strategic difference between basing policy on universalism or a plan of geographical morality. Both are merely expedient justifications for states thinking and acting in terms of interest defined as power.

*Hostile.* Revolutionism is hostile toward any plan of geographical morality because universalism is at the heart of the revolutionist tradition.

*Complacent.* Pluralistic rationalism can be interpreted as being complacent about geographical morality because international morality (i.e., morality between states) and international law in this tradition do not concern themselves directly with this problem. Indeed, under pluralistic rationalism, no shared system of ethical and legal behavior unites all peoples and governments. While pluralism encourages the development of interstate morality, it does not seek to harmonize ethical and legal principles inside states.

*Concerned.* Solidaristic rationalism can be interpreted as exhibiting concern about the problem of geographical morality, but the concern neither rises to the level of hostility nor sinks to the depths of cynicism. Outside the solidaristic core, radically different socio-economic conditions affect how the ethical and legal principles shared by the core operate. As a pragmatic matter, "double standards" have to be tolerated to a certain degree. Such ethical pragmatism makes solidarists uneasy, and the long-term objective is to create the conditions that would allow the solidaristic core to expand and include areas now in the periphery.

**IV. THE PROBLEM OF GEOGRAPHICAL MORALITY IN INTERNATIONAL LAW**

The geographical morality problem also affects international law. The area in which this problem has most prominently appeared is in international human rights law. As shown by the analysis in Part III, only liberal solidaristic rationalism and liberal revolutionism support a vigorous concept of human rights in international law. Realism has little tolerance for the concept of human rights; and pluralistic rationalism could only, at best, support a minimalist international law on human rights. As Vincent argued, "because of their suspicion of each other, and their worries about the causes and effects of intervention, the members of international society are united

137 R.J. VINCENT, HUMAN RIGHTS AND INTERNATIONAL RELATIONS 121 (1980) (noting that, under realism, "the ascendency of this or that theory of rights is merely the manifestation in doctrine of an underlying political balance").

138 Id. at 113-18 (discussing the impact of pluralism on concepts of human rights).
by a principle of non-intervention which bears witness to their minimal solidarity: not the absence of morality but the recognition of its limits."

The geographical morality problem has also been manifest in international human law in the long-running debate between universalists and cultural relativists. Universalists hold that human rights embodied in international law universally apply to every human being no matter where he or she lives. Cultural relativists deny the universality of human rights and claim that much of international human rights law derives from a specific cultural and philosophical source.

The controversy over the placebo-controlled trials does not, however, involve a clash between universalism and cultural relativism. Both critics and defenders of the placebo-controlled trials believe in the universality of human rights. The critics of the placebo-controlled trials argue that the defenders of such research have violated human rights, yet refrain from accusations that the defenders do not believe in human rights. One can see in the defenders of the placebo-controlled trials a procedural and contextual approach to the universal application of human rights. The geographical morality problem in these circumstances is, thus, more complex than universalism v. cultural relativism. This complexity includes not only the relevance of solidaristic rationalism but also the actual content of international human rights law and its application to the placebo-controlled trials. This Part IV delves into the international human rights law implicated by the placebo-controlled trials.

A. The Relevance of International Law

International law on human rights recognizes two basic kinds of fundamental human rights: (1) civil and political rights; and (2) economic, social, and cultural rights. Civil and political rights include the right to...
2001 / Placebo-Controlled HIV Clinical Trials

life;\textsuperscript{145} the right not to be subject to torture or cruel, inhuman, or degrading treatment or punishment;\textsuperscript{146} the right to liberty and security of person;\textsuperscript{147} the right to liberty of movement;\textsuperscript{148} the right to a fair trial;\textsuperscript{149} and the right to freedom of expression.\textsuperscript{150} States must protect civil and political rights without discriminating on any grounds.\textsuperscript{151}

Economic, social, and cultural rights include the right to work;\textsuperscript{152} the right to form and join trade unions;\textsuperscript{153} the right to social security;\textsuperscript{154} the right to an adequate standard of living;\textsuperscript{155} the right to health;\textsuperscript{156} and the right to enjoy the benefit of scientific progress.\textsuperscript{157} States must not discriminate on any grounds in ensuring individuals their economic, social, and cultural rights.

This discussion of international law on human rights may strike the reader as odd given that the debate over the placebo-controlled trials has been conducted at the ethical rather than the legal level. What is the relevance of international law on human rights? First, one might argue that some of the rules in the ethical framework for research involving clinical trials have international legal status through treaty law or customary international law. For example, George Annas has argued that the Nuremberg Code is an international legal document.\textsuperscript{159} In addition, a fundamental rule of the Nuremberg Code—the right not to be subjected to medical or scientific experimentation without free consent—has appeared in human rights treaties, such as the International Covenant on Civil and Political Rights (ICCPR).\textsuperscript{160}

\textsuperscript{145} See ICCPR, supra note 143, art. 6(1).
\textsuperscript{146} See id. art. 7.
\textsuperscript{147} See id. art. 9(1).
\textsuperscript{148} See id. art. 12(1).
\textsuperscript{149} See id. art. 14.
\textsuperscript{150} See id. art. 19(2).
\textsuperscript{151} See id. art. 2(1).
\textsuperscript{152} See ICESCR, supra note 144, art. 6(1).
\textsuperscript{153} See id. art. 8(1).
\textsuperscript{154} See id. art. 9.
\textsuperscript{155} See id. art. 11(1).
\textsuperscript{156} See id. art. 12(1).
\textsuperscript{157} See id. art. 15(1)(b).
\textsuperscript{158} See id. art. 2(2).
\textsuperscript{159} George J. Annas, The Changing Landscape of Human Experimentation: Nuremberg, Helsinki, and Beyond, 2 HEALTH MATRIX 119, 121 (1992) (claiming that the Nuremberg Code is "the most authoritative legal and ethical document governing international research standards, and one of the premier human rights documents in world history").
\textsuperscript{160} ICCPR, supra note 143, art. 7. For analysis of ICCPR Article 7, see Todres, supra note 26, at 743–46. Part IV.C.2 infra discusses the relevance of the principle of free consent to the placebo-controlled trials.
Second, one might argue that the principles of the Nuremberg Code, Declaration of Helsinki, and CIOMS Guidelines have become customary international law binding on all states except persistent objectors. To become a rule 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, called opinio juris. Rules of customary international law are binding on all states except those that persistently object to the rule in question. Examination of the behavior of government funding of national and international clinical trials might reveal some general and consistent state practice supporting the basic principles of the Nuremberg Code, Declaration of Helsinki and CIOMS Guidelines. As the Nuffield Council on Bioethics indicated, the Declaration of Helsinki and CIOMS Guidelines "have no inherent legal authority but are referred to by many regulatory bodies involved in formulating ethical guidelines or regulations for biomedical research." Such an examination might also reveal evidence that the general and consistent state practice is supported by opinio juris.

Third, general principles of law recognized by civilized nations—a third primary source of international law—might support the incorporation of international ethical standards into international law because many national systems of law require satisfaction of ethical standards in connection with government-funded research. The ethical standards as embodied in domestic law may be seen as general principles of law that can be elevated to binding international law if their widespread adoption throughout the international system is shown.

Fourth, both international human rights law and ethical codes function to protect individuals, indicating that human rights law and the ethical codes

---

161. The most recent amendment of the Declaration of Helsinki (2000) complicates arguments that the principles in the Declaration represent customary international law. The debates over the ethics of the placebo-controlled trials used the Declaration of Helsinki (1996), supra note 31, not the Declaration of Helsinki (2000), supra note 72, as the point of reference. For this reason, this Article primarily uses the Declaration of Helsinki (1996) in the international legal analysis because the Declaration of Helsinki (2000) has not been in existence long enough to influence state practice significantly for purposes of customary international law analysis.


163. Id. at 10.


166. The author is not aware that such an examination has ever been undertaken for purposes of determining whether customary international law exists in this area. Such an examination would confront problems inherent in the methodology of locating a rule of customary international law. Evidence of opinio juris is, for example, hard to locate and interpret. See David P. Fidler, Challenging the Classical Concept of Custom: Perspectives on the Future of Customary International Law, 39 GERM. Y.B. INT'L L. 198, 204–08 (1996) (discussing problems inherent in the concept of opinio juris); J. Patrick Kelly, The Twilight of Customary International Law, 40 VA. J. INT'L L. 449, 469–75 (2000) (analyzing the methodological problem of determining opinio juris).

167. See ICJ Statute, supra note 117, art. 38(1)(c).

168. See, e.g., Protection of Human Subjects, supra note 164.
flow from a common value system that elevates the importance of the individual. Even if the ethical codes do not have international legal status, their close relation to international human rights law justifies an international legal analysis of the placebo-controlled trials.

B. Is the Ethical Standard of “Best Proven Diagnostic and Therapeutic Method” Part of International Law?

The first question is whether the ethical standard of providing every clinical trial patient with the “best proven diagnostic and therapeutic method,” as required by the Declaration of Helsinki, forms part of international law. No treaty embodies this principle. Whether this standard can be considered international law through customary international law or general principles of law is debatable. The controversy over placebo-controlled trials suggests that disagreement exists among different countries and experts about what this ethical standard means and requires from governments and researchers involved in clinical trials. As Salim Abdool Karim argues:

The reality is that standards—in this case, the standard of care—differ across the world and even within countries; they are seldom agreed upon internationally. Although the ACTG 076 regimen of therapy is the standard of care in some countries, it is not an international standard, such as is set by the World Health Organization.

As noted earlier, UNAIDS concluded in May 2000 that no consensus exists internationally to support a universal standard of care and treatment. These observations make the substance of the “best available standard of care” ambiguous at best. Even if one were to claim that “the best available standard of care” is a principle of customary international law binding on states, the ambiguity in the standard means that the placebo-controlled trials would not necessarily be in violation of international law.

Nor do the October 2000 amendments to the Declaration of Helsinki, the May 2000 publication of the UNAIDS Guidance Document, or the proposed revisions to the CIOMS Guidelines necessarily clarify the substance of any international legal standard requiring the best proven diagnostic and

---

169. See Declaration of Helsinki (2000), supra note 72, princ. 8 (“Medical research is subject to ethical standards that promote respect for all human beings and protect their health and rights.”).

170. Declaration of Helsinki (1996), supra note 31, at II.3; Declaration of Helsinki (2000), supra note 72, prncs. 29, 30 (ethical standard of providing “the best proven prophylactic, diagnostic or therapeutic method”).

171. This disagreement points to divergent state practice and opinio juris, undermining arguments that the “best proven diagnostic and therapeutic method” standard as interpreted by opponents of the placebo-controlled trials is a rule of customary international law.


173. UNAIDS, ETHICAL CONSIDERATIONS IN HIV PREVENTIVE VACCINE RESEARCH, supra note 64, at 41.
therapeutic method. The World Medical Association (WMA) controls the Declaration of Helsinki, and CIOMS administers the CIOMS Guidelines; the WMA and CIOMS are non-governmental organizations and not states or international organizations like UNAIDS. While the WMA's revision of the Declaration of Helsinki and CIOMS' revision of its guidelines will be influential, what will matter for purposes of international law is whether states follow or reject aspects of the revised documents. If the CIOMS revisions support the Declaration of Helsinki (2000) in adopting a universal standard of care, but governments in the developed and developing worlds opt for a local standard of care in sponsoring clinical trials, then state practice and international law will gravitate toward the local standard of care principle. A conflict between international ethical guidelines and international law would thus emerge.

C. Civil and Political Rights

The next question to consider in an international legal analysis of the ethical controversy surrounding the placebo-controlled trials is what kind of rights the controversy affects: civil and political rights, or economic, social and cultural rights? The ethical controversy over the placebo-controlled trials actually implicates both kinds of rights, and the controversy also raises the geographical morality problem in both sets of rights. This section analyzes civil and political rights, and Part IV.D below analyzes economic, social, and cultural rights.

The controversy surrounding the placebo-controlled trials implicates three civil and political rights in international law: (1) the right to life; (2) the right not to be subjected to medical or scientific experimentation without the person's free consent; and (3) the right not to be subjected to degrading treatment.¹⁷⁴

1. The Right to Life

Critics of the placebo-controlled trials have argued that the failure to use the 076 regimen resulted in foreseeable, preventable deaths of children born to the HIV-infected women. Lurie and Wolfe concluded their New England Journal of Medicine article by referring to "hundreds of infants who have needlessly contracted HIV infection in the perinatal-transmission studies that have already been completed."¹⁷⁵ In sponsoring clinical trials that used placebos rather than the 076 regimen, did the sponsoring and host govern-

¹⁷⁴ See Todres, supra note 26, at 742-55. While Todres analyzes the possibility that the placebo-controlled trials violate international law on medical experimentation, cruel or inhuman treatment, and gross violations of internationally recognized human rights, he does not analyze whether the placebo-controlled trials violate the international human right to life.

¹⁷⁵ Lurie & Wolfe, supra note 15, at 855.
ments arbitrarily deprive children of their lives in violation of the right to life under international law?

International human rights law states that every human being has the inherent right to life and that no one shall be arbitrarily deprived of his or her life. The governmental duty to protect life under international law contains both negative and positive obligations. On the negative side, the right to life, inter alia, disciplines a criminal justice system in how it applies the death penalty. The right to life is, thus, a restraint on government power in connection with persons arrested for criminal offenses. On the positive side, the right to life imposes on states two duties. First, states must prevent activities that result in arbitrary deaths, such as criminal acts. Second, states must take action to reduce or eliminate threats to human life, such as malnutrition and infectious diseases.

Concluding that the failure to use the 076 regimen or some other proven intervention in the placebo-controlled trials violates the right to life in international law is difficult for a number of reasons. The positive obligations that the right to life imposes on governments applies to the placebo-controlled trials. The right to life is applicable to clinical trial research because a government is responsible for making sure such research does not result in arbitrary deaths among the research subjects. A government that conducts or allows unregulated and dangerous clinical trials to cause arbitrary deaths would violate the right to life under international law.

Case law within the European Convention on Human Rights (ECHR) supports this conclusion. In Association X v. United Kingdom, the European Commission of Human Rights held that a government complies with its obligation to protect life under Article 2 of the ECHR if it establishes a control and supervision system over a voluntary vaccination program to reduce as much as possible the number of deaths that might occur. One may interpret this case to mean that failure to regulate, control, and supervise clinical trials to reduce the risks of research subjects would violate the right to life under Article 2 of the ECHR. The same reasoning could apply under Article 6 of the ICCPR and Article 6 of the United Nations Convention on the Rights of the Child.

176. See European Convention for the Protection of Human Rights and Fundamental Freedoms, Nov. 4, 1950, art. 2(1), 213 U.N.T.S. 221 ("Everyone's right to life shall be protected by law. No one shall be deprived of his life intentionally save in the execution of a sentence of a court following his conviction of a crime for which this penalty is provided by law."); ICCPR, supra note 143, art. 6(1) ("Every human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life."); United Nations Convention on the Rights of the Child, Nov. 20, 1989, art. 6(1), 28 I.L.M. 1456 (1989) ("States Parties recognize that every child has the inherent right to life.").


179. See id.

The placebo-controlled trials do not, however, fall into the category of unregulated or unsupervised clinical trials that caused arbitrary deaths. Both the sponsoring and host countries reviewed the trials thoroughly before they commenced. To the author’s knowledge, no one has criticized the sponsoring or host governments of neglecting to monitor and supervise the placebo-controlled trials. Furthermore, the trials themselves did not directly cause any deaths that have occurred or may occur in the future from perinatal HIV transmission, as HIV was already present in the pregnant women.

The most relevant category within the right to life is the governmental obligation to reduce or eliminate threats to human life. Were the sponsoring and host governments of the placebo-controlled trials under an international legal obligation to reduce the threat of perinatal HIV transmission through the use of the 076 regimen or another proven intervention rather than a placebo? An affirmative answer to this question would stress that (1) the governments in question knew the threat of perinatal HIV transmission was foreseeable, significant, and dangerous to the health of the child; and (2) researchers had available a regimen proved effective elsewhere in reducing such transmission. Under this argument, failure to require use of the 076 regimen would represent a violation of the right to life of the research subjects’ children.

Cases decided by national courts support this position. In the Venezuelan Supreme Court case, *In the Matter of Cruz Bermudez v. Ministerio de Sanidad y Asistencia Social (MSAS)*, Venezuelan citizens living with HIV claimed that the Venezuelan government violated, *inter alia*, their right to life guaranteed by the Venezuelan Constitution and international law by not providing them with HIV therapies. The Venezuelan Supreme Court agreed with the plaintiffs, holding that the Venezuelan government’s failure to provide HIV therapies to persons in Venezuela living with HIV violated such persons’ right to life. The Venezuelan Supreme Court wrote:

> The right to life is, in fact, a positive right and not a negative right, such as the right to liberty. It is, therefore, fundamental that the State has public health policies. In consequence, in this case, the obligations imposed on the public authority in matters of prevention and treatment of HIV/AIDS are fundamental.

---

181. Varmus & Satcher, *supra* note 50, at 1005 (arguing that “the NIH- and CDC-supported trials have undergone a rigorous process of ethical review, including not only the participation of the public health and scientific communities in the developing countries where the trials are being performed, but also the application of the U.S. rules for the protection of human research subjects by relevant institutional review boards in the United States and in the developing countries”).


The plaintiffs did not accuse the Venezuelan government of infecting them with HIV (at least not in the way that, for example, government negligence and inaction led to the infection of many hemophiliacs with HIV through transfusions of contaminated blood). The right-to-life claim involved governmental failure to provide an available therapy to persons living with HIV.

Access to HIV therapies was also at the center of a case brought against El Salvador before the Inter-American Commission for Human Rights (Inter-American Commission).184 Twenty-seven El Salvadoran citizens argued before the Inter-American Commission that the El Salvadoran government's refusal to supply them with HIV therapies violated their right to life and health under the Inter-American system of international human rights law.185 The Inter-American Commission granted precautionary measures in favor of the HIV-positive petitioners by ordering the El Salvadoran government to provide the petitioners with the HIV therapies and other medical treatment necessary to prevent their deaths.186 While not a final determination that El Salvador violated the right to life of the HIV-positive petitioners, the order for precautionary measures connected this international human right to the question of access to HIV therapies187

These national and international legal precedents suggest that the sponsoring and host governments involved in the placebo-controlled trials had a duty under the international human right to life to provide the 076 regimen to the research subjects in order to reduce the significant, foreseeable, and dangerous threat of perinatal HIV transmission.

(unfinished LL.M. Thesis, University of Toronto School of Law) (on file with author) discussing a Costa Rican Supreme Court case (William Garcia v. Caja de Salud, Sala Constitucional de la Corte Suprema de Justicia (Costa Rica), Sept. 23, 1997) in which the Court used, among other rights, the right to life in the Costa Rican Constitution as the basis for ordering the government to provide HIV-positive Costa Ricans with HIV therapies.

186 Inter-American Commission on Human Rights, Annual Report 1999, supra note 184, Article 25 of the Rules of Procedure of the Inter-American Commission deals with Precautionary Measures and provides that, "[I]n serious and urgent cases, and whenever necessary according to the information available, the Commission may, on its own initiative or at the request of a party, request that the State concerned adopt precautionary measures to prevent irreparable harm to persons." Rules of Procedure for the Inter-American Commissioner of Human Rights, art. 25(1), http://www.oas.org/ (visited Mar. 15, 2001).
187 As of November 2000, the El Salvadoran government had not complied with the precautionary order of the Inter-American Commission. See discussion of this case in Torres, supra note 183, at 177-79.
Interpreting the human right to life to require the sponsoring and host governments of the placebo-controlled trials to administer the 076 regimen is not, however, without problems. The first set of problems arises from the sources of international law. Under what source of international law were the sponsoring and host governments required to administer the 076 regimen in the placebo-controlled trials? If the source is a human rights treaty, such as the ICCPR or the African Charter on Human and Peoples’ Rights,\(^{188}\) then the obligation to administer the 076 regimen or some other proven intervention must be found either in the text of the treaties or in the subsequent practice of States Parties to the treaties. A specific duty to administer the 076 regimen or some other proven intervention as the best available treatment to subjects of a clinical trial does not appear in any human rights treaty protecting the right to life. Nor, to the author’s knowledge, has such a specific duty been produced by the subsequent practice of states under any human rights treaty. The positive obligations created by the right to life may make international human rights law relevant to the controversy over the placebo-controlled trials, but they do not definitively indicate that the sponsoring and host governments had an international legal duty to administer the 076 regimen to the research subjects.

If the source of the alleged obligation is customary international law, then there should be general and consistent state practice supported by *opinio juris*. The fact that the sponsoring and host governments involved in the placebo-controlled trials did not administer the 076 regimen suggests that neither general and consistent state practice nor *opinio juris* exists to support an international legal obligation always to apply the best available treatment to research subjects. This fact relates to the disagreements that exist among countries and experts about what the best available treatment standard requires ethically in clinical trials. As UNAIDS argued in its Guidance Document, “there is no universal consensus regarding the level of care and treatment that should be provided.”\(^{189}\)

The third primary source of international law, general principles of law recognized by civilized nations, also has relevance in this analysis. One could argue that international law imposes an obligation *via* the right to life to use the 076 regimen as the best available treatment in clinical trials concerning HIV perinatal transmission because that is the rule and practice in developed states. There is agreement that the 076 regimen would have been administered to research subjects if the perinatal HIV transmission clinical trials had taken place in the United States or Europe. As Ronald Bayer argued, “[t]here is no question that a placebo-controlled trial of efforts to reduce further vertical transmission in the wake of clinical trial 076 would be

---

189. UNAIDS, *ETHICAL CONSIDERATIONS IN HIV PREVENTIVE VACCINE RESEARCH*, supra note 64, at 41.
considered unethical in the United States or any advanced industrial nation."

Perhaps this fact indicates that there might be a general principle of law within many national legal systems that should be elevated to the realm of international law to regulate international clinical trials.

Problems beset this "general principle of law" argument as well. First, general principles of law are not frequently used as a source of international law, rendering this source suspect as a foundation for a principle supplementing the right to life. Second, while the practice in developed states may be to apply the best available treatment, the situation in developing countries is different. The developing country governments hosting the placebo-controlled trials did not require foreign and local researchers to apply the best available treatment as a matter of domestic law. Thus, "best available treatment," interpreted as what applies in developed countries, may not be a general principle of national law throughout the international system.

Third, it may not be true that "best available treatment" is mandated by national law in developed states. In the United States, for example, would a woman participating in trials equivalent to the placebo-controlled trials have a constitutional claim that her child's right to life had been violated by the researchers' failure to administer the 076 regimen? The answer to this question under U.S. constitutional jurisprudence is probably negative because there is no constitutional right to any kind of medical treatment. Assuming that this woman was randomly selected to receive placebo rather than the 076 regimen, then she probably would not be able to argue that her child's treatment constituted racial discrimination in violation of the Constitution. Since only women would be research subjects in clinical trials involving perinatal HIV transmission, gender discrimination is also not a foundation for a constitutional claim. As for potential claims under federal statutory law, federal law on the protection of human subjects does not expressly mandate a best available treatment standard.

The ECHR provides a good lens through which to evaluate whether European governments would require the best available treatment standard. It simply is not clear from Article 2 case law under the ECHR whether failure to administer the 076 regimen would violate the right to life in a European country party to this treaty. While the obligation under Article 2 of the ECHR requires governments "not only to refrain from taking life 'inten-

190 Bayer, supra note 35, at 568.
191 Brownlie, supra note 162, at 15–18.
192 Abdool Karim, supra note 172, at 565 (noting that standards of care "differ across the world and even within countries; they are seldom agreed upon internationally").
193 Where a special custodial or other relationship exists between an individual and the government, however, the government may have a duty to provide medical care. See, e.g., Estelle v. Gamble, 429 U.S. 97 (1976) (holding that denial of medical care to a prisoner constitutes cruel and unusual punishment in violation of the Eighth Amendment to the Constitution). See also Youngberg v. Romeo, 457 U.S. 307, 315 (1982) (holding, inter alia, that an involuntarily committed mental patient has a right to medical care under the Fourteenth Amendment Substantive Due Process Clause).
194 Protection of Human Subjects, supra note 168.
tionally' but, further, to take appropriate steps to safeguard life, the reach of this positive obligation to safeguard life has not been the subject of much litigation under the ECHR. An argument could be mounted that failure to administer the 076 regimen in a European-based perinatal HIV transmission clinical trial would violate the right to life in the ECHR, but at the moment it is not clear as a matter of international law among the States Parties to the ECHR whether it would actually be a violation of Article 2.

The second set of problems with arguing that the placebo-controlled trials violated the right to life under international law is ambiguity about the breadth of the positive obligations this right imposes on governments. Commentators have observed that giving the right to life positive obligations for governments to fulfill brings the right close to economic, social, and cultural rights, such as the right to health. As examined further below in Part IV. D, economic, social, and cultural rights are not absolute but are achieved progressively subject to the availability of resources. Fulfillment of the right to health therefore remains subject to the availability of sufficient economic and human resources. Does the principle of progressive realization affect the positive obligations of the right to life?

As a matter of treaty law, the right to life is not subject to the principle of progressive realization because this principle is not included in treaties protecting economic, social and cultural rights. Thus, a state cannot excuse its failure to fulfill the positive obligations of the right to life on the basis of insufficient economic and human resources. Leaving aside the treaty argument, the principle of progressive realization does not affect the positive obligations of the right to life in connection with the placebo-controlled trials because the sponsoring and host governments together had enough resources to provide the 076 regimen to the research subjects. Thus, lack of financial resources cannot be argued to excuse the sponsoring and host governments of their positive obligations under the right to life in connection with the clinical trials. Further, this conclusion does not necessarily imply that the sponsoring and host governments had a broader duty under the right to life to treat all HIV-infected mothers in the host countries with the 076 regimen as the analysis can be confined to the clinical trials.

A final analytical step involves considering whether one could argue that the sponsoring and host governments legitimately derogated from the right

195. Association X v. United Kingdom, supra note 180, at 32.
196. The Inter-American Commission on Human Rights' precautionary measures order against the government of El Salvador in February 2000, see supra notes 184–187 and accompanying text, also raises the possibility that failure of the government in the Dominican Republic, which hosted a placebo-controlled trial (and is a party to the American Convention on Human Rights), to insist on testing the short-course AZT regimen against the 076 regimen rather than placebo constituted a violation of the right to life in the American Convention.
198. See Bayer, supra note 35, at 568 ("The issue is not whether the ACTG 076 would be affordable for the very limited number of research subjects. It is.").
to life in using placebos in the clinical trials. Unlike other civil and political rights, the right to life is not absolute. While increasingly outlawed and opposed, the death penalty remains a recognized derogation from the right to life. Economic and human resource constraints may also create legitimate derogations from the positive obligations imposed by the right to life. In connection with the placebo-controlled trials, defenders of the trials have variously argued that using placebos is (1) a better scientific method for the development of new HIV therapies and (2) a more appropriate approach given the socio-economic realities in the host countries. These arguments legally translate into the following propositions: the right to life may be violated in clinical trials if (1) saving an individual’s life compromises the scientific progress that could be made by allowing the individual to die, and (2) the treatment used to save lives is not affordably available in the country in question.

Both propositions turn the “geographical morality” problem into a “geographical legality” problem by suggesting that the right to life, as a matter of international law, is not applied equally in all countries. In other words, the content of the right to life is relative to the level of a country’s level of economic development. This perspective causes problems under international law because civil and political rights, such as the right to life, are to be secured without discrimination on any ground, including race, national origin, wealth, birth, or other status. Allowing governments to derogate from the right to life on socio-economic grounds is discrimination on the basis of economic status and is not allowed by international human rights law. This again raises the question why economic-status discrimination is defended by some in the ethical debates about the placebo-controlled trials. We seem to be back to the problem of “geographical morality” via international human rights law.

In addition, the argument that the right to life was violated could be supported by the principle in Article 3 of the United Nations Convention on the Rights of the Child:

In all actions concerning children, whether undertaken by public or private social welfare institutions, courts of law, administrative authorities or legislative bodies, the best interests of the child shall be a primary consideration.
It is simply not plausible to argue that it was in the best interests of the children born to the HIV-infected women in the placebo-controlled trials to deny them the benefits of the 076 regimen.

Defenders of the placebo-controlled trials respond by emphasizing the brutal facts about the poor condition of public health in developing countries. Robert Levine argues that asserting that the 076 regimen should have been used without also requiring the provision of infant formula (to prevent HIV transmission through breast feeding) and purified water (to prevent infant formula from causing diarrheal diseases from contaminated water) is inconsistent. Levine's arguments underscore the uncertainty about the scope of the positive obligations ostensibly required by the right to life as supplemented by the principles of non-discrimination and the best interests of the child. For Levine, economic reality imposes geographical morality on the international research community:

It is necessary to acknowledge with regret that there are great imbalances in the distribution of wealth among the nations of the world. Developing countries that cannot afford all the goods and services to promote health care that are available to residents of industrialized nations must be allowed to develop treatments and preventive interventions that they can afford. Research sponsors, both industrial and governmental, in industrialized countries should not be prevented from assisting developing countries in their efforts in this regard.

What this complicated analysis of the right to life suggests is that it is plausible under international human rights law to argue that the sponsoring and host governments violated the right to life in not administering the 076 regimen to all research subjects in the placebo-controlled trials. While the argument is plausible, however, it gets ahead of where international law on the right to life actually is today. At the very least, this analysis suggests that the controversy over the placebo-controlled trials raises important and unresolved issues in connection with the fundamental human right to life in international law. In addition, the analysis indicates that, for those who believe that the placebo-controlled trials were unethical, there is an opportunity to push this controversy onto the agenda of international human rights law and perhaps refine further the positive obligations triggered by the right to life. The principle of non-discrimination would support such an effort.

But this effort would quickly confront the question how far the positive obligations under the right to life extend in the context of clinical trials in developing countries. As Levine's analysis suggests, the broader these positive obligations, the more unrealistic the clinical trials become in connection with providing affordable, sustainable interventions for developing coun-

204. Levine, supra note 35, at 533.
205. Id. at 534.
tries. The positive protections of the right to life could be clarified and universalized, but would the long-run result be higher numbers of deaths because the universalization of the human right prevented tangible progress on treating dreaded diseases in the developing world? Would such a result be ethically and legally correct, or a product of ethical and legal imperialism?

2. Right of Free Consent to Medical or Scientific Experimentation

International law prohibits governments from conducting medical and scientific research on individuals without their free consent. Conceptually, the right of free consent connects with the more general human right of security of person. The right to free consent arose in international law to prohibit the kind of medical and scientific experiments conducted by Nazi and Japanese doctors and scientists on prisoners of war and those interned in concentration camps. These atrocities were also the direct source of the Nuremberg Code's first principle that "[t]he voluntary consent of the human subject is absolutely essential." The growth of peaceful clinical research on medicines for infectious and non-communicable diseases in the post-Second World War period gave the right of free consent a central role in medical and scientific progress against diseases.

As noted earlier, critics of the placebo-controlled trials have argued that these trials violate the ethical principle of free consent because of the desperate medical and socio-economic condition in which the pregnant women in the host countries found themselves. These accusations connect with longstanding concerns about the application of the free consent principle in poor countries. The right of free consent has proven difficult to implement in developing countries because the cultures in many of these countries do not adhere to the liberal concept of individual rights. The notion of an individual freely granting consent to medical or scientific research may have been

206. See ICCPR, supra note 143, art. 7 ("[N]o one shall be subjected without his free consent to medical or scientific experimentation."); Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine, Apr. 4, 1997, Europ. T. S. No. 164, art. 5 [hereinafter European Bioethics Convention] ("An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time.").

207. ICCPR, supra note 143, art. 9(1).


210 See Annas & Grodin, supra note 25, at 562; see also Todres, supra note 26, at 757-58 (analyzing whether informed consent was obtained in drug trials and arguing that it would require detailed evidentiary examination at a trial to determine whether such consent was obtained); 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 Countries, 9 COLUM. J. GENDER & L. 91 (1999).

alien to the cultures in which the placebo-controlled trials took place. In addition, medical and scientific researchers have confronted problems in obtaining "free consent" in developing countries because the low level of education among research subjects makes it difficult to determine whether a person fully understands to what he or she is giving consent. In this situation, cultural diversity complicates ethical and international legal application of the right to free consent.

To the author's knowledge, the right of free consent has not been the subject of claims before international human rights bodies in connection with the conduct of clinical trials, so there are no precedents to assist international legal analysis. (The right of free consent has been implicated in the use of medical treatment against political prisoners in connection with allegations of torture and inhuman or degrading punishment or treatment.) Analysis of the right of free consent in the clinical trial context cannot have as its objective the determination that the person in question really gave full, informed, and free consent. This kind of subjective test would prove impossible to implement as a practical matter. Instead, whether the right of free consent has been violated has to be determined according to objective, procedural standards. First, evidence must exist that the person in question was fully informed by the researchers of the risks of participating in the research. Second, evidence must be presented that the person gave his or her consent. Third, the context in which the consent was given must be free of duress or pressure applied or created by the researchers.

This analytical framework does not eliminate all difficult questions created by the right of free consent in the context of cultural diversity. Can, for example, the population from which the research subjects are drawn consist largely of low- or uneducated, and sometimes illiterate, individuals?

---

212. See Ruth Macklin, Against Relativism: Cultural Diversity and the Search for Ethical Universals in Medicine 190 (1999) (noting that "some researchers in non-Western countries have complained that it is 'ethical imperialism' to impose North American procedures requiring strict adherence to informed consent on cultures in which patients normally do not have to give consent to treatment or research maneuvers").

213. Todres, supra note 26, at 757 ("In a number of research studies in developing countries, the population from which the research subjects are drawn consists largely of low- or uneducated, and sometimes illiterate, individuals.").


215. But cf. Todres, supra note 26, at 758 (noting that "one must wonder whether a team of foreign researchers that has the additional burden of overcoming cultural barriers is capable of obtaining truly informed consent from the research subjects").

216. Lackey argued similarly when he stated that "the old requirement that consent should be voluntary and informed be replaced by a new requirement that consent should be uncoerced and undeceived." Lackey, supra note 19, at 10. Lackey’s reformulation of the free consent principle places the focus on what the researchers do rather than on whether the research subject really understood the consent process or the clinical trial. Lackey further argued: "Coercion in research is morally wrong; deception in research is morally wrong. The consent process must rule them out. But the inability of subjects to comprehend the details of the consent process is not so much a moral issue as a fact of life." Id.

217. Protection of Human Subjects, supra note 164, § 4.6.116 (General Requirements for Informed Consent); see also European Bioethics Convention, supra note 206, art. 16(iv).

218. European Bioethics Convention, supra note 206, art. 16(v).

219. See id. art. 5.
example, the consent of a tribal or community leader substitute for individual consent under international law? The answer to that question under international law is probably in the negative and that the individual's consent has to be obtained. If the individual will not give his or her consent without permission from the community leader, then such permission is an important condition to the individual's consent, but it cannot be a substitute. Cutting the individual out of the consent procedure would not be acceptable under international human rights law. This conclusion made proposed revisions of the Declaration of Helsinki (1996) that would have diluted the principle of free consent alarming from not only an ethical perspective but also an international legal perspective.  

The placebo-controlled trials did not, however, involve the disregard of individual consent. The arguments about the right to free consent in connection with these trials do not involve accusations that the researchers failed to inform the research subjects of the risks or that the research subjects' consent was not obtained. The arguments concentrate on the third test mentioned above by asserting that the context in which the clinical trials took place tainted the consents that were obtained. In other words, the consent of pregnant African women infected with HIV to participate in the clinical trials was not freely given in a substantive rather than procedural sense because of the desperate health situation these women faced. Their socio-economic condition acted as a coercive force in the consent process that the researchers did not create but of which they took advantage.

Under international human rights law, the context of medical or scientific treatment or experimentation is important. In connection with the right of free consent in Article 7 of the ICCPR, the Human Rights Committee has stated "that special protection in regard to such [medical and scientific] experiments is necessary in the case of persons not capable of giving valid consent, and in particular those under any form of detention or imprisonment." The right of free consent applies to fully autonomous persons, but

220. See Letter to Human, supra note 65 (arguing that "the proposed Declaration, by creating a set of glaring loopholes in the informed consent requirements, is the first significant step backward in the evolution of informed consent guidelines"). The World Medical Association apparently strengthened the revised Declaration of Helsinki in a subsequent revised proposal. See Letter to Human (July 31, 2000), supra note 65.

221. See Varmus & Satcher, supra note 50, at 1004.

222. Public Citizen did, however, demand to see the individual consent documentation from the placebo-controlled trials. Press Release, Public Citizen, Health Group Files Suit Over NIH Experiments on HIV-Positive Women in Developing Countries: NIH Fails to Produce Consent Forms and Other Documents for Unethical Experiments on Pregnant Women (Mar. 18, 1998) (stating that the NIH was unwilling or unable to produce the consent forms supposedly completed by the subjects of the placebo-controlled trials), http://www.citizen.org/press/pr-sid-4.htm (visited Mar. 15, 2001); see also Letter to Shalala, supra note 29 ("We have not yet obtained the informed consent forms for these studies, and so it is conceivable that additional principles of the [Nuremberg] code have not been followed and that the studies are therefore even more unethical than we state here.").

223. See Annas & Grodin, supra note 25, at 562.

224. Svensson-McCarthy, supra note 178, at 429.
what the Human Rights Committee stresses is the need for extra vigilance in connection with vulnerable people. Traditionally in international human rights law, that vulnerability has arisen in connection with involuntary detention or imprisonment. The research subjects of the placebo-controlled trials were not involuntarily detained or imprisoned, but their socio-economic condition made them vulnerable.

Vulnerability does not, however, mean that a person cannot give free consent within the meaning of that right under international law. Vulnerability is a warning for, not an absolute bar to, medical and scientific experimentation. The European Bioethics Convention's rules on free consent address the protection of persons not able to consent (i.e., minors, the mentally ill, and those in the midst of a medical emergency), but it does not contain rules about dealing with socio-economic vulnerability of research subjects. Nor can any such rules be found in other treaties. The Declaration of Helsinki (2000) states:

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.

National laws sometimes contain the principle that additional safeguards are needed in research projects including physically, economically, or educationally disadvantaged persons in order to protect the rights and welfare of such persons. Assuming that this principle of extra safeguards for economically or educationally disadvantaged persons appeared generally and consistently in state practice with the requisite opinio juris, then a rule of customary international law exists. But this rule would not prohibit involving persons in bad socio-economic conditions in medical and scientific research because it only requires extra care and diligence on the part of governments sponsoring such research.

It is also not apparent whether a stricter, prohibitory rule should be developed to address the problem perceived to be caused by bad socio-

225. European Bioethics Convention, supra note 206, arts. 6–8.
227. Protection of Human Subjects, supra note 164, subparts B (additional protections pertaining to research involving fetuses, pregnant women, and human in vitro fertilization), C (additional protections pertaining to research involving prisoners as subjects), and D (additional protections for children involved as subjects in research).
228. Lackey, supra note 19, at 9, writes:
It is . . . a principle of both law and morals that persons cannot be held to contracts made from desperation. It would follow, then, that these subjects could not be held to any agreements made upon entering into the studies, a consideration guaranteed in any event by the rule of research ethics that every subject is free to withdraw without penalty at any time.
economic conditions. First, to assume someone in poor socio-economic conditions is incapable of giving free and informed consent cuts into the core assumptions of the right of free consent: that each individual is autonomous and capable of individual self-determination. Second, assuming someone in poverty is not capable of giving consent is akin to treating them like children or the mentally ill, which again is antithetical to the norms of autonomy and self-determination informing the right of free consent.

Third, determining how much socio-economic deprivation would be necessary to vitiate the right of free consent would be fraught with subjectivity. Fourth, such subjective line-drawing seems ill-designed to be able to produce consensus among states through the mechanisms of treaty law or customary international law. Fifth, determining that a certain level of socio-economic deprivation renders an individual incapable of giving free consent is *prima facie* discrimination on the basis of economic status in violation of the fundamental human rights principle of non-discrimination.

For these reasons, believing that states through international law have taken or will take away the right of free consent from individuals in poor socio-economic conditions and thus cut off access to them for medical and scientific researchers is neither factually persuasive nor normatively attractive. Critics of the placebo-controlled trials are right to point out the vulnerability of the developing-country populations in the context of HIV therapy clinical trials, but international law provides no support for terminating clinical research in developing countries because of such vulnerability. In addition, this international legal analysis bolsters ethical opposition to proposed changes in international ethical guidelines that dilute the principle of free consent.

This analysis of the right of free consent shows the strains exhibited by solidaristic rationalism in action outside the core. The entire edifice of international law on the right of free consent is built on Western liberalism's assumptions and beliefs about individuals. Such assumptions and beliefs work well within the solidaristic core. But when the right of free consent comes to Africa, for example, cultures clash. The dogmatic insistence that individual consent be obtained in clinical trials undertaken in cultures that do not conceive of individuals as autonomous and self-determining is the imposition of the core on the periphery. Liberal revolutionism supports such an imposition because of its belief in the unity of humankind. With the right of free consent, the geographical morality problem is not one of intent but of consequences. Applied beyond the solidaristic core, the right of free consent underscores the hegemony of the core and the lack of autonomy and self-determination suffered by the periphery. With regard to the free consent principle, both proponents and opponents of the placebo-controlled trials are

---

229 Id. ("The crucial moral point is not whether desperation is present, but whether the presence of desperation signifies an absence of consent ... Among ethicists, there is not consensus that desperation invalidates consent.")
simply talking over the heads of the African women they profess to respect. In the background, the realist watches the debate and concludes that international law, even on human rights, reflects power and its exercise in international relations.

3. The Right Not To Be Subjected to Degrading Treatment

Both treaty law and customary international law prohibit torture and cruel, inhuman, and degrading punishment or treatment of individuals by governments. This prohibition involves levels of government misconduct, with torture constituting the most serious and degrading treatment the least serious. This section analyzes whether the failure of the sponsoring and host governments to administer the 076 regimen to all research subjects in the placebo-controlled trials constituted degrading treatment under international human rights law.

Raising this particular civil and political right may be offensive to supporters of the placebo-controlled trials. Torture and other forms of cruel, inhuman, and degrading punishment and treatment are endemic in the international system, and to lump the placebo-controlled trials with atrocities such as these demeans the suffering of the victims of such gross violations of a fundamental civil and political right and grossly misrepresents what took place in the placebo-controlled trials. While understandable, hostility towards raising the prohibition against degrading treatment in connection with the placebo-controlled trials does not settle the issue. In fact, a 1997 case decided by the European Court of Human Rights provides some support for applying the right not to be subject to degrading treatment of the placebo-controlled trials.

In Case of D. v. United Kingdom, a citizen of the island of St. Kitts, who was suffering from AIDS, argued that his deportation by the United Kingdom to St. Kitts would constitute cruel, inhuman, or degrading treatment or punishment because he would not receive adequate AIDS treatment in St. Kitts, which would hasten his death. D had been arrested and imprisoned in the United Kingdom for drug trafficking, and he had also been in the United Kingdom illegally. The European Court of Human Rights re-


231. See Press Release, Amnesty International, Fighting Torture—A Global Problem, A Common Goal, June 25, 1999 (stating that "all over the world, people continue to be tortured on a large scale . . . in 125 countries worldwide").

232. See, e.g., Todres, supra note 26, at 752-55 (analyzing the relevance of prohibition against cruel or inhuman treatment in connection with the placebo-controlled trials).


234. Id. at 447.
ceived evidence that showed AIDS therapies and adequate medical treatment for opportunistic infections would not be available to D in St. Kitts because of the poor condition of its health care system. The European Court of Human Rights ruled that D's deportation by the United Kingdom to St. Kitts would constitute cruel, inhuman, or degrading treatment or punishment within the meaning of Article 3 of the ECHR.

In making this ruling, the European Court of Human Rights acknowledged that (1) D had violated the law of the United Kingdom; (2) the British government had treated and cared for D's AIDS-related health problems; and (3) the United Kingdom was not responsible for the poor condition of the St. Kitts health care system. Nevertheless, the European Court of Human Rights ruled against the United Kingdom in this case. The Court stressed that it considered important the fact that D's health condition was deteriorating rapidly. But more important than the particular facts of this case was an underlying principle of international human rights law. Critical to the European Court of Human Right's ruling was its position that the right not to be subject to cruel, inhuman, or degrading treatment or punishment is an absolute right against which no derogation shall be permitted. Under the ECHR, the United Kingdom would violate the treaty by acting in a way that would foreseeably hasten a person's death from AIDS, even when the death would occur in another country and the United Kingdom was not responsible for the underlying cause of death. The European Court of Human Rights advanced human rights universalism in how it dealt with the case.

Case of D. v. United Kingdom provides an intriguing backdrop against which to analyze whether the placebo-controlled trials constituted degrading treatment in violation of international law. The sponsoring and host governments involved in the placebo-controlled trials acted in a way that would foreseeably lead to the death of children born to HIV-infected women. The sponsoring and host governments had an alternative choice—using the 076 regimen rather than a placebo—that would have saved lives. How different is the situation of African children born with HIV from the situation in which D found himself?

235 Id. at 430.
236 Id. at 454.
237 Id. at 447.
238 Id. at 448-49.
239 Id. at 449.
240 Id. at 448.
241 Id. at 447. See also European Convention on Human Rights, supra note 176, art. 15(2) (providing that no derogation from Article 3's prohibition on torture or inhuman or degrading treatment is allowed during time of war or public emergency threatening the life of the nation); ICCPR, supra note 143, art. 4(2) (providing that no derogation from Article 7's prohibition on torture and inhuman or degrading treatment and protection of the right to free consent to medical experimentation is allowed in time of public emergency threatening the life of the nation).
An analysis of whether the placebo-controlled trials constituted degrading treatment under international law does, however, have to grapple with factual differences between D's situation and that of the placebo-controlled trials. The placebo-controlled trials did not take place in a State Party to the ECHR while D was being held in custody in the United Kingdom. As a matter of treaty law, Case of D. v. United Kingdom's interpretation of Article 3 of the ECHR does not apply to developing states that hosted the placebo-controlled trials.\textsuperscript{242}

Whether customary international law binding on all sponsoring and host governments reflects the holding in Case of D. v. United Kingdom is doubtful. At most, customary international law prohibits the denial of medical treatment to persons deprived of their liberty by a government in connection with the operation of its criminal justice or mental health system. The holding in Case of D. v. United Kingdom was unusual even in terms of ECHR jurisprudence, suggesting that it is not supported by general and consistent state practice and \textit{opinio juris}.

A second fundamental difference between Case of D. v. United Kingdom and the placebo-controlled trials is that D had been deprived of his liberty by the United Kingdom government. None of the research subjects in the placebo-controlled trials were detained by their governments to participate in the trials. They participated voluntarily and gave their consent. It is hard to comprehend that the research subjects gave free consent to degrading treatment within the context of international human rights law.

For argument's sake, assume that the placebo-controlled trials took place in a State Party to the ECHR and not in developing countries. Would the governments sponsoring and hosting the clinical trials have engaged in degrading treatment of research subjects who received the placebo within the meaning of Article 3 of the ECHR? I think the answer to this question is negative mainly because the research subjects are not deprived of their liberty and thus become especially vulnerable to government mistreatment. Arguing that the research subjects receiving the placebo had been subject to degrading treatment would be tantamount to asserting that all HIV-infected pregnant women in the country in question received degrading treatment because they do not receive therapies to prevent perinatal HIV transmission. Lack of access to government-supported public health and health care facilities and services is not degrading treatment within the meaning of international human rights law.

\textsuperscript{242} Vienna Convention on the Law of Treaties, May 23, 1969, 1155 U.N.T.S. 331, art. 34 ("A treaty does not create either obligations or rights for a third State without its consent.")
D. Economic, Social, and Cultural Rights: The Right to Health

The controversy over the placebo-controlled trials implicates the right to health, one of the economic, social, and cultural human rights. The argument here is that the failure to use the 076 regimen or other proven intervention rather than a placebo deprived the children born to HIV-infected women in the host developing countries of their right to health.

Two central complexities arise in connection with such an argument. First, who is under this international legal duty, and to whom is the duty owed? Second, what is the scope of the duty? Human rights rhetoric claims that economic, social, and cultural rights are universal and have equal importance with civil and political rights, which suggests that all states are under a duty to fulfill the rights to health. Economic, social, and cultural rights have not, however, been as firmly established under international law as the civil and political rights discussed earlier. The United States has, for example, been historically hostile to economic, social, and cultural rights generally and the right to health specifically. European states have been less antagonist toward economic, social, and cultural rights (see, e.g., the European Social Charter), but these rights have been overshadowed in European practice by civil and political rights, which are enshrined in the ECHR. Thus, arguments that the United States and other developed-country sponsors of the placebo-controlled trials violated the children's rights to health confront a difficult international legal context because of the political controversy that surrounds the right to health.

The rare cases in which an international body has addressed the right to health provide little in the way of support for the argument that the placebo-controlled trials violated the right to health of the children born to the HIV-infected women. In the Status of the Yanomami Indians case, the Inter-American Commission on Human Rights found that Brazil had violated the right to health in the American Declaration of Human Rights by exposing


244. See Vienna Declaration and Programme of Action, supra note 140, at ¶ 5 (“All human rights are universal, indivisible, and interdependent and interrelated.”).

245. See MATTHEW C.R. CRAVEN, THE INTERNATIONAL COVENANT ON ECONOMIC, SOCIAL, AND CULTURAL RIGHTS: A PERSPECTIVE ON ITS DEVELOPMENT 10 (1995) (“In the majority of States, economic, social, and cultural rights are almost entirely absent from the common discourse on human rights.”).

246. The United States is not, for example, a party to the ICESCR.


the Yanomami Indians to epidemic diseases through deforestation of the Amazon. In this case, the Brazilian government was responsible for creating or allowing the environmental degradation in its territory that produced outbreaks of infectious diseases among the Yanomami. These facts bear no resemblance to the placebo-controlled clinical trials.

In the Ache Tribe Case, the Inter-American Commission on Human Rights held that Paraguay violated the right to health in the American Declaration on Human Rights by failing to provide the Ache Indians in its territory proper immunization against and treatment for infectious diseases. The Inter-American Commission indicated that the failure was discriminatory in effect against the Ache Indians. The Inter-American Commission seems to have assumed that such immunizations and treatment were within the financial means of the government of Paraguay. In the case of the placebo-controlled trials, no one has suggested the host governments acted discriminatorily against any racial or ethnic group or had sufficient financial resources to pay for the 076 regimen.

To employ the Ache Tribe Case as a precedent against the placebo-controlled trials, one would have to argue that the sponsoring governments, such as the United States, discriminated against the children born to the HIV-infected women and had sufficient resources to use the 076 regimen rather than a placebo. Given that all the children borne to women participating in the clinical trials were nationals of the country hosting the trials, discrimination within the research group does not seem to have been a feature of the clinical trials. While the sponsoring governments had resources to pay for or obtain the 076 regimen for all women participating in the clinical trials, the clinical trials were not public health programs for the general population. The facts of the Ache Tribe Case, like those of the Yanomami Tribe Case, are not consonant with the facts of the placebo-controlled trials.

Uncertainty about the scope of economic, social, and cultural rights compounds the problems with the right to health. All economic, social, and cultural rights are subject to the principal of progressive realization, which means that the substance of the rights varies according to the economic resources available to the government. Under international law, then, the substance of the right to health is not universal but is expressly relative to a given country's level of economic resources.

251. ICESCR, supra note 144, art. 2(1) ("Each State Party to the present Covenant undertakes to take steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures.").
This “progressive realization” dynamic appeared in a South African Constitutional Court case that required the Court to interpret the right to health under the South African Constitution. Section 27(1) of the South African Constitution provides that “[e]veryone has the right to have access to (a) health care services . . . .” 252 Section 27(2) provides that “[t]he state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realization of each of these rights.” 253 Section 27(3) provides that “[n]o one may be refused emergency treatment.” 254 In Soobramoney v. Minister of Health (Kwazulu-Natal), 255 the plaintiff argued that his right to emergency treatment and right to access to health care services were violated by a hospital’s refusal to make renal dialysis available to him. 256 The plaintiff was in the final stages of chronic renal failure, and renal dialysis would have prolonged his life. The South African Constitutional Court ruled that the plaintiff’s medical situation did not constitute an emergency, so Section 27(3) did not apply. 257 The Court then held that the South African government’s obligations under 27(1) are qualified by Section 27(2)’s recognition of financial constraints. 258 The right to access to health care services is expressly limited by the lack of available resources.

Occasionally national courts have rejected lack of financial resources as an excuse for the government’s failure to provide health services. 259 The Venezuelan Supreme Court case noted earlier, In the Matter of Cruz Bermudez, involved the Court rejecting the government’s defense of scarce resources to allegations of violations of the right to health in connection with access of persons living with HIV to HIV therapies. 260 The Supreme Courts of Costa Rica and Mexico similarly found their respective governments in violation of a constitutional right to health in not supplying HIV-positive citizens with HIV therapies. 261 But trying to discern from these cases the core content of the right to health against which budgetary scarcity cannot be argued proves difficult in international law.

Efforts to give the right to health some minimum core meaning that applies universally have not so far borne fruit in international law. In fact, arguing that there is a minimum core meaning to the right to health in international law that is not subject to the principle of progressive realization is
The principle of progressive realization has always accompanied the right to health in all treaties in which the right is embedded. Under principles of treaty interpretation, it is not possible to prevent the principle of progressive realization from applying to the elements of a minimum core meaning for the right to health. The general rule of treaty interpretation is to interpret treaties “in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in light of its object and purpose.” Interpretation can also be assisted by subsequent practice between States Parties to the treaty as to the meaning of a treaty term. Both the texts of treaties including the right to health and subsequent state practice under them do not support removing the principle of progressive realization from some core set of health services that must in all cases be provided by a government.

Thus, the scope of the right to health remains indeterminate in international law. It is therefore hard to maintain that the failure of the sponsoring and host governments to use the 076 regimen rather than placebo constitutes a violation of the right to health. It is clear that the right to health under international law does not require governments to provide expensive HIV therapies to all persons living with HIV/AIDS. Further, arguing that participation in clinical trials somehow triggers a more protective right to health for research subjects than members of the general population has no basis in contemporary international law.

The right to health is expressly a plan of geographical morality and legality. Under international law, the principle of progressive realization makes the right to health relative to a country’s level of economic development and how it prioritizes public health and health care in an environment of scarce resources. No moral or legal standard exists that gives the right to health universal meaning. Although support exists for protecting some minimum core from the impact of the principle of progressive realization, this support has not had definitive impact on treaty law or customary international law on the right to health. The right’s place in international law is precarious, which makes it a weak international legal basis from which to attack the placebo-controlled trials.

262. See, e.g., Toebes, supra note 243, at 275–84 (proposing a core content for the right to health).

263. Vienna Convention on the Law of Treaties, supra note 242, art. 31(1).

264. Id. art. 31(3)(b).

265. See Fidler, supra note 182, at 307.

266. See Katarina Tomasevski, Health, in 2 UNITED NATIONS LEGAL ORDER 859, 873 (O. Schachter & C.C. Joyner eds., 1995) (arguing that “the right to health has not conceptually progressed from the time it was first proclaimed, not even to define the core terms health and right in the proclaimed right to health”).

267. The South African, Venezuelan, Costa Rican, and Mexican cases mentioned earlier were based on constitutional law, not international law. Even so, these cases might be seen as evidence of state practice for purposes of customary international law analysis in connection with the right to health. More relevant to international legal analysis will be whether the Inter-American Commission on Human Rights makes a final determination on the right to health in connection with El Salvador’s failure to provide HIV-positive citizens with HIV therapies.
E. Does the Double Standard Violate the Principle of Nondiscrimination in International Law?

One of the bedrock principles of international human rights law is nondiscrimination in the enjoyment of all human rights. In connection with the controversy over the placebo-controlled trials, Ronald Bayer asked "can it be considered ethical to provide placebos to women in Uganda when doing so would constitute an outrage in Brooklyn?" This question raises the issue whether the "double standard" seen at work in the placebo-controlled trials constituted discrimination against people living in developing countries.

In order to determine whether the trials involved discrimination in violation of international human rights law, one must first identify the specific human rights enjoyed by the research subjects in the clinical trials. The principle of non-discrimination is not a mandate for governments to treat all people the same in every situation; it protects the equal enjoyment of specific human rights. Thus, the argument that immigration restrictions against persons with HIV/AIDS violate international human rights law because such restrictions discriminate on the basis of serologic status is not persuasive because no person has a human right to enter other countries freely. Similarly, for the principle of non-discrimination to apply in the context of the placebo-controlled trials, the research subjects provided placebos must first show that the researchers and participating governments violated a specific human right to which the non-discrimination attaches. As analyzed in Part IV, research subjects who received the placebo rather than AZT will have a very hard time showing that any human right recognized in international law was violated.

V. CONCLUSION: THE PROBLEM OF GEOGRAPHICAL MORALITY AND THE ETHICS OF THE PLACEBO-CONTROLLED TRIALS

Analyzing the geographical morality problem from the perspectives of international relations theory and international law does not simplify the controversy over the ethics of the placebo-controlled trials. This ethical controversy sparks debates within international relations theory and international law, thus adding new layers to the controversy. But the new layers indicate that the arguments over the placebo-controlled trials are about more than interpreting international ethical codes. The ethical arguments implicate international law and how we think about the way humanity is organized and should interact.

268. See ICCPR, supra note 143, art. 2(1); ICESCR, supra note 144, art. 2(2).
269. Bayer, supra note 35, at 568.
270. See, e.g., GOSTIN & LAZZARINI, supra note 211, at 87 (arguing that "denying entry to individuals based solely on HIV infection fundamentally infringes on human rights").
271. See FIDLER, supra note 243, at 206.
At the heart of the controversy is a political, legal, and moral struggle about how to deal with the global injustice reflected in the great economic and health inequities between the developed and developing world. Echoing revolutionism, opponents of the placebo-controlled trials assert the existence of a universal ethical and legal framework that can and should be applied regardless of disparities in wealth among peoples. Defenders of the trials seem to follow an approach resembling solidaristic rationalism because those material inequalities between the core and the periphery affect ethical and legal reasoning. The international relations and international legal analyses in this Article suggest that the universalistic ethical and legal framework animating opposition to the placebo-controlled trials is not firmly established.

The debates over the placebo-controlled trials also tap directly into discourse over the post-Cold War ascendance of liberal political and economic thinking. The revolutionism and solidaristic rationalism seen in the arguments about the placebo-controlled trials are informed by liberalism as both sides argue from the same liberal-inspired set of international human rights norms. The debates over the placebo-controlled trials support the arguments of some that all philosophical and ideological challengers to liberalism have been vanquished in the world of ideas.

The contemporary problem of geographical morality thus differs from the geographical morality against which Burke protested. Burke's criticism of Hastings's behavior came at a time when civilizations were only really beginning to clash in earnest. Unlike his contemporaries, Burke thought Indian civilization and the Indian peoples morally equal to Europeans and European civilization. He wanted the two civilizations to co-exist without one destroying the other. Today, the ascendance of liberalism as the global paradigm has buried concepts of civilizational co-existence. The geographical morality problem today arises not out of deep philosophical and cultural dissonance but out of deep economic, technological, and educational inequalities between rich and poor states rather than philosophical and cultural dissonance.

These material inequalities frustrate both liberal revolutionism and liberal solidaristic rationalism in the areas of ethics and international law. For both perspectives, such inequalities are reminders of the superficial nature of lib-

---

272. See supra Part III.B.3.
273. See supra Part III.B.2.
274. See supra note 132, at 3.
276. See supra note 132, at 3.
277. See supra note 132, at 3.
278. But see SAMUEL P. HUNTINGTON, THE CLASH OF CIVILIZATIONS AND THE REMAKING OF WORLD ORDER (1996) (arguing that this philosophical and cultural dissonance—a clash of civilizations—will characterize the next phase of international relations).
eralism’s triumph and daunting challenges to physicians, ethicists, lawyers, and diplomats to deepen human solidarity.

In connection with this goal, the international relations and international legal analyses in this Article may encourage us to follow one of three paths. The first path leads us to the conclusion that compromises are inevitable in international ethics and international law, even in connection with clinical trial research. Following pluralistic rationalism, we should approximate ethical standards and concepts of human rights through state interaction without expecting to achieve them fully on a global scale because of material inequalities. Such a position counsels against joining the critics of the placebo-controlled trials. Geographical morality, in other words, remains an unavoidable feature of international relations.

The second path leads to a re-enforcement of staunch ethical universalism. Politics and law are inevitably compromised by the sordid state of the world, but on ethical issues we should maintain a position of no compromise. The ethics of scientists and medical researchers should be held always to the highest standard. Once scientists and medical researchers begin to act like diplomats and international lawyers, the ethical slippery slope has been reached. The application of the international ethical standards should be animated by the spirit of revolutionism in order to avoid the quagmire of geographical morality in which the diplomats and international lawyers wallow. Thus, the placebo-controlled trials should be condemned.

The third path charts a middle way between the resignation of the first and the zeal of the second. The third path forces us to ask how the problem of geographical morality can realistically be managed in international relations. The path leads us to consider utilizing a dynamic version of solidaristic rationalism. The broader and deeper the solidarity between governments and citizens the better are the prospects of increasing the global application of international ethical standards and strengthening international legal principles. This path is a liberal path because the solidarity it seeks is based on liberal beliefs, values, and practices. This path is also a homogenizing path as it seeks to spread liberalism farther and deeper in the international system. But it recognizes that ideas and idealism alone do not heal diseases and feed the hungry. Material inequality forces liberal solidarism to compromise in the application of ethical norms outside the core in order to make material progress against disease in developing countries. The result is geographical morality.

Universalists would deny, of course, that material inequalities justify plans of geographical morality. The way to deepen liberalism in interna-


The future of international society is likely to be determined, among other things, by the preservation and extension of a cosmopolitan culture, embracing both common ideas and common values, and rooted in societies as well as their elites, that can provide the world international society of today with a kind of underpinning enjoyed by the geographically smaller and culturally more homogeneous international societies of the past.
tional relations is not to allow material inequalities to pervert liberal principles but rather to apply liberal principles universally at all times. Ethical norms and international human rights will never be universally enjoyed unless liberals truly believe they are universally applicable.

The international legal analysis in this Article suggests that the universalist position is too simplistic. Opponents of the placebo-controlled trials assert that human rights were violated, but when international human rights law is analyzed, it becomes more difficult to substantiate these assertions. Law and ethics are not synonymous, so the failure to find violations of international human rights law in the placebo-controlled trials is not definitive from an ethical point of view. Law is, however, often the real-world mechanism through which societies make their ethical values and practices affect human behavior. Presumably international human rights law enshrines fundamental liberal understandings about protecting human rights. The international legal analysis thus cannot be dismissed summarily by opponents of the placebo-controlled trials.

The cooperation that occurred between the sponsoring and host governments and foreign and local researchers in connection with the placebo-controlled trials might be a model for dynamic solidaristic rationalism in the world of international clinical trials. The solidaristic core set the basic parameters guiding the clinical trials, but it was flexible in the face of local conditions and input from host country researchers and government officials. The gaping material and health inequalities between the sponsoring and host countries reveal, however, that dynamic solidarism is needed in many more areas than simply clinical trials.280

Laments are frequently heard about the failure of the rich, Western countries adequately to support developing countries struggling under the enormous burden that HIV/AIDS and other infectious diseases are imposing on them.281 This immediately raises the accusation against the placebo-controlled trials that any successful drug regimens that resulted from them would not be available to developing countries' populations because of their expense. Supporters of the placebo-controlled trials have no good response to this accusation other than emphasizing the primary need to develop new therapies before worrying about their cost or potential availability. People living in developing countries are justified in viewing such arguments with a skeptical eye. The behavior of the United States toward South Africa in connection with the latter's desire to increase access to HIV therapies through compulsory licensing stands as evidence of U.S. arrogance and in-

280. See, e.g., Amir Attaran, Human Rights and Biomedical Research Funding for the Developing World: Discovering State Obligations under the Right to Health, 4 HEALTH & HUM. RTS. 27 (1999) (arguing that developed countries' failure to allocate more public funds for research on diseases of fundamental concern to developing countries involve "ubiquitous and grievous violations of international law").

281. See, e.g., Amir Attaran & Jeffrey Sachs, Defining and Refining International Donor Support for Combating the AIDS Pandemic, 357 THE LANCET 57 (2001) (arguing that the international aid effort against HIV/AIDS is greatly incommensurate with the severity of the pandemic).
difference about Africa's public health problems. Why is it plausible that new therapies developed through placebo-controlled trials will be any more available to developing countries' populations than the therapies that currently exist?

More broadly, the ethical dispute over the placebo-controlled trials connects with criticisms of the West's general indifference toward the problems of developing countries, particularly those in sub-Saharan Africa. The response from the West and international organizations to the scale of the HIV/AIDS crisis has been severely criticized as inadequate. The indifference is manifest, however, outside the HIV/AIDS context. How developing countries' governments are roughly handled by the World Bank and International Monetary Fund through structural adjustment policies has been the subject of intense criticism. The United Nations' failure to intervene in the genocide that took place in Rwanda serves as a symbol of the weakness of contemporary liberal solidarism with respect to Africa. Historically, the aftermath of colonial and imperial exploitation of developing countries by the West is still being felt today.

These observations mean that debates over the placebo-controlled trials have to be put into perspective with the larger relationship between developing countries and the West. Solidaristic rationalism's preference for ethical flexibility and a local standard of care in connection with international clinical trials as a way to deepen solidarity between the core and periphery is a gamble that, against the depressing context of the core's general attitude and policies toward developing countries, should be feared rather than embraced.

The gamble will only be justified when clinical trials organized under plans of geographical morality produce drugs that the West makes affordably available to developing countries. Nothing in the defense of the placebo-controlled trials even hints at a sustainable plan to improve developing countries' access to new drugs developed through international clinical research. This is a glaring problem given the terrible obstacles that confront increasing access to drugs in developing countries. Absent a sustainable plan for access to new drugs, liberal solidarism's gamble in the placebo-controlled trials may quickly resemble past Western exploitation of developing countries. Echoing Burke, we must ask what liberal solidarism's gamble with geographical morality will leave inhabitants of developing countries in the way of scientific advances against disease.

282. See, e.g., id.

283. See Fidler, supra note 277, at 388 (describing criticisms of structural adjustment policies of the World Bank and International Monetary Fund).


Moving in an ethical and legal direction toward a local standard of care in international clinical trials brings liberal solidarism closer to pluralistic rationalism and realism in accepting or exploiting a plan of geographical morality. In this plan, the moral and international legal duties of governments and medical and scientific researchers are not governed by liberal principles, but climates, degrees of longitude and latitude, and socio-economic inequalities—parallels not of human dignity, but of geography and poverty. When we have crossed these parallels, liberal principles shrink in the face of human suffering and we commence an old order and system of things based on exploitation and raison d'état disguised in the enigmatic, liberal garb of globalization.