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Research and Accountability: The Need for Uniform Regulation of International Pharmaceutical Drug Testing

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COMMENTS

RESEARCH AND ACCOUNTABILITY: THE NEED FOR UNIFORM REGULATION OF INTERNATIONAL PHARMACEUTICAL DRUG TESTING

Dawn Joyce Miller

I.	Introduction	198
II.	The Rules	202
	A. Nuremberg and Helsinki: The First Ethical Documents.....	202
	B. United States Food and Drug Administration Rules	205
	C. European Convention on Biomedicine	206
	D. International and Multinational Documents ...	207
	1. World Ethical Agreements Beyond Nuremberg and Helsinki.....	207
	2. Human Rights Conventions.....	209
	E. Conclusion: The Need for a Clear Set of Enforceable Regulations	211
III.	Medical Testing in Developing Nations	211
	A. The Boom of Infectious Diseases and the Need for Family Planning	212
	B. The Difficulties of Informed Consent	213
	C. Use of Placebos and The Issue of Standard of Care	216
	D. The Use of Vulnerable Populations	219
	E. Determining the Beneficiaries of the Treatment	223
	F. Governmental Pressures in Developing Nations	225
IV.	Responding Ethically	226
	A. The Recognition of the Importance of Ethics...	226

B. An International Legal Regime	226
C. Regulation of Nationals	227
D. Solutions from the Research Community	228
E. Necessary Rules	229
V. Conclusion	231

I. INTRODUCTION

In Europe fifty years ago, "doctors" and "researchers" conducted experiments on human beings under horrendous circumstances. Prisoners in Nazi concentration camps were exposed to a multitude of diseases including malaria, jaundice, and typhus to see how the diseases grew.¹ The prisoners were then subjected to numerous untested antibiotics, not for their own benefit, but for the purpose of the research itself.² The Nazis also conducted altitude and freezing experiments in which individuals were subjected to extreme altitudes and extreme cold without any protection from the elements.³ "Doctors" then charted the reactions of the human bodies to these conditions.⁴ Those subjects who did not die from the disease research or the altitude and freezing experiments were either subjected to more "medical" tests or executed.⁵ The research and the experiments conducted by the Nazis were, of course, not designed to benefit the actual human subjects involved. On the contrary, no regard at all was given to the welfare of these subjects; rather, they were the victims of torture.⁶

Following Allied victory in Germany, many of those responsible for these atrocities were tried at Nuremberg.⁷ The Nurem-

¹ See Matthew Lippman, *The Nazi Doctors Trial and the International Prohibition on Medical Involvement in Torture*, 15 LOY. L.A. INT'L. & COMP. L.J. 395, 410-12.

² See *id.*

³ See *id.*

⁴ See *id.*

⁵ For more detail on Nazi experiments see *id.*; see also WILLIAM L. SHIRER, *THE RISE AND FALL OF THE THIRD REICH: A HISTORY OF NAZI GERMANY* 985 (1960); see also *THE NAZI DOCTORS AND THE NUREMBERG CODE: HUMAN RIGHTS IN HUMAN EXPERIMENTATION*, (George J. Annas & Michael A. Grodin eds., 1992). [hereinafter NAZI DOCTORS].

⁶ See Lippman, *supra* note 1, at 412.

⁷ See Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10: Nuremberg, October 1946-1949 (U.S. Government Printing Office, 1949) reprinted as *The Nuremberg Code*, in SOURCEBOOK IN BIOETHICS: A DOCUMENTARY HISTORY 11 (Albert R. Jonsen, et al., ed. 1998); also

berg trials resulted in the first enunciation of ethical principles for medical research involving human beings—the Nuremberg Code.⁸ The trials also ignited the first international debate about the creation of standards that would allow for effective research while ensuring that people are not treated as guinea pigs.

Unfortunately, the Nazis are not the only group responsible for committing wrongdoing in the name of medical or scientific research. Thirty years ago, in the United States, the Tuskegee medical experiments came to light.⁹ These experiments, which went on for decades, involved the denial of effective medical treatment to certain black men suffering from syphilis.¹⁰ Even when it became apparent that penicillin was capable of completely curing the disease, the drug was withheld to allow researchers to continue studying the course of the disease.¹¹ The apparent justification for this course of action was the fact that the subjects did receive some degree of medical care through the study. It was argued that but for the subjects' participation in the study, they would have received no treatment for the disease at all.¹²

The men in this study were not only denied effective medical treatment, the researchers actively deceived them. They were told neither that they had syphilis nor that there was a cure for the disease.¹³ Researchers Fairchild and Bayer succinctly describe the abuses of this experiment:

The study involved, first, deceptions regarding the very existence and nature of the inquiry into which individuals were lured. As such, it deprived those seeking care of the right to choose whether or not to serve as research subjects. Second, it entailed an exploitation of social vulnerability . . . Finally, Tuskegee research-

reprinted in NAZI DOCTORS, *supra* note 5, at 137 [hereinafter *The Nuremberg Code*]. The Nuremberg Code was part of the judgment rendered against the Nazi doctors. *See id.*

⁸ *See id.*

⁹ *See* Marcia Angell, *The Ethics of Clinical Research in the Third World*, reprinted in TUSKEGEE'S TRUTHS 578, 578 (Susan M. Reverby, ed. 2000) [hereinafter *Clinical Research*].

¹⁰ *See generally* JAMES H. JONES, *BAD BLOOD* (1993).

¹¹ *See id.*

¹² *See Clinical Research*, *supra* note 9, at 579.

¹³ *See* Amy L. Fairchild & Ronald Bayer, *The Uses and Abuses of Tuskegee*, reprinted in TUSKEGEE'S TRUTHS, *supra* note 9, at 590.

ers made a willful effort to deprive subjects of access to appropriate and available medical care. . .¹⁴

When the Tuskegee experiment was made public, it spawned the creation of enforceable Food and Drug Administration Rules (FDA Rules) for the conduct of medical experiments in the United States.¹⁵ Among other things, the FDA Rules rendered illegal medical tests conducted with placebos¹⁶ in cases in which there was a known therapy for the disease.¹⁷ The rules further required that researchers secure informed consent from their subjects prior to the performance of any medical experiments.¹⁸

While the FDA Rules represent progress in terms of research ethics, serious problems remain to be addressed. Some of these problems stem from diseases like AIDS that have challenged traditional research. The increase in infectious diseases such as AIDS, the lack of family planning assistance, and the lower cost of conducting experiments in developing nations make the developing world a prime spot for drug experimentation.¹⁹ This research is performed, for the most part, for the benefit of humankind, yet drug research in the developing world presents new, unsolved, ethical dilemmas.

While strict rules often apply to research conducted within the United States and within many European countries, when researchers from the United States and Europe perform research in developing nations, they are largely free from such research limitations. The research performed in developing na-

¹⁴ *Id.* at 590.

¹⁵ See Federal Food, Drug, and Cosmetic Act, 21 C.F.R. §50, 45 C.F.R. §46.116; 21 U.S.C. §301.

¹⁶ Patients given a placebo are given a non-drug such as vitamin C or a sugar pill. See MERRIAM-WEBSTER'S MEDICAL DESK DICTIONARY (1996). Placebo groups are then compared to groups of people receiving treatment to study the effectiveness of a particular treatment. See *id.*

¹⁷ See Bill Sloat & Keith Epstein, *Living Proof Ugandans in American-Run Study expected treatment, but some pills were dummies*, THE PLAIN DEALER, Nov. 9, 1998, at 1A [hereinafter *Ugandan Study*].

¹⁸ See 21 C.F.R. §50.20, 45 C.F.R. §46.116.

¹⁹ See *New \$150m Initiative to Combat AIDS and Contribute to international prevention efforts*, M2 PRESSWIRE, January 11, 2000, available at 2000 WL 4795162 [hereinafter *AIDS initiative*].

tions is, therefore, often suspect.²⁰ The potential for abuse is significantly increased when vulnerable groups are involved in this research.²¹ Women and children, for example, are often regarded in developing nations as wards of the state.²² Furthermore, principles of informed consent often give way to state fears of disease and to the desire for expedient research.²³ There is increasing concern that U.S. and European drug companies are moving testing to less developed nations where "costs are low, patients are plentiful, and government oversight lax."²⁴ This article argues that developed nations need to do more to protect the rights of people in less developed nations from unnecessary and unscrupulous medical experiments, particularly drug experiments.

Part II of this paper will explore the historical development of the rules for ethical research, specifically the first documents regarding the use of humans in research. It will then describe both the FDA Rules regarding drug testing and the provisions of the European Convention on Biomedicine. Finally, it will address current international rules, regulations, and ethical guidelines regarding medical testing to determine whether international law is capable of filling in where domestic laws do not. Part III will explore the current problem of testing in those countries where medical standards may not be compatible with those standards adopted by developed countries. It will explain the current fear regarding infectious diseases and overpopulation, and it will discuss how these fears can lead governments to put their own citizens at risk. It will further note how developed nations' drug companies may take advantage of the poor, the sick, and the dying, particularly women and children. Finally, it will explore the problem of informed consent and other standard procedures that may, in fact, be inadequate to protect

²⁰ See Charles W. Henderson, *CEL-SCI Announces Data from Phase II Study*, AIDS WEEKLY, December 13, 1999, available at 1999 WL 10041741.

²¹ See M. Dickens, *Research Ethics and HIV/AIDS*, 16 MED. & L. J. 196 (1997).

²² See Kevin M. King, *A Proposal for Effective International Regulation of Biomedical Research Involving Human Subjects*, 34 STANF. J. INT'L. L. 163, 192 (1998) [hereinafter *Effective International Regulation*].

²³ See *id.* at 192.

²⁴ Mary Pat Flaherty & Joe Stephens, *Pa. Firm Asks FDA to Back Experiment Forbidden in U.S.*, WASH. POST A03, February 23, 2000, available at 2001 WL 2546189.

people in these countries. Finally, Part IV will explore possible solutions to the problem of medical experimentation in developing nations as well as the limits of those solutions.

II. THE RULES

A. *Nuremberg and Helsinki: The First Ethical Documents*

At the end of World War II, the world was horrified to learn of the medical experiments conducted by Nazi doctors in concentration camps.²⁵ These experiments ultimately led to the creation of the Nuremberg Code (Nuremberg Code or Code), the first articulation of standards for medical research involving human subjects.²⁶ The Code sets out ten requirements for human research including voluntary consent, the avoidance of unnecessary pain and suffering for the subjects, and the right of the subject to withdraw at any time.²⁷ The Code clarifies "consent" as follows: 1) a person must have legal capacity to consent; 2) a person must be free to exercise choice without fraud, duress, deceit or constraint; 3) and a person must have sufficient comprehension of the nature of the experiment and the treatment to enable him to understand the decision he is making.²⁸ In addition to consent, the Code requires that an experiment should only be conducted where a societal good will result.²⁹ The Code, however, does not explicitly address the use of placebos or vulnerable populations in research.

Unfortunately, the international community never officially adopted the Nuremberg Code.³⁰ In addition, its creation

²⁵ See generally NAZI DOCTORS, *supra* note 5.

²⁶ See *The Nuremberg Code*, *supra* note 7.

²⁷ See *id.* Other provisions of the Code include the requirement that tests not be random or unnecessary and that they be based on adequate animal and other research. Research that doctors believe will result in death or disabling injury is prohibited. The Code also requires that there be proper facilities for the research subject and that only a qualified professional conduct research. The risk of the experiment must be in proportion to the danger of the disease to society. Finally, the researcher is required to terminate the research if at any time in his professional judgment disabling injury or death might result. *Id.*

²⁸ See *id.*

²⁹ See *id.*

³⁰ See George J. Annas & Michael A. Grodin, *Medical Ethics and Human Rights: Legacies of Nuremberg*, 3 HOFSTRA L. & POL'Y SYMP. 111, 113-14 (1999).

during the Nuremberg Trials³¹ left the impression that it was formed solely in response to the horrible experiments of Nazi Germany rather than to provide a code for medical experiments today.³² The Code responded to experiments that clearly were performed against the will of the human subjects, all of whom were prisoners of the Nazi state.³³ Furthermore, the experiments were clearly not intended for the benefit of the subject or the subject's community.³⁴ Thus, the Code was a response to purely non-therapeutic research.³⁵ As a result, those in the biomedical field (both law and science) differ on the effectiveness of the Code in preventing abuses in international medicine.³⁶ In addition, many have questioned the applicability of its more stringent provisions when the research is clearly for the benefit of the patient.³⁷

In response to the Code, the World Physician's Organization³⁸ formed and wrote the Helsinki Declaration.³⁹ The Helsinki Declaration separates therapeutic and scientific research.⁴⁰ The former occurs for the benefit of the individual patient, while the latter is research performed purely to achieve

³¹ The Nuremberg Trials were instituted by the allies following World War II in order to try various Nazi criminals. The Doctor's Trials were a part of that process. See *The Nuremberg Code*, *supra* note 7.

³² See generally Annas & Grodin, *supra* note 29.

³³ See Sharon Perley, et al., *The Nuremberg Code: An International Overview*, in NAZI DOCTORS, *supra* note 5, at 150.

³⁴ See *id.*

³⁵ See *id.*; see also Leonard H. Glantz, *The Influence of the Nuremberg Code on U.S. Statutes & Regulations*, in NAZI DOCTORS, *supra* note 5, at 183-85.

³⁶ See Perley, *supra* note 33, at 150; see also generally Annas & Grodin, *supra* note 30.

³⁷ See, e.g., THE ETHICS OF RESEARCH INVOLVING HUMAN SUBJECTS FACING THE 21ST CENTURY, 8 (Harold Y. Vanderpool, ed. 1999) [hereinafter FACING THE 21ST CENTURY].

³⁸ The World Physicians Organization was a body of medical professionals governed by medical professionals. It was formed in large part to create guidelines that were not as severe as the Nuremberg Code. For a more complete discussion on the formation of this organization, the Helsinki Guidelines, and subsequent developments see George J. Annas, *The Changing Landscape of Human Experimentation Nuremberg, Helsinki, and Beyond*, 2 HEALTH MATRIX 119 (1992) [hereinafter *Changing Landscape*]; see also *Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects*, reprinted in SOURCEBOOK IN BIOETHICS, *supra* note 7, at 13 [hereinafter *Helsinki Declaration*].

³⁹ See *Helsinki Declaration*, *supra* note 38.

⁴⁰ See *id.*

scientific knowledge.⁴¹ The treatment of the patient is different under the two standards. The consent of the patient is not required for therapeutic treatment if the physician researcher, acting in the best interest of the patient, believes that informed consent would be too difficult and unnecessary.⁴² On the other hand, experimentation conducted with little or no expectation of direct benefit to the patient requires full consent.⁴³ Drug research is somewhat ambiguous in this respect. For example, experimental drugs may be included in therapeutic treatment, but they may be given with little expectation of benefiting the patient. The difference between the two types of research is, therefore, often blurred.

In addition to the guidelines for consent, the Helsinki Declaration also requires that patients undergoing experimental treatment, including members of a control group, should always be provided with the "best proven diagnostic and therapeutic methods."⁴⁴ The overriding principle of the Declaration is that "concern for the interests of the subject must always prevail over the interest of science and society."⁴⁵

The Nuremberg Code and the Helsinki Declaration have served as the basis for the creation of national and international rules governing biomedical research on humans.⁴⁶ Yet, despite their influence, there is great debate as to whether either has been adopted as binding customary international law.⁴⁷ In light of the absence of a consensus on international law in this area, national laws regarding experimentation are significant.

⁴¹ See *id.*

⁴² See *id.*

⁴³ See *Helsinki Declaration*, *supra* note 38, at 13.

⁴⁴ See *id.* at 14.

⁴⁵ See *id.* at 14.

⁴⁶ See George J. Annas & Michael Grodin, *Conclusions*, in *NAZI DOCTORS*, *supra* note 5, at 311-13.

⁴⁷ See *Changing Landscape*, *supra* note 38, at 3 (for a further discussion on whether the Nuremberg Code or Helsinki Declaration are binding customary international law or merely ethical guidelines). Note, however, that United States Courts have cited the Nuremberg Code as binding authority. See *e.g.*, *United States v. Jaffe*, 663 F.2d 1226 (3d Cir. 1981); *United States v. Stanley*, 483 U.S. 669 (1987).

B. *United States Food and Drug Administration Rules*

The FDA Rules state that research is only permissible with "the legally effective informed consent of the subject or the subject's legally authorized representative."⁴⁸ Informed consent is further defined by several elements including the provision of a description of the study and its purposes, disclosure of any foreseeable adverse or beneficial effects, and notification of any alternative treatments available.⁴⁹ The subject must also be informed of the freedom to withdraw from the project at any time as well as the process for doing so.⁵⁰ The non-military exceptions to informed consent are very narrow.⁵¹ To bypass informed consent, a physician must certify the following: 1) that the subject confronts a life threatening situation; 2) that informed consent cannot be obtained from the subject; 3) that time is not sufficient to gain consent from the legal representative; and 4) that there are no other available methods of treatment.⁵² It is important to note that if the subject or the subject's legal guardian is capable of consenting, then consent must be obtained under the guidelines.⁵³ The rules also offer great detail regarding the process of setting up an independent review board to approve and monitor the experiment.⁵⁴ Where an independent review board is established, there is greater latitude in obtaining consent.⁵⁵ If such a board determines that obtaining consent is not practicable and that there is no more than a minimal risk to the patients involved, consent may be entirely waived.⁵⁶

In cases involving pregnant women, the FDA Rules additionally require that the research be intended to help the mother and that the fetus will not be placed at great risk.⁵⁷ Children and prisoners are also given particular protections be-

⁴⁸ See 21 C.F.R. §50.20

⁴⁹ See 21 C.F.R. §50.25

⁵⁰ See *id.*

⁵¹ See 21 C.F.R. §50.23, §50.24.

⁵² See 21 C.F.R. §50.23.

⁵³ See *id.*

⁵⁴ See 45 C.F.R. §46.107-115.

⁵⁵ See 45 C.F.R. §46.116 (c)(d).

⁵⁶ See 45 C.F.R. §46.205.

⁵⁷ See 45 C.F.R. §46.207.

cause of their increased vulnerability.⁵⁸ Importantly, however, unless the research in question is conducted or funded by the United States' government, the FDA Rules apply only within the borders of the United States.⁵⁹

C. *European Convention on Biomedicine*⁶⁰

The European Convention on Biomedicine (European Convention) recognizes "the primacy of the human being" in medical research.⁶¹ Several conditions must be met prior to the beginning of research.⁶² While the consent of the subject is required prior to experimental treatment,⁶³ the subject need only be given "appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks."⁶⁴ If a child subject is involved, a legal guardian must give consent, but the child's opinion will also be considered.⁶⁵ Even after granting consent, the subject may at any time withdraw such consent.⁶⁶ Finally, just as is also true under the FDA Rules, the European Convention enables a physician to avoid informed consent if obtaining such consent is not practicable and if the action taken is for the direct benefit of the subject.⁶⁷

In order for research to be conducted on human subjects under the European Convention, the following conditions must be met: 1) no comparable alternative research is capable of being undertaken; 2) the risks to the person are not disproportionate to the benefits; 3) an independent review board has approved the research; 4) the subjects have been informed of

⁵⁸ See 45 C.F.R. §46.306 (prisoners) and 45 C.F.R. §46.405 (children).

⁵⁹ See 45 C.F.R. §46.101(a)(1)(2).

⁶⁰ It is important to remember that each European country has its own ethical code. The European Convention on Biomedicine is used here because of the limitations of this article and also because of its place as a representative document. For a brief analysis of various national European laws see ARTHUR ROGERS AND DENIS DURAND DE BOUSINGEN, *BIOETHICS IN EUROPE* (1995).

⁶¹ Convention on Human Rights and Biomedicine, Apr. 4, 1997, E.U., Europ. T.S. No. 164, (entered into force Jan. 12, 1999) reprinted in 36 I.L.M. 817, 821 (July 1997) [hereinafter *European Convention on Biomedicine*].

⁶² See *id.* at art. 5, art. 16. These conditions are similar to those required under the Helsinki Declaration. See generally *Helsinki Declaration*, *supra* note 38.

⁶³ See *European Convention on Biomedicine*, *supra* note 61, art. 5.

⁶⁴ See *id.*

⁶⁵ See *id.* art. 6(2).

⁶⁶ See *id.* art. 16(v).

⁶⁷ See *id.* art. 6(1).

their rights; and 5) adequate informed consent has been given.⁶⁸ It is important to note that the European Convention was intended to embody broad guidelines that would begin to unify practices in the European Union.⁶⁹ The national laws of each country provide more detailed regulation of research.⁷⁰ Given that the European Convention must be acceptable to several European nations, it is understandably less detailed than the FDA Rules.⁷¹

D. *International and Multinational Documents*

1. *World Ethical Agreements Beyond Nuremberg and Helsinki*

Following the first Helsinki Declaration and its revision, the Council for International Organizations of Medical Sciences (CIOMS) and the World Health Organization (WHO) created the Proposed International Guidelines for Biomedical Research Involving Human Subjects (Bioethics Guidelines).⁷² The Bioethics Guidelines, revised in 1992, "contained restrictions on the use of pregnant and nursing women, prisoners, children, and persons with mental or behavioral disorders."⁷³ The Bioethics Guidelines was also the first international document to specifically address the problems of international medical research in developing nations.⁷⁴ The Bioethics Guidelines ad-

⁶⁸ See *id.* art. 16.

⁶⁹ See Council of Europe Directorate of Legal Affairs, *Explanatory Report to the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine* ¶ 4, reprinted in, 36 I.L.M. 826, 827 (January 1997).

⁷⁰ See *id.* at ¶7; see also European Convention on Biomedicine, *supra* note 61, art. 4.

⁷¹ Compare European Convention on Biomedicine, *supra* note 61, at art. 5 with 21 C.F.R. §50.20-25 and 45 C.F.R. §46.116 (both detailing guidelines for informed consent).

⁷² See International Ethical Guidelines for Biomedical Research Involving Human Subjects (1993) [hereinafter International Ethical Guidelines], reprinted in BEYOND REGULATIONS: ETHICS IN HUMAN SUBJECTS RESEARCH (Nancy M.P. King, et al., eds. 1999) [hereinafter BEYOND REGULATIONS].

⁷³ *Effective International Regulation*, *supra* note 22, at 183.

⁷⁴ See, e.g., International Ethical Guidelines, *supra* note 72, at guidelines 8, 10, 15 (for provisions specifically referencing rights and responsibilities where research involves developing nations).

dress the problems of research in developing nations⁷⁵ by requiring that before research may begin, the researcher must certify the following: 1) that the research could not be carried out reasonably well in more developed communities; 2) that the research is responsive to the health needs of the community; 3) that every effort will be made to obtain informed consent; and 4) that the research has been approved by a review board familiar with the community in question.⁷⁶ In those cases in which research is sponsored by the researchers of one nation but is conducted in another nation (externally sponsored research), the Bioethics Guidelines specify that the research must pass ethical review in the researchers' home nation as well as in the nation hosting the research.⁷⁷ In addition, the Bioethics Guidelines contain an equitable principle that the community that bears the burden of the experiment should also be the community to receive benefits from the research.⁷⁸

Because of growing research in the area of diseases, CIOMS also created the International Guidelines for Ethical Review of Epidemiological Studies (Epidemiological Guidelines).⁷⁹ The preamble requires protection of vulnerable populations.⁸⁰ In addition to reinforcing the requirements of the Bioethics Guidelines, the Epidemiological Guidelines stress the need to ensure that participants in developing communities do not consent to research merely to receive much needed health care.⁸¹ They also explain and emphasize the importance of training local health professionals to continue care for the participants after the foreign researchers have departed.⁸² The Epidemiological Guidelines also note the need for cultural sen-

⁷⁵ It is important to note that a "developing community" refers to both an underdeveloped nation and an underdeveloped part of a developed nation. *See id.* at art. 8; *see also Community-based HIV Research*, in *BEYOND REGULATIONS* *supra* note 72, at 82-107.

⁷⁶ *See* International Ethical Guidelines, *supra* note 72, at guideline 8.

⁷⁷ *See id.* at guideline 15. As used in this article, home country refers to the place the researchers are based out of, usually a developed nation. Host country refers to the place where research occurs, usually a developing nation.

⁷⁸ *See id.* at guideline 10.

⁷⁹ *See* CIOMS, International Guidelines for Ethical Review of Epidemiological Studies (Geneva 1991) [hereinafter *Epidemiological Guidelines*], *reprinted in* *BEYOND REGULATIONS*, *supra* note 72, at 239.

⁸⁰ *See id.* at preamble.

⁸¹ *See id.* at guideline 11.

⁸² *See id.* at guideline 17.

sitivity in research, and they continue to require that researchers not conduct research that would be considered unethical in their home nations.⁸³

Both the Bioethics Guidelines and the Epidemiological Guidelines clearly indicate that they are persuasive only; they do not embody law or regulation.⁸⁴ Thus, although the persuasive ethical intent of these documents is evident, nations are not bound to require their researchers to act in accordance with their principles. Nor is there any enforcement mechanism for violations of either set of guidelines.

2. *Human Rights Conventions*

International human rights law and ethics are closely related.⁸⁵ A fundamental concept of both ethics and current human rights law is human dignity.⁸⁶ International treaties and declarations repeatedly prohibit conduct that destroys human dignity. International law prohibits torture, slavery, and genocide, and it promotes the right to life and the right to humane treatment.⁸⁷ Thus, medical experiments that violate the principles of human dignity are likely to be condemned.

The United Nations (U.N.), as a body, has issued no specific declaration regarding human testing, nor has there been any international treaty dealing specifically with this issue.⁸⁸ There are, however, a multitude of organizations within the U.N. that have issued statements regarding human experimentation, and several U.N. treaties have offered broad statements regarding medical testing.⁸⁹ The strongest of these statements is that found in the International Covenant on Civil and Political Rights (ICCPR).⁹⁰ The ICCPR states, "no one shall be subjected without his free consent to medical or scientific

⁸³ See *id.* at guideline 25.

⁸⁴ See NAZI DOCTORS, *supra* note 5, at 161.

⁸⁵ See MALCOM M. SHAW, *INTERNATIONAL LAW* 197 (4th ed. 1997).

⁸⁶ See *id.* at 198.

⁸⁷ See *generally id.* at 203-04.

⁸⁸ See Sonia Le Bris, et al., *International Bioethics, Human Genetics, and Normativity*, 33 Hous. L. Rev. 1363, 1365 (1997).

⁸⁹ See *id.*

⁹⁰ International Covenant on Civil and Political Rights, Dec. 16, 1966, 999 U.N.T.S. 171 (entered into force Mar. 23, 1976), G.A. Res. 2200 A, U.N. GAOR, 21st Sess., Supp. No. 16, at 49, U.N. Doc. A/0316 (1966), available at <http://www.umn.edu/humanrt/instree/b3ccpr.htm>. [hereinafter ICCPR].

experimentation.”⁹¹ The principle of informed consent is, therefore, clearly present in international law.

Another concept found throughout international human rights law is that of bodily integrity. This concept could serve as a basis for condemning improper human experimentation.⁹² For example, the Universal Declaration of Human Rights states “[e]veryone has the right to life, liberty and the security of person.”⁹³ In fact, the concepts of “bodily integrity” and “security of person” are standard provisions of human rights conventions throughout the world.⁹⁴

Although the U.N. as a whole has not yet issued a declaration on the subject, various human rights branches of the U.N. have issued declarations on the issue of human experimentation. The High Commission on Human Rights issued the Resolution on Human Rights and Bioethics,⁹⁵ and The World Conference on Human Rights addressed the issue of human experimentation in the Vienna Programme of Action (Vienna Programme).⁹⁶ The Vienna Programme echoes the Covenant on Economic, Social and Cultural Rights⁹⁷ in stating that everyone has the right “to enjoy the benefits of scientific progress and its applications.”⁹⁸ The Vienna Programme goes on to recognize the problems inherent in the current advances of biomedicine

⁹¹ *Id.* art. 7.

⁹² For a discussion of the possible use of “bodily integrity” as a means of involving international law in bioethics see *Effective International Regulation*, *supra* note 22, at 173-8.

⁹³ Universal Declaration of Human Rights (UDHR), art. 3.

⁹⁴ See Convention for the Protection of Human Rights and Fundamental Freedoms, art. 5(1) Apr. 11, 1950, Europ., 213 U.N.T.S. 222, (entered into force Sept. 3, 1953); American Convention on Human Rights, art. 7(1) Nov. 22, 1969, 1144 U.N.T.S. 123 (entered into force July 18, 1978), *reprinted in* 9 I.L.M. 673 (1969); African Charter on Human and Peoples’ Rights (Banjul Charter), arts. 4, 6 June 27, 1981, *reprinted in* 21 I.L.M. 59 (1981) arts. 4, 6.

⁹⁵ *Resolution on Human Rights and Bioethics*, E.S.C. Res. 1993/91, U.N. ESCOR, Hum. Rts. Comm., 49th Sess., 67th mtg., Supp. No. 3, at 267, U.N. Doc. E/CN.4/1993/122 (1992).

⁹⁶ Vienna Declaration and Programme of Action, U.N. GAOR, 48th Sess., pt. I, 11, U.N. Doc. A/Conf. 157/24 (1993), *reprinted in* 32 I.L.M. 1661, 1667 (1993) [hereinafter Vienna Declaration].

⁹⁷ International Covenant on Economic, Social and Cultural Rights, Dec. 16, 1966, 993 U.N.T.S. 3, art. 15(1) (entered into force Jan. 3, 1976) G.A. Res. 2200A (XXI), 21 U.N. GAOR Supp. No. 16, U.N. Doc. A/6316 (1966) [hereinafter CESCR].

⁹⁸ Vienna Declaration, *supra* note 96, at 1667; see also CESCR, *supra* note 97, art. 15(1).

and calls for international cooperation to "ensure that human rights and dignity are fully respected."⁹⁹ Thus, although the U.N. as a whole has not yet drafted a specific convention on biomedical research with human subjects, such research is a recognized problem with broadly articulated basic principles: human dignity and bodily integrity.

E. *Conclusion — The need for a clear set of enforceable regulations*

Although the FDA Rules and the European Convention set strict standards for studies performed within the United States and the European Union respectively, these rules do not apply extraterritorially.¹⁰⁰ Furthermore, although the problem of bioethics is clearly recognized in international treaties, there is neither a binding international treaty nor an unambiguous set of customary international rules for multinational drug companies to follow. Several international guidelines provide the beginning of a framework, but until they are clearly consolidated, it will remain possible for researchers to pick and choose which ethical rules to follow. In the absence of binding, enforceable international rules or guidelines, research abuses will continue to occur.

III. MEDICAL TESTING IN DEVELOPING NATIONS

There are two primary concerns raised by the internationalization of human experimentation: first is the potential for the exploitation of subjects in developing countries, and second are differences in ethical standards between the host and sponsoring communities. . . it can actually undermine the regulation of human experimentation by creating an incentive for countries to underregulate or underenforce scientific research, including research involving human subjects.¹⁰¹

⁹⁹ Vienna Declaration, *supra* note 96, at 1667.

¹⁰⁰ See, e.g., 21 C.F.R. §312.120 (requiring that foreign studies use the Helsinki Declaration); see also 15 CFR § 101; and *FACING THE 21ST CENTURY*, *supra* note 37, at 224 (noting that only when research is government funded do higher standards apply outside the United States).

¹⁰¹ *Effective International Regulations*, *supra* note 22, at 202.

A. *The Boom of Infectious Diseases and the Need for Family Planning*

"In 1969, the United States Surgeon General announced that the public health, medical, and scientific communities had conquered infectious disease. In 1996, the World Health Organization (WHO) reported that a 'world crisis' in infectious diseases is underway."¹⁰² The WHO has observed that diseases like tuberculosis and AIDS are spreading at an incredible rate in both the developed and the developing world.¹⁰³ Tuberculosis was expected to produce ninety million new cases and thirty million deaths by 2000,¹⁰⁴ and AIDS will infect between thirty and one hundred and ten million people by the year 2000.¹⁰⁵ As these diseases know no borders, drug research to combat these and other diseases has become increasingly important to developed nations.¹⁰⁶

For the governments of developing nations, the research is often welcome. The percentage of people infected with deadly diseases in many developing nations is at crisis levels.¹⁰⁷ In Sub-Saharan Africa, over twenty-two million people were infected with AIDS or HIV at the end of 1999, and an estimated eleven thousand more people become infected every day.¹⁰⁸ In South and Southeast Asia, it is estimated that nearly six and one-half million people are presently infected with AIDS or HIV.¹⁰⁹ Approximately half of these infected people are in India, where concentrated populations facilitate the spread of the virus.¹¹⁰ Even more frustrating for leaders in these developing nations, the cost of potentially helpful drug treatments is too high for a substantial portion of their infected population. Moreover, the government cannot afford the cost of massive

¹⁰² David P. Fidler, *Mission Impossible? International Law and Infectious Diseases*, 10 TEMP. INT'L & COMP. L. J. 493, 494 (1996).

¹⁰³ David P. Fidler, *Return of the Fourth Horseman: Emerging Infectious Diseases and International Law*, 81 MINN. L. REV. 771, 775 (1997).

¹⁰⁴ *Id.* at 777.

¹⁰⁵ *Id.* at 780.

¹⁰⁶ *Id.* at 783.

¹⁰⁷ See *AIDS Initiative*, *supra* note 19.

¹⁰⁸ See *id.*

¹⁰⁹ See Pamela Philipose, *Irrational Complacency, Irrational Fears*, INDIAN EXPRESS, October 22, 1999, available at 1999 WL 5583328.

¹¹⁰ See *id.*

medical research to find new treatments.¹¹¹ Enter pharmaceutical companies willing to fund research that can be lifesaving for the populations of the countries.¹¹² In 1996, for example, southern Africa alone received about \$2.3 billion from pharmaceutical companies researching cures to infectious diseases.¹¹³

Another strong concern facing developing nations is a desperate need for family planning and affordable contraception.¹¹⁴ Overpopulation, pregnancy-related deaths, and unwanted infants in poverty-stricken nations are problems that lead governments to seek outside assistance.¹¹⁵ Pharmaceutical companies are often willing to offer such assistance because the women in such nations are attractive test subjects for new contraceptive devices.¹¹⁶

Where difficult circumstances like these exist, governments may sacrifice human rights to obtain the favor of drug companies;¹¹⁷ or in the alternative, drug companies may pander to governments in order to continue their research in less costly environments.¹¹⁸ In addition, cultural and language barriers may operate to dehumanize research patients in developing nations.¹¹⁹ Finally, standards for conducting research in developing nations may fall far below the requirements in developed nations.¹²⁰

B. *The Difficulties of Informed Consent*

The principle of informed consent has been ingrained in the jurisprudence of the developed world since the Nuremberg

¹¹¹ See Mark Schoofs, *Ending the Epidemic*, THE VILLAGE VOICE, December 21, 1999, at 57.

¹¹² Kurt Shillinger, *African Officials Pursue AIDS Vaccine: Governments are Skeptical of High-Cost Western Drugs such as AZT and Global Imbalances in Research*, PORTLAND OREGONIAN, January 9, 2000, at A16 (noting that one of the largest pharmaceutical companies in the world was considering investing in the area).

¹¹³ See Simon Barber, *U.S. Pharmaceutical Company Eyes South Africa for Tests*, AFRICAN NEWS. SERV., October 21, 1998, available at 1998 WL 21351167.

¹¹⁴ See *Horizon: The Human Laboratory* (British Broadcasting Corporation broadcast, November 5, 1995), available at <http://www.africa2000.com/INDX/bbchorizon.html> [hereinafter *Human Laboratory*].

¹¹⁵ See generally *id.*

¹¹⁶ See *id.*

¹¹⁷ See *Effective International Regulation*, *supra* note 22, at 202.

¹¹⁸ See Shillinger, *supra* note 112, at 104.

¹¹⁹ See Perley, *supra* note 33, at 162.

¹²⁰ *Id.*

Code.¹²¹ Nevertheless, problems involving informed consent are often ignored in developing nations.¹²² Some studies have even questioned the applicability of individual consent in situations where such a concept is entirely foreign.¹²³ At least one study has suggested that in communal societies, like those in much of Africa and parts of Asia, the consent of the community is a necessary precursor to individual consent.¹²⁴ Following this line of thought, the WHO/CIOMS guidelines do allow consent to be given by a community leader.¹²⁵

While community involvement may be necessary in certain societies, requiring only community (or government) consent raises serious concerns about whether the best interests of the individual research subjects will be adequately addressed. Considering the high levels of infectious disease and the costs involved in treating these diseases, community leaders may sacrifice the best interests of the individual research subjects for the perceived greater good.¹²⁶ Furthermore, if consent is gained from the government rather than from the individual research subjects, such government may not have "the same incentive to verify representations of the researchers or to continually supervise the experiment to ensure that it is being carried out as planned."¹²⁷ Government officials may even have an incentive to consent to dangerous research in order to achieve some official policy.¹²⁸

¹²¹ For a discussion of the primacy of consent and the problems with that paradigm see Richard W. Garnett, *Why Informed Consent? Human Experimentation and the Ethics of Autonomy*, 36 CATH. LAW. 455, 455 (1996).

¹²² See Perley, *supra* note 33, at 162.

¹²³ See, e.g., Sheila Conway, *Principles of Ethics in Research*, at <http://health.upenn.edu/bioethics/Museum/Conway/ETHIC1-1.HTM> (last visited December 31, 2000); see also Ruth Macklin, *Is Ethics Universal?*, in *BEYOND REGULATIONS*, *supra* note 72, at 27-8 [hereinafter *Is Ethics Universal?*].

¹²⁴ See generally *Practical Experiences in Obtaining Informed Consent for a Vaccine Trial in Rural Africa*, 336(5) NEW ENG. J. MED. 43 (January 30, 1997).

¹²⁵ See *Changing Landscape*, *supra* note 38, at 125.

¹²⁶ See, e.g., *African AIDS Sufferers Perplexed with Government's AZT Stance*, *NEWSDAY*, December 12, 1999, at A25. See also *Changing Landscape*, *supra* note 38, at 125 (1992); see also Barton Gellman, *S. African President Escalates AIDS Feud; Mbeki Challenges Western Remedies*, *WASH. POST*, April 19, 2000, at A1, available at 2000 WL 19604435. These articles discuss the position of the South African government, which has criticized proven AIDS treatments.

¹²⁷ See *Effective International Regulation*, *supra* note 22, at 192.

¹²⁸ See Rachel Baggailey & Eric von Praag, *Antiretroviral interventions to reduce mother-to-child transmission of human immunodeficiency virus: challenges*

The offering of birth control through government family planning programs has proven particularly problematic because of the government's desire to decrease birth rates. The contraceptive device Norplant was tested in the slums of both Bangladesh and Haiti, prior to its release in the developed world.¹²⁹ In Bangladesh, one native doctor began to hear disturbing stories about women who had been given the Norplant insert, but had been denied removal of the insert on their request.¹³⁰ Her investigation resulted in a military raid of her offices and in several threats from the government.¹³¹ Research trials in Haiti involved similar scenarios of women suffering adverse side effects from Norplant, yet being denied removal of the insert.¹³² These studies highlight the dangers posed by governmental desires that override the wishes of research subjects.

Even when researchers do go directly to potential research subjects for consent, language barriers and cultural differences may impede true understanding of the testing procedure.¹³³ Such lack of understanding is evident in the stories of many subjects of a placebo-controlled tuberculosis study in Uganda.¹³⁴ One English-speaking, university-educated test subject stated that he had understood the word "placebo" to be a "medical word that I was not required to know."¹³⁵ Others thought that "placebo" was simply a different drug that they were being given.¹³⁶ Few of the subjects, if any, understood that they could be part of the control group that would receive Vitamin C tablets instead of the proven medical treatment.¹³⁷

Researchers may not be able to explain to test subjects that they might be placed in a control group not receiving treatment.

for health systems, communities and society, BULLETIN OF THE WORLD HEALTH ORG., August 1, 2000, at 1036 (discussing the problem in the context of mother-to-infant HIV transmissions, the authors note "some countries may claim a compelling interest in protecting the health of unborn children, and in this circumstance it is conceivable that HIV-positive women would be forced to accept anti-retroviral drugs.").

¹²⁹ See *Human Laboratory*, *supra* note 114.

¹³⁰ See *id.*

¹³¹ See *id.*

¹³² See *id.*

¹³³ See Perley, *supra* note 33, at 162.

¹³⁴ See *Ugandan Study*, *supra* note 17, at 1A.

¹³⁵ *Id.*

¹³⁶ See *id.*

¹³⁷ See *id.*

One researcher involved in the tuberculosis tests recalled telling patients they could receive a drug that was "nothing."¹³⁸ The patient subjects interviewed, however, understood only that they were receiving treatment.¹³⁹ Finally, the promise of medical care and the free examinations that often accompany drug testing may serve as inducements that render true, voluntary consent unlikely.¹⁴⁰

While informed consent may appear to be only a signature on a piece of paper, a mere formality that pales in comparison to the threat of AIDS and like diseases, the reality is much different. Dire consequences have resulted from the testing of drugs where doctors have not been required to obtain fully informed consent.¹⁴¹ In many circumstances, informed consent serves as a check on unethical testing.¹⁴² If drug companies cannot obtain willing subjects for their research projects after full disclosure, such projects should not be conducted at all.¹⁴³

C. *Use of Placebos and The Issue of Standard of Care*

Much of the recent controversy surrounding drug testing in developing countries involves the standard of care and the use of placebo control groups. At issue is the ethical guideline requiring that control groups be given the best possible treatment.¹⁴⁴ Recent debate has centered around fifteen placebo-controlled tests¹⁴⁵ that involved administering a shortened, less costly course of an antiviral drug to pregnant women in an attempt to stop the transmission of AIDS to their unborn chil-

¹³⁸ *Ugandan Study*, *supra* note 17, at 1A.

¹³⁹ *Id.*

¹⁴⁰ See *Effective International Regulation*, *supra* note 22, at 201-02; see also Dickens, *supra* note 21, at 193.

¹⁴¹ See Michelle D. Miller, RN, MPH, *The Informed Consent Policy of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use: Knowledge is the best Medicine*, 30 CORNELL INT'L L. J. 203, 219 (1997).

¹⁴² See *id.*

¹⁴³ See *id.*; see also Dickens *supra* note 21, at 195.

¹⁴⁴ See *Helsinki Declaration*, *supra* note 38, sec. II, para. 3. For the debate as it has appeared in the medical community, see generally *Clinical Research*, *supra* note 9, 578-583 (use of placebos deemed unethical), but see Harold Varmus & David Satcher, *Ethical Complexities of Conducting Research in Developing Countries*, reprinted in *TUSKEGEE'S TRUTHS*, *supra* note 9, 584-588 (use of placebos deemed ethical).

¹⁴⁵ See Fairchild & Bayer, *supra* note 13, at 598.

dren.¹⁴⁶ Included in the tests were placebo groups, the members of which would receive no medication at all.¹⁴⁷

A few years prior to these experiments, tests completed in the United States demonstrated the effectiveness of giving mothers a full course of zidovudine (AZT).¹⁴⁸ Those tests showed that the full course of the drug almost completely eliminated the transmission of HIV to the child.¹⁴⁹ Subsequent to these findings, the use of the longer AZT treatment became standard in developed countries.¹⁵⁰ Thus, the tests using placebo groups instead of control groups being given the longer treatment regime would have been considered unethical in the developed world because the best possible treatment was not being given to the control group.

Those criticizing the placebo-control research note that researchers funded by money from the United States have an ethical duty to provide the same standard of care to research subjects in developing nations as would be given in the United States.¹⁵¹ These critics also point out that the women in the placebo groups will receive no treatment, despite the fact that effective treatment does exist. As a result, these women and their babies are likely to die.¹⁵²

Defenders of the placebo-control tests offer a two-fold argument for denying AZT treatment to the control groups during the research trials. First, it is argued that such treatment is too costly to be standard treatment in the test countries.¹⁵³ The cost of a standard, long course treatment of AZT for one preg-

¹⁴⁶ See David Brown, *Short-Term Drug Therapy Cuts Infants' Risk of AIDS*, CHICAGO SUN-TIMES, February 3, 1999 at 52. The shortened course was AZT during the last few weeks of pregnancy.

¹⁴⁷ See *id.* The United States, Denmark, France, South Africa, and the United Nations Program on Acquired Immune Deficiency Syndrome funded these tests. See Fairchild & Bayer, *supra* note 13, at 598.

¹⁴⁸ See Brown, *supra* note 146, at 52. A full course was AZT during the last trimester of pregnancy.

¹⁴⁹ *Id.*

¹⁵⁰ See Clinical Research, *supra* note 9, at 579.

¹⁵¹ See David M. Studdert & Troyen A. Brennan, *Clinical Trials in Developing Countries: Scientific and Ethical Issues*, 169 MED. J. AUSTRAL. 545-548 (Nov. 16, 1998), available at <http://www.mja.com.au/public/issues/nov16/studdert/studdert.html>.

¹⁵² See *id.*

¹⁵³ See Varmus & Satcher, *supra* note 144, at 587.

nant woman is between \$400 and \$900.¹⁵⁴ In Sub-Saharan Africa, however, the funding available for medical treatment amounts to approximately \$14 per person per year.¹⁵⁵ In denying the treatment to the control groups, therefore, it is argued that the pregnant women in these control groups are in no worse position than they would ordinarily be.¹⁵⁶ Second, as one researcher noted, if all test subjects were to receive AZT treatment, it would be nearly impossible for researchers to determine whether the new treatments being tested were better than no treatment at all.¹⁵⁷

Placebo-controlled tests conducted in Uganda to determine the effectiveness of new tuberculosis drugs present an even greater stretch of ethical boundaries. Despite the fact that effective tuberculosis treatments were available prior to the testing, control groups of Ugandan tuberculosis patients with AIDS received no treatment at all.¹⁵⁸ In contrast, virtually identical tests had previously been conducted in fifty-two locations within the United States, Mexico, Haiti and Brazil,¹⁵⁹ and in none of these tests had the researchers deemed it necessary to give placebos to any of the patients.¹⁶⁰ The control groups in these tests received the standard twelve-month treatment.¹⁶¹ Without leaving any patients vulnerable to untreated tuberculosis, the United States, Mexico, and Haiti tests successfully concluded that a two-month supply of the new tuberculosis drugs was as effective as a twelve month supply of the old drugs.¹⁶²

In Uganda, on the other hand, patients were left untreated for at least nineteen months while U.S. researchers tracked the

¹⁵⁴ See Dennis R. Cooley, *Second Best: A Case for Lowering Testing Standards in Third World Countries*, Paper presented at the 20th World Congress of Philosophy (Aug. 15, 1998), available at <http://www.bu.edu/wcp/Papers/Bioe/BioeCool.htm>.

¹⁵⁵ See *id.*

¹⁵⁶ See Varmus & Satcher, *supra* note 144, at 586.

¹⁵⁷ See Kim Dalton, *AZT Trials in the Third World: Tuskegee Redux or Cheap Shot?*, available at <http://www.columbia.edu/cu/21stC/issue-3.3/dalton.htm>.

¹⁵⁸ See *Ugandan Study*, *supra* note 17, at 1A.

¹⁵⁹ See *id.*

¹⁶⁰ See *id.*

¹⁶¹ See *id.*

¹⁶² See *id.*

course of the disease.¹⁶³ Researchers in Uganda defended the decision on the grounds that the Ugandan government required a placebo group before testing would be allowed.¹⁶⁴ This dichotomy between the treatment of test subjects in the developing world and the treatment of those in the developed world has led at least one researcher from the Center for Disease Control to comment, "Is it possible that a study that is 'unethical' in one socioeconomic and epidemiologic setting can be 'ethical' in a different setting?"¹⁶⁵

This cultural relativism has been widely defended and criticized.¹⁶⁶ As noted by a prominent civil rights attorney, Fred D. Gray, formerly involved in lawsuits pertaining to the Tuskegee experiments, "A human life in a foreign country is as valuable to them as our lives are in this country."¹⁶⁷ Rather than insisting on the best possible treatment for the individual test subjects as patients and people, the individual becomes an unacceptable means to an end—the development of a drug or the pleasing of a government official.¹⁶⁸ Meanwhile, those receiving placebos unnecessarily are left at risk to fully develop a disease, or worse yet, to die from an existing disease for which there is effective treatment.¹⁶⁹

D. *The Use of Vulnerable Populations*

One ethical problem with clinical tests in developing nations is that the people of these nations, by their circumstances, constitute vulnerable populations. They are, therefore, entitled to a higher standard of care.¹⁷⁰ Following the public disclosure

¹⁶³ See *Ugandan Study*, *supra* note 17, at 1A.

¹⁶⁴ See *Tuberculosis Study*, THE PORTLAND OREGONIAN, November 26, 1998, at A09, available at 1998 WL 20388040. In fact, the cost of the tuberculosis treatment was relatively inexpensive. See *id.*

¹⁶⁵ *Ugandan Study*, *supra* note 17, at 1A (quoting a researcher from the Center for Disease Control).

¹⁶⁶ See *Clinical Research*, *supra* note 9, at 580-81.

¹⁶⁷ See *Ugandan Study*, *supra* note 17, at 1A.

¹⁶⁸ See Marcia Angell, *Editorial Responsibility: Protecting Human Rights by Restricting Publication of Unethical Research*, in NAZI DOCTORS, *supra* note 5, at 277.

¹⁶⁹ See *Ugandan Study*, *supra* note 17, at 1A.

¹⁷⁰ See Fairchild & Bayer, *supra* note 13, at 597 ("In the case of Third World trials to prevent maternal-fetal HIV transmission, two core elements of Tuskegee were at issue: the exploitation of impoverished vulnerable populations and the denial of access to effective treatment.").

of the Tuskegee experiments, the Belmont Report was issued.¹⁷¹ This report contained three principles for research—autonomy, beneficence, and justice.¹⁷² Inherent in the concept of justice is the protection of vulnerable populations from bearing a disproportionate share of medical research.¹⁷³ Not only are the people of developing nations subject to an extraordinary amount of medical research, but much of that research centers on women and children.

Under the Bioethics Guidelines, women (particularly pregnant women) and children are accorded special protections during biomedical testing.¹⁷⁴ The Epidemiological Guidelines also note the importance of protecting vulnerable populations.¹⁷⁵ Protection of vulnerable populations is not, however, a new concept. The United Nations Convention on Economic, Social and Cultural Rights (CESCR), states:

“Special protection should be accorded to mothers during a reasonable period before and after childbirth . . . Special measures of protection and assistance should be taken on behalf of all children and young persons. . . Children and young persons should be protected from economic and social exploitation.”¹⁷⁶

Achieving protection may, however, be difficult in those nations in which women are viewed as the property of their husbands.¹⁷⁷ In these circumstances, partners may pressure women not to get tested for AIDS or enter clinical trials so as to avoid the social stigma of such diseases.¹⁷⁸ Alternatively, male partners may push women to take part in the studies, regardless of the woman's desire.¹⁷⁹ This concern is particularly relevant when a woman is pregnant, as the father of the unborn child may force the woman to undergo treatment for the benefit of the child, ignoring the potential consequences for the wo-

¹⁷¹ See generally JONES, *supra* note 10.

¹⁷² See *id.*; see also Conway, *supra* note 123.

¹⁷³ See Conway, *supra* note 123.

¹⁷⁴ See International Ethical Guidelines, *supra* note 72, at guidelines 5, 11.

¹⁷⁵ See Epidemiological Guidelines, *supra* note 79, at preamble.

¹⁷⁶ See CESCR, *supra* note 98, art. 10.

¹⁷⁷ See Ruth Macklin, *Universality of the Nuremberg Code*, in NAZI DOCTORS, *supra* note 5, at 251[hereinafter *Universality of Nuremberg*].

¹⁷⁸ See Baggailey & Von Praag, *supra* note 128, at 1036.

¹⁷⁹ See *id.*

man.¹⁸⁰ Under such circumstances, principles of confidentiality and consent are difficult to uphold.¹⁸¹

An inability to obtain valid consent from women is particularly problematic in the context of family planning because the failure to obtain consent amounts to a failure to protect bodily integrity. In the Norplant test in Bangladesh, for example, the data of the sponsoring organization indicated that the repeated requests of over one hundred women for removal of the Norplant device were refused.¹⁸² One researcher fighting the Norplant trials in Bangladesh told British Broadcasting Corporation reporters, "our woman [sic] are cheaper here . . . they can be easily controlled and their bodies can be easily tested."¹⁸³

Birth control is not the only area of concern when women are involved in research. With medical resources scarce in many developing nations, those seeking basic medical treatment may regard clinical trials as the only avenues by which they may obtain such treatment. In order to protect their unborn children, pregnant women, particularly those infected with AIDS, are often the most willing to participate in any medical test offering a ray of hope.¹⁸⁴ Thus, a disproportionate number of the participants in research trials in African or Asian countries are pregnant women and their unborn children.¹⁸⁵

While participation in clinical trials can be life saving, dangers do exist. Many women have no other realistic means of receiving normal health care for themselves or their children,¹⁸⁶ thus, they may feel that they are being coerced into participating in drug research simply to receive basic medical care.¹⁸⁷ Informed consent, therefore, is potentially lacking. Furthermore, while the effects upon adult women are often considered in the development of drugs and vaccines, the effects of the same

¹⁸⁰ See *id.*

¹⁸¹ See *Universality of Nuremberg*, *supra* note 172, at 251.

¹⁸² See *Human Laboratory*, *supra* note 114.

¹⁸³ See *id.* (quoting Farida Akhter).

¹⁸⁴ See Dickens, *supra* note 21, at 193; see also Brown, *supra* note 146, at 52; and FACING THE 21ST CENTURY, *supra* note 37, at 115-17.

¹⁸⁵ See *Effective International Regulation*, *supra* note 22, at 194.

¹⁸⁶ See Wendy K. Mariner, *AIDS Research and the Nuremberg Code*, in NAZI DOCTORS, *supra* note 5, at 295.

¹⁸⁷ See *id.*; see also Baggailey & von Praag, *supra* note 128, at 1036.

drugs and vaccines on pregnant women and their fetuses are often unknown.¹⁸⁸ The dangers of testing drugs with unknown side effects on pregnant women and their unborn children are well-documented.¹⁸⁹

Children may also be particularly vulnerable. In the first place, it is questionable whether or not children are even capable of consenting to research performed on them.¹⁹⁰ The special situation of children and research has frequently been addressed. The European Convention, for example, recognizes the particular vulnerability of children. It requires that children only be used when the research provides a direct benefit to them and only when no other comparable research can be conducted on adults.¹⁹¹ The Convention on the Rights of the Child also requires that children be afforded special protection.¹⁹² The FDA Rules require that the Independent Review Board (IRB) ensure that the consent of a parent or legal guardian is obtained,¹⁹³ that there be an additional showing that there is no other way to conduct the research,¹⁹⁴ and that the research is for the benefit of the child.¹⁹⁵ Finally, the Bioethics Guidelines include similar provisions requiring both consent and a demonstration that alternative methods of research are lacking.¹⁹⁶

In addition to the concerns expressed in the various international Conventions and Guidelines, the use of children in research raises practical scientific concerns. Most drugs are tested in the laboratory solely for their effect on adults.¹⁹⁷ The effects on children, like those on the fetus, are usually not the top priority of researchers. Rather than specifically considering the potential effects of the experimental drugs on children as

¹⁸⁸ See, e.g., *FACING THE 21ST CENTURY*, *supra* note 37, at 118, detailing the development and release of Thalidomide.

¹⁸⁹ See *id.* Thalidomide was a drug given to pregnant women to control morning sickness. It caused severe birth defects in over 8,000 babies. See *id.*

¹⁹⁰ See *Effective International Regulation*, *supra* note 22, at 192.

¹⁹¹ See European Convention on Biomedicine, *supra* note 61, at art. 17.

¹⁹² See generally Convention on the Rights of the Child, G.A. Res. 44/25, annex, 44 U.N. GAOR, Supp. No. 49) at 167, U.N. Doc. A/44/49 (1989), *reprinted in* 28 I.L.M. 1448 (1989).

¹⁹³ See 21 C.F.R. §46.408.

¹⁹⁴ See 21 C.F.R. §46.407.

¹⁹⁵ See 21 C.F.R. §46.406.

¹⁹⁶ See International Ethical Guidelines, *supra* note 72, at guideline 5.

¹⁹⁷ See *FACING THE 21ST CENTURY*, *supra* note 37, at 116.

opposed to adults, researchers may simply use smaller dosages when using children for research. For many drugs, however, simply giving a child a smaller dose will not appropriately address health concerns.¹⁹⁸

E. *Determining the Beneficiaries of the Treatment*

For a clinical trial to be justly administered, it must be conducted only on a population likely to benefit from the specific research being conducted.¹⁹⁹ Thus, tests in the developing world must be capable of solving problems in the community where the test occurs, and the solution must be one that will be realistically available to the community.²⁰⁰ Diseases such as AIDS present difficulties in this respect because there are several strains of the disease.²⁰¹ A drug may be effective on one strain, but not on others.²⁰² This problem begins to affect developing nations when their citizens are used to find cures for the strains of diseases not present in their own nations, but rather for strains present in the developed world.²⁰³

Strains of AIDS common in developed nations often differ from those present in developing African nations.²⁰⁴ Yet, the vaccines tested in these developing nations are generally intended to produce treatments for the strains of disease present in developed nations.²⁰⁵ Thus, the very people on whom the drugs are being tested will not, in many cases, receive any benefit from the drug. Nor will the developing nations that allow large pharmaceutical concerns to perform research within their borders derive any benefit for their citizens from the research. This situation represents a direct violation of those provisions of the Bioethics Guidelines and the Epidemiological Guidelines requiring that the benefit to the subject population be proportional to the risk that population bears.²⁰⁶

¹⁹⁸ See *id.*

¹⁹⁹ See Conway, *supra* note 123.

²⁰⁰ See *id.*

²⁰¹ See Dickens, *supra* note 21, at 192.

²⁰² See *id.*

²⁰³ See *id.*

²⁰⁴ See *id.*

²⁰⁵ See *id.*; see also Henderson, *supra* note 20.

²⁰⁶ See International Ethical Guidelines, *supra* note 72, at guideline 10; see also Epidemiological Guidelines, *supra* note 79, at preamble.

Why would a government allow research to occur for strains different from those within its borders? First, many developing nations are absolutely dependent on the help of the pharmaceutical concerns of developed nations for any drug treatments.²⁰⁷ Such nations cooperate with the research of pharmaceutical concerns to ensure that their citizens receive at least a modicum of medical protection. Secondly, government officials in developing nations may hope that a cure for one strain will lead to a cure for others, or that a side effect of serving as a testing ground for developed nations will be the discovery of a solution for their own problems. Finally, the governments of developing nations are probably aware that the subjects of the trials likely fail to understand that they are being treated for strains of the disease different from the strain with which they are afflicted.²⁰⁸ Such popular ignorance may reduce fears of political backlash.

Furthermore, pharmaceutical researchers could take advantage of popular ignorance and government acquiescence to test potentially dangerous levels of new drugs. For example, some have leveled accusations at pharmaceutical concerns claiming that women in developing nations are being used to test the doses of hormone levels in advance of similar testing in the developed world.²⁰⁹ If such accusations are accurate, it would be quite clear that a lesser value is being placed on the health and the lives of the research subjects in the developing nations.

Another very real problem is whether a particular drug is realistically available for use by the host country. Again, the issue of resources is at the heart of the problem. In the case of the tuberculosis studies, there was no evidence that the Ugandan government intended to use the drug being tested, or even that it had any ability at all to do so.²¹⁰ While not all researchers agree, many researchers believe that the testing of drugs in developing countries which are realistically only of use

²⁰⁷ See *AIDS Initiative*, *supra* note 19.

²⁰⁸ See *Perley*, *supra* note 33, at 162.

²⁰⁹ See *Human Laboratory*, *supra* note 114.

²¹⁰ See *Ugandan Study*, *supra* note 17, at 1A.

only to developed nations is a violation of "our most basic understanding of ethical behavior."²¹¹

F. *Governmental Pressures in Developing Nations*

Even when researchers attempt to act according to the highest ethical standards, they may encounter problems within the host country. The importance of maintaining good relationships with the host country government often takes precedence over the rights of the individual research subjects.²¹² A leading researcher at Johns Hopkins University described the problem succinctly, "You often end up having to do studies that may not be absolutely scientifically necessary but are needed to convince people it's the right thing to do."²¹³ In other words, drug tests are often conducted simply because the government officials want them done.

A situation involving the government of South Africa and the testing of an anti-AIDS drug is instructive.²¹⁴ The Health Minister of South Africa has refused to allow doctors to provide a drug known to prevent the contraction of AIDS to rape survivors unless there is a control group of rape victims who do not receive the drug.²¹⁵ Doctors protest the use of a control group calling it "tantamount to murder."²¹⁶ The doctors specifically note the existence of data that shows the drugs will prevent the contraction of AIDS, and they lament the denial of medication to women who have "fought so hard to live and to survive the rape."²¹⁷ Nevertheless, while doctors and government officials debate, the \$100-million dollar grant from pharmaceutical companies remains unused, and more and more women are each day denied a chance to receive the life-saving drug.²¹⁸ Quite simply, doctors and medical researchers are often caught between firm adherence to ethical testing procedures and at-

²¹¹ See Varmus & Satcher, *supra* note 144, at 584.

²¹² See *Ugandan Study*, *supra* note 17, at 1A (quoting Dr. Neal Halsey).

²¹³ See *id.*

²¹⁴ See Charlene Smith, *Zuma Resist Rape/HIV Studies*, AFRICAN NEWS SERV., May 21, 1999, available at 1999 WL 17314778.

²¹⁵ *Id.*

²¹⁶ *Id.*

²¹⁷ *Id.*

²¹⁸ *Id.*

tempting to placate those government officials without whose cooperation no testing at all would occur.²¹⁹

IV. RESPONDING ETHICALLY

A. *The Recognition of the Importance of Ethics*

When dealing with any transnational endeavor, questions about applicable rules always arise.²²⁰ Nowhere is this more true than in medical ethics.²²¹ Nevertheless, despite the existence of real cultural differences, it has been argued "that the ethical requirements for human subjects research rest on universal ethical principles."²²² Such universal principles would include the principles of human dignity and bodily integrity. The recognition of universal ethical principles is an important first step in their application to transnational research.²²³ Without this recognition, any regulation undertaken by one country, even when limited in effect to its own researchers, is subject to the charge of cultural imperialism.²²⁴ On the other hand, if international agreement regarding the primacy of the human being is reached, meaningful rules for the field of transnational bioethics can be formulated and enforced.²²⁵

B. *An International Legal Regime*

Perhaps the greatest problem facing international bioethics regulation is the fact that no enforceable international law exists, and no enforcement mechanism is in place.²²⁶ This has prompted some to call for the creation of an internationally binding document. M. Cherif Bassiouni, for example, has drafted a convention for the prevention of unlawful human

²¹⁹ *Id.*

²²⁰ *See generally Is Ethics Universal*, *supra* note 123, at 23-7 (discussing some of the conflicts in ethical principles when research is conducted internationally).

²²¹ *See generally id.* at 23-4.

²²² *Id.* at 24.

²²³ For a detailed analysis of the difference between the universality of bioethical principles and the non-universality of bioethical procedures, *see id.*

²²⁴ *See id.* at 27.

²²⁵ For an assessment of the problem with allowing countries to claim cultural relativism, *see generally id.*; *see also Universality of Nuremberg*, *supra* note 177, at 253.

²²⁶ *See Effective International Regulation*, *supra* note 22, at 185.

rights experiments.²²⁷ Others have called for the addition of a protocol to Article 7 of the ICCPR.²²⁸ Finally, still others have noted the need for either a statute to the new International Criminal Court or a permanent international tribunal to hear international violations of medical research ethics.²²⁹ Whatever the form such a binding agreement and enforcement mechanism should take, it is becoming increasingly evident that countries cannot deal with these problems on their own.²³⁰

C. *Regulation of Nationals*

The WHO/CIOMS states that pharmaceutical testing conducted in developing nations by researchers from developed nations must meet the standards of both the home nation as well as those of the developing nation hosting the research.²³¹ To actually follow these guidelines, researchers within the United States would be bound by the FDA Rules and those in Europe would be required to follow both the European Convention and their own national research laws. All researchers would be required to abide by the laws of the individual developing nations in which the research is performed. Unfortunately, however, unless a nation formally adopts the WHO principles as law, they are not binding, but merely suggestive.²³² Widespread adoption of such principles by the governments of developing nations is, therefore, necessary in order to create a uniform standard for research in developing nations.

Developed nations, however, need not rely on developing nations to adopt ethical principles in order to regulate their own doctors, researchers, and corporations. It has long been a tenet of international law that a state may exercise jurisdiction over its citizens and its corporate entities wherever they may be located.²³³ "The nationality of a corporation (more so than the nationality of its employees) is (or should be) an important consideration in determining the degree to which domestic laws

²²⁷ See Perley, *supra* note 33, at 166.

²²⁸ See *Effective International Regulation*, *supra* note 22, at 11.

²²⁹ See Annas & Grodin, *supra* note 30, at 118.

²³⁰ See *id.*

²³¹ See International Ethical Guidelines, *supra* note 72, at guideline 15.

²³² See *id.*

²³³ See P. T. MICHULINSKI, MULTINATIONAL ENTERPRISES AND THE LAW 124 (1996).

and standards apply extra-territorially.”²³⁴ Thus, the governments of the United States and of European nations could choose to force drug companies to comply with national laws regarding consent, the use of placebos, and the implementation of testing safeguards for vulnerable test populations.²³⁵

As is true of most international law, the principle of extra-territorial regulation of nationals is not absolute.²³⁶ It has been toned down by the “rule of reasonableness.”²³⁷ This rule requires nations using extraterritorial laws in the regulation of their nationals to yield their laws when enforcement would “unreasonably interfere with the interests of other states.”²³⁸ The rule requires a balancing approach to consider which nation’s interests should prevail.²³⁹ Under this rule, however, attempted enforcement of bioethics principles in order to protect the individual human rights of subjects is likely to be deemed “reasonable.” The governments of developed nations should, therefore, insist that their pharmaceutical concerns and their researchers conduct research under the highest possible standard of ethics.²⁴⁰

D. *Solutions from the Research Community*

While legally enforceable regulations could solve medical research problems involving individual companies, in the larger picture something more is needed. The world of biomedicine is inherently an ethical one.²⁴¹ Thus, “authorities that seek to persuade, cajole, and shame can do more to create effective policy than those that exercise coercive power.”²⁴²

²³⁴ Mark Gibney & R. David Emerick, *The Extraterritorial Application of United States Law and the Protection of Human Rights: Holding Multinational Corporations to Domestic and International Standards*, 10 TEMP. INT'L & COMP. L.J. 123 (1996).

²³⁵ See MICHULINSKI, *supra* note 233, at 124.

²³⁶ For a fairly complete treatment of the use of laws that operate extraterritorially to regulate nationals, see A.V. LOWE, *EXTRATERRITORIAL JURISDICTION* (1983).

²³⁷ See THE EXTRATERRITORIAL APPLICATION OF NATIONAL LAWS 46-7 (Dieter Lange & Gary Born, eds. 1987).

²³⁸ *Id.*

²³⁹ *Id.*

²⁴⁰ See Gibney & Emerick, *supra* note 234, at 124.

²⁴¹ See Robert Schwartz, *Bioethics Policy: Looking Beyond the Power of Sovereign Governments*, 33 HOUS. L. REV. 1283, 1284 (1997).

²⁴² *Id.*

The refusal of reputable medical journals to publish test results from unethical experiments would go far to prevent the research from taking place.²⁴³ The Second Helsinki Declaration recognized this concept with its admonitions that “[r]eports not in accordance with the principles laid down in this Declaration should not be accepted for publication.”²⁴⁴ As most researchers compete for limited funding, and as most funding is contingent on past success (as evidenced by publication), such a refusal can have great practical effect.²⁴⁵ Many reputable journals already adhere to the Helsinki principles,²⁴⁶ and continued adherence is important as it demonstrates that research is not justified by its conclusions.²⁴⁷ This principle cannot be ignored when research is conducted in developing nations.²⁴⁸

E. *Necessary Rules*

When attempting to create enforceable ethical rules for drug trials in developing nations, some principles should take priority. First, informed consent does not in and of itself justify unethical research. While informed consent is certainly a necessity, no one should be asked to consent to a study that is of no meaningful benefit either to the subjects of the study or to the greater community involved. If people were not asked to participate in such studies, concerns about people consenting solely for the purpose of receiving medical treatment would likely be diminished.

In order to ensure that research is conducted in an ethical manner, the U.S. National Bioethics Advisory Commission has issued recommendations for guidelines that would require researchers to submit an explanation of how the treatment, if successful, will be made available to the host country.²⁴⁹ This recommendation has sparked a serious out-cry, but it actually

²⁴³ For a comprehensive analysis of this issue, see Angell, *supra* note 168, at 276.

²⁴⁴ See *Helsinki Declaration*, *supra* note 38, at principle 8.

²⁴⁵ See Angell, *supra* note 168, at 279.

²⁴⁶ See *Clinical Research*, *supra* note 9, at 581.

²⁴⁷ See *id.*

²⁴⁸ See *id.*

²⁴⁹ See, e.g., Gretchen Vogel, *Stricter Rules for Third-World Trials?*, SCIENCE DAILY INSIGHT, (Oct. 2, 2000), at <http://www.apnet.com/insight/10022000/graphb.htm> (quoting several researchers).

represents the highest ethics. If a drug is incapable of use by a host country, using the people of that country to test the drug renders them little more than guinea pigs. While at least one bioethicist has commented, "If people are consenting . . . the whole assumption that somehow we owe them something seems illogical,"²⁵⁰ such an opinion shows a callous disregard for those participating in clinical trials. Researchers clearly owe a duty to those persons involved in a study to conduct research according to the highest ethical standards, and to perform such research for the benefit of their subjects' communities.

Second, where there is reason to believe that a community or government is compromised in giving informed consent, such as where there is a health crisis or a government policy at issue, informed consent should be obtained directly from those who would participate in the trial. Some members of the community, particularly women, may not feel entirely comfortable giving consent on their own, but researchers can address this problem by spending time in dialogue with the host community. Such dialogue could be modeled after researchers' experiences with poor communities within the United States.²⁵¹ The use of community review boards and attempts to create a dialogue with the specific research population prior to the beginning of the research can improve cooperation during the research.²⁵² Such an approach allows people and local government leaders to feel invested in the research, rather than simply subjects of it.²⁵³ The open dialogue approach could also help to allay some of the problems with host governments. Where a government is educated as to the nature and purpose of the research, and where host country doctors are included in the trial, the result is likely to be greater understanding and adherence to ethical procedures. This approach is already being used in some communities.²⁵⁴ In some South African villages, for example, field

²⁵⁰ See *id.* (quoting bioethicist Norman Frost of the University of Wisconsin, Madison).

²⁵¹ See generally *Community-based HIV Research*, in *BEYOND REGULATIONS*, *supra* note 72, at 83-107.

²⁵² See *id.* at 95. For the complete story of how community based research was conducted in underdeveloped communities within the United States, see *id.* Also, note the problems created when a review board begins to be a part of the research team rather than representatives of the community. See *id.* at 104-05.

²⁵³ See *id.* at 101.

²⁵⁴ See Smith, *supra* note 214, at A16.

workers have spent more than a year preparing the community for a possible AIDS vaccine program that is not even developed yet.²⁵⁵

In addition to proper preparation, it is important that the host community not believe that it will be abandoned after the researchers leave. Willingness to train indigenous medical personnel to ensure care after the researchers have departed can also contribute to better cooperation.²⁵⁶ Additionally, such training will provide a community with lasting benefits from a research project even if the vaccine being tested proves ineffective.²⁵⁷

V. CONCLUSION

The ethical problems of research in developing countries are far from being solved. As this article is completed, a Pennsylvania drug company has asked the FDA to approve clinical trials in Latin America of a new treatment for infants with life-threatening lung illnesses.²⁵⁸ The company has requested that a placebo group be approved, despite the existence of known treatments for the disease.²⁵⁹ Perhaps most disturbing, the company can perform the tests even without FDA approval.²⁶⁰ Similar trials in Europe will not involve placebos.²⁶¹ The FDA is still considering the experiments.²⁶²

Perhaps the most important solution to the ethical dilemmas in medical research is awareness. Pharmaceutical companies are as subject to political and public pressure as the next profit-seeking enterprise. Furthermore, researchers are often dependent on university or government funding. As political and public pressure can influence funding decisions, the exertion of such pressures on universities and governments will effectively control the nature and manner of the research being performed. An insistence by people in developed nations that the rights of people in other countries be respected is, in actual-

²⁵⁵ See *id.*

²⁵⁶ See Dickens, *supra* note 21, at 194.

²⁵⁷ See *id.*

²⁵⁸ See Flaherty & Stephens, *supra* note 24, at A03.

²⁵⁹ See *id.*

²⁶⁰ See *id.*

²⁶¹ See *id.*

²⁶² See *id.*

ity, simply an insistence that there be no deviation from standards that protect all people from dangerous research. It is only too easy to justify unethical research at home once it has been performed abroad. Vigilant adherence to basic protections in medical experiments ensures that no one will become a victim of unethical research.