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PFIZER'S EPIDEMIC: A NEED FOR INTERNATIONAL REGULATION OF HUMAN EXPERIMENTATION IN DEVELOPING COUNTRIES

David M. Carr[†]

"[O]ne cannot consider rights without also considering duties. Whenever a human right is stated, it implies an obligation on someone else to do something for the possessor of the right . . . and when I recognize the rights of other people, I incur a duty to act so that the rights are in fact realized. Rights and duties are the positive and negative sides of the same process."¹

Introduction

In 1996, an outbreak of spinal meningitis struck West Africa, reportedly claiming more than fifteen thousand lives.² Pfizer, Inc.—a major international pharmaceutical company—rushed to the nation's aid, bringing needed supplies and medical staff, but Pfizer had something extra in its pocket for Nigeria: Trovan, an experimental drug for the treatment of meningitis.³

Doctors treated close to one hundred children with Trovan and, six weeks later, left Nigeria with their research findings.⁴ Shortly after Pfizer's departure, locals began reporting severe health problems, even death,

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¹ M. Weatherall, *Research Sponsored by Industry*, in MEDICAL EXPERIMENTATION AND THE PROTECTION OF HUMAN RIGHTS: PROCEEDINGS OF THE XIITH CIOMS ROUND TABLE CONFERENCE 52 (Dr. Normal Howard Jones & Dr. Zbigniew Bankowski eds., 1978).

² David Warsh, Where the Germs Are, *Boston Globe*, Jan. 2, 2001, at C1; Families: Pfizer Hurt, Killed Kids, Sept. 3, 2001, at http://www.swisstox.net/en/news_e.php?st_lang_key=en&st_news_id=735.

³ Joe Stephens, *The Body Hunters: Exporting Human Experiments: Where Profits and Lives Hang in the Balance: Finding an Abundance of Subjects and Lack of Oversight Abroad, Big Drug Companies Test Offshore to Speed Products to Market*, *WASH. POST*, Dec. 17, 2000, at A1.

⁴ *Id.* According to Pfizer, the oral form of Trovan had never before been tested on children. *Id.*

resulting from their involvement with Pfizer's research.⁵ Investigations by news reporters showed indications of forgery of research documents,⁶ lack of oversight of research procedures,⁷ and a failure to administer effective treatment to needy participants.⁸ In August of 2001, the families of the children who participated in the Kano research brought a lawsuit claiming that Pfizer had violated international and national laws in carrying out experimental research on humans.⁹ Pfizer's case is the first instance in U.S. history of foreign individuals bringing a lawsuit against a private corporation for wrongful experimentation in violation of U.S. and international law.¹⁰ The facts of the Pfizer case illustrate the declining effectiveness and trust in national courts, and the growing need for international intervention.¹¹

In December 1998, the Director-General of the World Health Organization ("WHO"), Dr. Gro Harlem Brundtland, stood before an international body commemorating the celebration of the fiftieth anniversary of the Universal Declaration of Human Rights and called for an

⁵ *Id.* The alleged health problems include blindness, deafness, and other meningitis-related problems resulting from a lack of treatment. *Id.*

⁶ See Sarah Boseley, *New Drug 'Illegally Tested on Children': Pfizer Accused of Irregularities During Clinical Trial in Nigeria*, THE GUARDIAN (LONDON), Jan. 17, 2001, at 19 (noting that a letter authorizing the research may have been written months after the research team had left Nigeria). Parents of the children participating also complained that they did not know the research to be experimental. See Sam Eferaro, *Trovan: Sifting the Facts From Fiction*, AFRICA NEWS, Jan. 21, 2001, available at LEXIS, News Library, Africa News File.

⁷ Doctors in the area contradict Pfizer's claims of prior approval by alleging that no approval committees were existent at the time Pfizer conducted the research, and also that some doctors had aided in forging permission forms. See Boseley, *supra* note 6.

⁸ Some patients were shown to have progressively declined in health while taking Trovan and were not taken off Trovan when their lives were threatened. See Eferaro, *supra* note 6.

⁹ *Pfizer Prays U.S. Court to Dismiss Case*, AFRICA NEWS, Nov. 29, 2001, available at LEXIS, News Library, Africa News File.

¹⁰ Patti Waldmeir, *The Guinea Pigs Demand Justice: Those Who Claim to Have Suffered in Medical Trials are Seeking Redress the American Way—Through the Courts*, FIN. TIMES (LONDON), Oct. 18, 2001, at 19.

¹¹ Pfizer's case is not the only example of multinational corporations accused of abusing developing countries as targets for experimental research. "[W]hat Pfizer did in Kano was typical of how multinationals go to developing countries and take advantage of lack of rules or their enforcement to do what they wanted. 'It fits the pattern of multinational corporations in the third world.'" 'Why We Sued Pfizer in US', AFRICA NEWS, Dec. 5, 2001, available at LEXIS, News Library, Africa News File (quoting Ali Ahmad, the attorney bringing the Phizer case to the United States). For other examples of corporations involved in ethical problems with experimental research in developing countries see Stephens, *supra* note 3.

international recognition of human health¹² as a basic human right.¹³ Dr. Brundtland acknowledged the need for recognizing, protecting, and enforcing health as a basic human right.¹⁴ The basic human right to health poses a dangerous dichotomy. On one hand, the right supports the notion of researching and developing new medical treatments to preserve and/or aid health; on the other hand, the right to health and the drive to discover new medical technology creates a need for human experimentation, including the need to protect patients and doctors involved in experimental research.¹⁵ An international standard is needed to provide a minimum bar of ethical considerations and legal guidelines to protect the rights of individuals subject to experimental research.

In 1947, the judges at the Nuremberg criminal trials introduced an international standard of human rights for patients involved in human experimentation.¹⁶ The world has changed a great deal since the Nuremberg trials. National borders have thinned and technology and medical science are screaming forward at a pace unparalleled in the history of the world.

In response to the increase in science and technology, the laws of developed nations have evolved in order to control growth and prevent a recurrence of events similar to the Nazi medical experiments. However, the increase in national regulation also brings an increase in the cost of research and a need to preserve the rights of patients and physicians involved in

¹² Article 25 of the Universal Declaration of Human Rights reads:

Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.

G.A. Res. 217A (III), U.N. GAOR, 3d Sess., at 71, U.N. Doc. A/810 (1948).

¹³ Press Release, WHO, *Director-General Sets Out WHO Stance on Health and Human Rights* (Dec. 8, 1998), at <http://www.who.int/inf-pr-1998/en/pr98-93.html> (Dr. Brundtland stated, “The Principle of Health for All, and of equal access to health services for all, is . . . central to humankind’s development, and the securing of basic human rights. . . .”).

¹⁴ *Id.*

¹⁵ Harold H. Phillips, *Externally Sponsored Research*, in MEDICAL EXPERIMENTATION AND THE PROTECTION OF HUMAN RIGHTS: PROCEEDINGS OF THE XXIIITH CIOMS ROUND TABLE CONFERENCE 56, 56-57 (Dr. Norman Howard-Jones & Dr. Zbigniew Bankowski eds., 1978) (recognizing the need for “adequate control” and that situations may arise that indicate specific needs for control). Pfizer’s case is a good example of new circumstances arising indicating the necessity of control.

¹⁶ Judges Harold Sebring, Walter Beals, & Johnson Crawford, *The Nuremberg Doctors’ Trial: The Judgment*, in HEALTH AND HUMAN RIGHTS: A READER 292-300 (Jonathan M. Mann et al. eds., 1999).

experimental research.¹⁷ Because of the strict regulations in the developed countries, as well as increasing costs of research, private companies have turned their medical experimentation to less developed countries, where legal and governmental systems have yet to develop similar controls and where the cost of research is significantly lower.¹⁸ Lower health standards in developing countries enable diseases to run rampant, providing opportunities for private companies to test experimental medical procedures on human subjects.¹⁹ Experimental research is a benefit to both the developing country and the private company because it can help struggling countries control disease as well as provide much-needed information to company physicians conducting experiments.²⁰

Human experimentation has the potential to cause great harm to populations in developing countries.²¹ Due to the differences between national laws, there is a real danger of abuse in human experimentation. Many developed countries have regulations that prescribe procedures for physicians to follow, but these regulations often apply only to those receiving federal aid in research.²² Further, because there are no international treaties governing experimentation on humans, international law is devoid of regulations on human experimentation.²³ "As a result, the international documents dealing with research trials have little legal effect."²⁴ It is therefore critically important to provide guidance to companies conducting research abroad in order to maximize the benefits

¹⁷ Jennifer Washburn, *Undue Influence: How the Drug Industry's Power Goes Unchecked and Why the Problem is Likely to Get Worse*, THE AMERICAN PROSPECT, Aug. 13, 2001, at 16, 20, 22 (stating that it costs pharmaceutical companies millions every day FDA approval is delayed and suggesting that more federal regulation of commercial research will better protect patients). See also Ileana Domingues-Urban, *Harmonization in the Regulation of Pharmaceutical Research and Human Rights: The Need to Think Globally*, 30 CORNELL INT'L L.J. 245, 245 (1997) (regulations increase costs but also protect patients).

¹⁸ Domingues-Urban, *supra* note 17, at 270-71.

¹⁹ This is also true with publicly funded research, but publicly funded research is guided by United States regulation. The focus of this paper will be on private companies doing research abroad and will not approach publicly funded research.

²⁰ Clinical research on new drugs or vaccines can be beneficial to research participants and the communities involved. Research participants receive "cost-free vaccines or drugs that may prove beneficial in the prevention or treatment of . . . disease," and "have access to general medical care that would be practically impossible to receive" otherwise. E. Maxine Ankrah & Lawrence O. Gostin, *Ethical and legal Considerations of the HIV epidemic in Africa*, in AIDS IN AFRICA 547, 555 (Max Essex et al. eds., 1994).

²¹ "Research in [developing countries] is therefore critically important." *Id.*

²² See Domingues-Urban, *supra* note 17, at 272 (noting that "a great deal of research is federally regulated because of its federal funding.").

²³ *Id.* at 273.

²⁴ *Id.*

provided to developing countries, protect the corporations' interest in continuing research,²⁵ and minimize the potential for abuse.²⁶

Section One of this paper will provide legal background behind current international standards concerning human experimentation. Section Two of this paper will discuss the details behind the events that took place in Nigeria between Pfizer and the Nigerian families involved in the lawsuit. Section Three will provide an analysis of voluntary consent and enforcement under current international standards, as they stand compared with the facts of Pfizer. Section Four will provide possible solutions to problems discussed in Section Three. Section Five will conclude that regulation of human experimentation in the international setting is needed to protect individuals, researchers, and developing countries.

I. Legal Background of Existing International Standards

Currently, three central standards provide guidelines by which doctors measure their conduct for experimental research in international settings: the Nuremberg Code (the "Code"), the Declaration of Helsinki (the "Declaration") and the WHO-CIOMS Guidelines (the "Guidelines"). Each of these standards was developed by different international entities, with individual purposes, goals, and focal points.

A. The Nuremberg Code

In December of 1946, the criminal trials began for abuses of human experimentation by Nazi doctors on imprisoned Jews, Gypsies, and other minorities.²⁷ These proceedings were the first attempt at criminalizing abuse by medical experimentation on human beings in an international

²⁵ See Thomas Donaldson, *Adding Corporate Ethics to the Bottom Line*, FIN. TIMES (LONDON), Nov. 13, 2000, at 2.

²⁶ With more than eighty percent of all experimental clinical trials in the world today conducted by private pharmaceutical companies, it is more important than ever to set forth clear, binding guidelines in order to protect not only private companies that conduct experimental procedures across borders, but also individuals in developing countries, and national interests abroad. Washburn, *supra* note 17, at 20. International guidelines would help companies like Pfizer, a large U.S.-based pharmaceutical corporation, that have been accused of human rights violations relating to experimental research. The urgency to enact and enforce international Sebring, Beals & Crawford standards that will provide guidance to doctors and companies conducting research in developing countries to safeguard national diplomatic channels, protect companies, and preserve the integrity of current international human rights is paramount. See Sebring, Beals & Crawford, *supra* note 16, at 297-98.

²⁹ Tedford Taylor, *Opening Statement of the Prosecution*, in THE NAZI DOCTORS AND THE NUREMBERG CODE: HUMAN RIGHTS IN HUMAN EXPERIMENTATION 67 (George J. Annas & Michael A. Grodin eds., 1992).

setting,²⁸ and were among the first to create standards by which the international practice of medicine might be controlled, thereby deterring future abuse of medical experimentation on human beings.²⁹

The tribunal judges provided a list of requirements for doctors conducting experimental research which is now known as the Nuremberg Code.³⁰ The list was meant to prescribe physician conduct to certain minimums of ethical behavior as are required by universal moral, ethical and legal concepts; the violation of which would bring down the condemnation of society.³¹

The tests conducted by the Nazi doctors were of an unusually cruel nature and performed without the consent of the individual or group.³² Some of the experiments at Nuremberg had quasi-legitimate ends in furthering medical knowledge to aid the military in caring for soldiers, but these ends were gained at the expense of the patient.³³ Most of the experiments, however, had no legitimate end and were aimed only at more effective control over certain populations or the eradication of a specific ethnicity.³⁴

The Nuremberg criminal trials carried the dual purpose of holding specific individuals accountable for their barbarous acts against humanity and recording the committed acts into history.³⁵ This second purpose was perhaps the most striking and progressive move in the history of medicine and law. It sought to establish international norms whereby others might be held accountable for similar activity and sought to establish clear guidelines

²⁸ Sharon Perley, et al., *The Nuremberg Code: An International Overview*, in THE NAZI DOCTORS AND THE NUREMBERG CODE: HUMAN RIGHTS IN HUMAN EXPERIMENTATION 149, 150 (George J. Annas & Michael A. Grodin eds., 1992).

²⁹ See Jay Katz, *Human Experimentation and Human Rights*, 38 ST. LOUIS U. L.J. 7, 8-9 (1993); see also Thomas John Babbo, *Begging the Question: Fetal Tissue Research, the Protection of Human Subjects, and the Banality of Evil*, 3 DEPAUL J. HEALTH CARE L. 383, 399-400 (2000) (recognizing the Nuremberg Code as the first guideline for human subjects research).

³⁰ Sebring, Beals & Crawford, *supra* note 16, at 298-99.

³¹ *Id.* at 297-98.

³² Without any of the patients' interests in mind, the Nazi doctors singled out individuals based on ethnicity and race. These doctors subjected patients to high altitude tests, freezing experiments, malaria experiments, poison gas tests, seawater tests, and limb and organ transplantation testing. Most of the tests resulted in the death of the subject. *Id.* at 293-96.

³³ *See id.*

³⁴ *Id.*

³⁵ Telford Taylor, *The Nuremberg Doctor's Trial: Opening Statement of the Prosecution*, in HEALTH AND HUMAN RIGHTS: A READER 284, 284-85 (Jonathan M. Mann et al. eds., 1999).

to prescribe acceptable conduct for future human subjects medical experiments.³⁶

Because the Nuremberg Code was the first to attempt to create a standard for ethical behavior in international human experimentation, the Code has played a large part in influencing national regulation of human experimentation in most Western countries.³⁷ The Nuremberg Code has had a direct influence in the creation of several biomedical ethics organizations.³⁸ Respect for the principles contained in the Code has carried over into the language and principles of many other international guidelines.³⁹

The Nuremberg Code requires the voluntary consent of all participants in experimental research.⁴⁰ Voluntary consent is defined as the ability to exercise free power of choice, the legal capacity to give consent,⁴¹ and “sufficient knowledge and comprehension . . . as to enable him to make an understanding and enlightened decision.”⁴² The Code places the burden of ensuring the quality of the consent on the person initiating the research.⁴³

The Code defines the ability to exercise “free power of choice” as the right to remain free from “force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion.”⁴⁴ The Code requires that all

³⁶ Michael Grodin, *Historical Origins of the Nuremberg Code*, in THE NAZI DOCTORS AND THE NUREMBERG CODE: HUMAN RIGHTS IN HUMAN EXPERIMENTATION 121 (George J. Annas & Michael A. Grodin eds., 1992). Sebring, Beals & Crawford, *supra* note 16, at 298-99.

³⁷ Many of the cases giving the start to modern U.S. legislation protecting human subjects in experimental research refer directly to the Nuremberg Code. See, e.g., *In re Weberlist*, 360 N.Y.S.2d 783, 787 (1974); *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807, 817 (2001); *Washington v. Harper*, 494 U.S. 210, 237, n. 2 (1990); *United States v. Stanley*, 483 U.S. 669, 687 (1987); *Wentzel v. Montgomery General Hosp., Inc.*, 293 Md. 685, 716 (1981).

³⁸ See Dawn Joyce Miller, *Research and Accountability: The Need for Uniform Regulation of International Pharmaceutical Drug Testing*, 13 PACE INT'L L. REV. 197, 203 (2001). The WMA and the WHO are two examples of such entities.

³⁹ See World Medical Association, Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects, 284 JAMA 3043 (2000) [hereinafter Declaration of Helsinki]; *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, WHO-Council for International Organizations of Medical Sciences (CIOMS) (Geneva 2002) [hereinafter WHO-CIOMS Guidelines].

⁴⁰ 2 Trials of War Criminals Before the Nuremberg Military Tribunals under Control Council Law No. 10, 181, 181-82 (U.S. Gov’t Printing Office 1949), reprinted in JUDITH AREEN ET AL., LAW, SCIENCE AND MEDICINE 996-98, art. 1 (2d ed. 1996) [hereinafter Nuremberg Code].

⁴¹ Legal capacity to give consent is not explained further in the Code.

⁴² Nuremberg Code, *supra* note 40, at art. 1.

⁴³ *Id.*

⁴⁴ *Id.*

participants in experimental research be aware of their ability to terminate research participation at any point.⁴⁵ The patient may withdraw from research “if he has reached the physical or mental state where continuation of the experiment *seems to him* to be impossible.”⁴⁶

The Code requires that all participants have sufficient knowledge and comprehension of the research subject matter to make an informed decision.⁴⁷ This requirement carries with it the responsibility to explain the nature, duration, and purpose of the experiment, the method and means by which the experiment is to be conducted, and an estimation of risks and benefits to the participant.⁴⁸

Other than placing the burden of evaluating the quality of consent given on the person initiating the experimental research, the Code does not provide specific measures of enforcement to assure physician adherence to its standards.⁴⁹

B. The Declaration of Helsinki

In September of 1947, inspired by the Nuremberg criminal trials, a large group of private physicians gathered to establish an international association, the World Medical Association (“WMA”), to focus on global issues confronting physicians.⁵⁰ The WMA was created to ensure the “independence of physicians, and to work for the highest possible standards of ethical behavior and care by physicians. . . .”⁵¹ Since its inception, the WMA has actively participated in the international community to protect the interests of physicians and to promote its own ideals in shaping public health policy through information gathering and dissemination in the international health arena.⁵²

The Declaration of Helsinki (the “Declaration”), created by the WMA in 1964, set forth a list of duties and responsibilities that are expected of all physicians taking part in experimental research on humans.⁵³ The Declaration secondarily addressed a minimum standard of rights and

⁴⁵ *Id.* at art. 9. The physician is required to terminate the research if probable cause arises that the research will likely end in injury, disability, or death to the participant. *Id.* at art. 10.

⁴⁶ *Id.* at art. 9 (emphasis added).

⁴⁷ *Id.* at art. 1.

⁴⁸ *Id.*

⁴⁹ *Id.*

⁵⁰ See WORLD MEDICAL ASSOCIATION, INC., WMA Policy, at <http://www.wma.net/e/about.html> (last visited Mar. 10, 2002).

⁵¹ *Id.*

⁵² *See id.*

⁵³ Declaration of Helsinki, *supra* note 39, at 3043, para. 1-13.

special treatments reserved for patients or groups involved in experimental research.⁵⁴

The Declaration requires that all subjects of experimental research be volunteers and informed participants.⁵⁵ The researcher must first inform each subject of the "aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail."⁵⁶ After informing the participant, the researcher should then obtain the subject's freely given consent, preferably in writing.⁵⁷ If not in writing, the consent must be formally documented and witnessed.⁵⁸

The Declaration mandates that physicians give "special attention" to those patients that may give consent under duress.⁵⁹ The Declaration requires that patients participating in therapeutic research receive additional protection from doctors.⁶⁰ Participants in therapeutic research are assured additional care by the "best-proven . . . therapeutic measures" at the end of the research.⁶¹ Participants may abstain from any part of the experimental research.⁶² The refusal of a patient to participate in therapeutic research should not interfere with the doctor-patient relationship.⁶³ When obtaining consent from a participant in a dependent relationship with a physician, researchers should be "particularly cautious" to assure that the participant does not consent under duress.⁶⁴

Physicians should not conduct research on legally incompetent individuals unless the research is necessary to promote the health of the population represented⁶⁵ and if research can otherwise be performed on legally competent individuals.⁶⁶ The Declaration recognizes the need for special attention for "vulnerable" individuals participating in research,⁶⁷ defining "vulnerable" as those who cannot give consent for themselves,

⁵⁴ See *id.* at 3044-45, para. 14-29.

⁵⁵ *Id.* at 3044, para. 20.

⁵⁶ *Id.* at para. 22.

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ *Id.* at 3043, para. 8.

⁶⁰ *Id.* at 3044, para 28.

⁶¹ *Id.* at 3045, para. 30.

⁶² *Id.* at 3044, para. 22.

⁶³ *Id.* at 3045, para. 31.

⁶⁴ *Id.* at 3044, para. 23.

⁶⁵ *Id.* at para. 24.

⁶⁶ *Id.*

⁶⁷ *Id.* at 3043, para. 8. The Declaration also acknowledges the need for physician recognition of the economically and medically disadvantaged. *Id.*

such as a minor child.⁶⁸ Informed consent may be obtained from the legal guardian of individuals that are legally incompetent and are unable to provide consent for themselves.⁶⁹ Where proxy consent cannot be obtained from individuals because of their incompetence, research should only be done if the condition causing legal incompetence is a necessary characteristic of the research population.⁷⁰

The Declaration establishes that physicians should submit proposals of experimental research to an independent ethical oversight committee. The ethical oversight committee is to apply the standards of the country wherein the research is being conducted,⁷¹ but should not allow standards to fall below those prescribed in the Declaration.⁷² The independent ethical oversight committee is allowed continuous oversight for the duration of the research.⁷³ The Declaration provides that information obtained through a breach of standards provided in the Declaration should not be published.⁷⁴

C. The WHO-CIOMS Guidelines

The World Health Organization (“WHO”) is the health and human rights arm of the United Nations. The United Nations, in 1947, created the WHO in an effort to ensure “health to all people,” and to protect the ability of each individual on the earth to obtain health-related services.⁷⁵ The United Nations empowered the WHO with the ability to report on the status of health in all the world⁷⁶ and to ensure that governments live up to their responsibility to provide “adequate health and social measures” to their

⁶⁸ See *id.* at 3043, 3044, para. 8, 25. In some countries, classes of persons are not legally given the right to consent for themselves: such as women, children, those suffering from mental conditions, and other potentially vulnerable groups. See Ruth Macklin, *University of the Nuremberg Code, in THE NAZI DOCTORS AND THE NUERMBERG CODE: HUMAN RIGHTS IN HUMAN EXPERIMENTATION* 240, 251 (George J. Annas & Michael A. Grodin eds., 1992).

⁶⁹ Declaration of Helsinki, *supra* note 39, at 3044, para. 24, 25.

⁷⁰ *Id.* at para. 26.

⁷¹ *Id.* at 3043, para. 13.

⁷² *Id.* at para. 9.

⁷³ *Id.* at para. 13 (placing burden on the researcher to produce “monitoring information” to the oversight committee, including adverse results). The physician also carries the burden of reporting sources of funding, conflicts of interest, sponsors, institutional affiliations, and any other potential conflicts of interest to the ethical oversight committee. *Id.*

⁷⁴ *Id.* at 3044, para. 27.

⁷⁵ Constitution of the World Health Organization, opened for signature July 22, 1946, pmbl., 62 Stat. 2679, 2680, 14 U.N.T.S. 185.

⁷⁶ *Id.* at art. 2, 62 Stat. at 2681-82, 14 U.N.T.S. at 187-89.

populations.⁷⁷ The WHO can propose regulations and make recommendations, with respect to international health matters, to the United Nations.⁷⁸ The WHO also cooperates with other agencies and associations to accomplish its goals.⁷⁹

The World Health Assembly (“WHA”), an elected body comprised of technically qualified persons representing each member nation,⁸⁰ directs decision-making in the WHO. The WHA has the power to adopt regulations that govern all member nations of the WHO as stated in the WHO Constitution.⁸¹ The WHO’s interests lie in appealing to the professional field of medical sciences, in satisfying the legal demands of the United Nations, and in protecting and informing the general public of health related issues.

The Council for International Organizations of Medical Sciences (“CIOMS”) is an international, non-governmental organization established by the WHO and UNESCO⁸² in 1949.⁸³ The main objectives of CIOMS are to promote international biomedical activities, serve the scientific interests of the international biomedical community, and maintain relations with the WHO and the United Nations.⁸⁴ While CIOMS does not have the power to make binding regulations, it does report to the WHO and can influence decisions made by the WHO.⁸⁵ CIOMS has released a set of guidelines for physicians and others conducting experimental research in the international setting.⁸⁶

The WHO-CIOMS Guidelines (the “Guidelines”) require that each individual give informed consent before participating in experimental research.⁸⁷ Informed consent requires that the physician inform the potential patient of the nature,⁸⁸ the aims, methods, risks and benefits,

⁷⁷ *Id.* at pmb., 62 Stat. at 2680, 14 U.N.T.S. at 186-87; *see also id.* at art. 2, 62 Stat. at 2681-82, 14 U.N.T.S. at 187-89.

⁷⁸ *Id.* at art. 2(k), 62 Stat. at 2681, 14 U.N.T.S. at 188.

⁷⁹ *Id.* at art. 2, 62 Stat. at 2681-82, 14 U.N.T.S. at 187-89.

⁸⁰ *Id.* at art. 11, 62 Stat. at 2683, 14 U.N.T.S. at 190; *see also WHO Governance*, at <http://www.who.int/m/topicgroups/governance/en/index.html> (last visited Mar. 17, 2002).

⁸¹ See Constitution of the World Health Organization, *supra* note 76, at art. 22, 62 Stat. at 2685, 14 U.N.T.S. at 193.

⁸² United Nations Educational, Scientific and Cultural Organization.

⁸³ COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES, *What is CIOMS?*, at http://www.cioms.ch/frame_what_is_cioms.htm (last visited Sept. 18, 2002).

⁸⁴ *Id.*

⁸⁵ *See id.*

⁸⁶ *Id.*

⁸⁷ WHO-CIOMS Guidelines, *supra* note 39, guideline 4.

⁸⁸ *See id.* guideline 5. (stating “that the individual is invited to participate as a subject in research . . .” (emphasis added)).

alternative treatments available,⁸⁹ and of the patient's ability to refuse to participate or withdraw from the research at any point without repercussion.⁹⁰ The Guidelines require prior approval of the scientific and ethical aspects of the research by an ethical review committee.⁹¹ The Guidelines require constant vigilance but not supervision by an investigator and/or ethical review committee.⁹² The Guidelines provide that the right to compensation for accidental injury incurred in experimental research cannot be waived⁹³ and provide that any benefit derived from the research should be returned, in part, to the community from which information was gathered.⁹⁴ The Guidelines also allow sanctions to be imposed by the hosting state where researchers violate local or international standards of ethical conduct in experimental research.⁹⁵

Investigators are required to work with ethical review committees to ensure that there is no undue inducement to participate in research.⁹⁶ They are also required to recognize and exclude the possibility for potentially coercive circumstances,⁹⁷ which are defined as situations involving deception,⁹⁸ undue influence,⁹⁹ and intimidation.¹⁰⁰ Intimidation in any

⁸⁹ *Id.*

⁹⁰ *Id.* The Code does not address whether informed consent need be written. The Declaration only requires that patients receive oral informed consent, written informed consent is preferred, but is by no means required. Declaration of Helsinki, *supra* note 39, at 3044, para. 22. Written consent should never completely replace oral consent, but should be used as supplemental to oral consent. Written consent in addition to oral consent seems unnecessary, but serves as proof of patient consent. Many of the patients in Kano claimed that they never consented to the research. See Tamar Lewin, *Families Sue Pfizer on Test of Antibiotic*, N.Y. TIMES, Aug. 30, 2001, at C1. See WHO-CIOMS Guidelines, *supra* note 9, guideline 6 (requiring written consent as the primary means of evidentiary compliance).

⁹¹ WHO-CIOMS Guidelines, *supra* note 39, guidelines 2, 3.

⁹² *Id.*

⁹³ *Id.* guideline 19. Compensation is limited to "significant" injuries occurring in the course of non-therapeutic research. *Id.* guideline 19 cmt. Compensation is not available to those suffering from expected effects of treatment or predicted adverse effects made available to the subject in informed consent. *Id.* Where the distinction is unclear as to whether the purpose of the treatment is for research or therapy, the ethical review committee determines which injuries will be compensated. *Id.*

⁹⁴ See *id.* guideline 10.

⁹⁵ *Id.* guideline 2 cmt. Ethical review committees will inform local authorities of significant violations. *Id.*

⁹⁶ *Id.* guideline 6, cmt. This supervision includes the ability to ensure that compensation to patients does not unduly induce participation through unjustified deception, undue influence, and intimidation. See *id.* guideline 7.

⁹⁷ See *id.* guideline 4 cmt.

⁹⁸ Deception can be used in certain circumstances in human subjects research, but is never allowed when the risk to the participant is more than minimal. See *id.* guideline 6 cmt.

form invalidates consent to participate.¹⁰¹ The Guidelines further acknowledge the possibility of circumstantial coercion by creating special standards for underdeveloped countries and vulnerable persons.¹⁰²

For research conducted in developed and underdeveloped countries, investigators "must obtain the voluntary informed consent of the prospective subject. . . ."¹⁰³ Individuals must be informed in language they can understand.¹⁰⁴ The Guidelines address community-consent issues by urging researchers to obtain prior approval of research by community leaders where community concerns are involved.¹⁰⁵

All participants in experimental research must give informed consent to participate,¹⁰⁶ unless the participant is not capable of giving informed consent.¹⁰⁷ The Guidelines define persons incapable of providing informed consent as young children, persons with severe mental or behavioral disorders¹⁰⁸ and prisoners.¹⁰⁹ In the case of children, researchers must take special precautions to protect the child.¹¹⁰ Consent must be obtained from

⁹⁹ Undue influence, as explained in the Guidelines' commentary, can originate from the physician, investigator or community leader. *Id.* It is not clear whether the Guidelines seek to include external influences on the participant as possible sources of undue influence. *See id.*

¹⁰⁰ *Id.* guideline 6.

¹⁰¹ *Id.* guideline 6 cmt.

¹⁰² *See id.* guidelines 10, 13.

¹⁰³ *Id.* guideline 4.

¹⁰⁴ *Id.* guideline 5.

¹⁰⁵ *See id.* guidelines 6 cmt., 8 cmt.

¹⁰⁶ *Id.* guideline 4. The investigator must ensure that the patient understands the information involved in consent to participate. *Id.* guideline 4 cmt. The importance of this requirement increases as the risk involved increases. In some cases, investigators may be required to conduct a test of the potential participant's understanding of the information provided for consent. *Id.*

¹⁰⁷ *Id.* guideline 4. As a general rule, consent should be written. *Id.* guideline 4 cmt. The ethical review committee may waive written consent when the risk to subjects is minimal. *Id.* Investigators bear the burden of proving oral consent. *Id.* The investigator is also required to renew the consent of each subject if there are material changes in the conditions or procedures of the research. *Id.* guideline 4 cmt., 6.

¹⁰⁸ The Guidelines acknowledge that in some circumstances, the individual affected by a mental or behavioral disorder may be considered by family members as a burden, thereby casting suspicion on the consent of family members. *See id.* guideline 15 cmt. This may be especially true where the individual has been committed to an institution. *Id.* Consent from an ethical review committee, the institution, or a court may be necessary before involving these individuals in experimental research. *Id.*

¹⁰⁹ *Id.* guideline 4 cmt., 9 cmt.

¹¹⁰ *See id.* guideline 14. These precautions include a heightened level of assurance that therapeutic benefit of the treatment is at least as advantageous to the individual as any

the child to the extent of their capacity to understand.¹¹¹ A legal guardian must supplement the child's consent even if the child has the capability to understand the consequences of his or her decision.¹¹² Where the child does not possess the capacity to understand, proxy consent by a properly authorized representative is sufficient.¹¹³ Involvement of children in the experimental research must be justified by the benefit of potential results specifically related to children.¹¹⁴

Additional precautions are required for those deemed "vulnerable" or for research conducted in underdeveloped countries.¹¹⁵ "Special justification" is required for research involving vulnerable individuals and is combined with a strictly applied scrutiny of standards, in order to protect the vulnerable individual's rights and welfare.¹¹⁶ According to the Guidelines, research conducted in underdeveloped countries requires the physician make "every effort" to ensure that individual consent be informed.¹¹⁷

II. Pfizer's Epidemic

In February of 1996, the World Health Organization posted on its website news of an outbreak of cerebrospinal meningitis in northern Nigeria, reporting over 3,000 cases and more than 400 deaths.¹¹⁸ By March, the number of cases reported counted 17,668 with 2,500 additional deaths,¹¹⁹ and thousands of reported cases were being added to the WHO's

available treatment. *Id.* guideline 14 cmt. Parental or legal guardian consent is required. *Id.* guideline 14. The researcher must also respect the child's refusal to participate unless there is no medically accepted alternative. *Id.* guideline 14 cmt. A child's right to refuse cannot be overridden by proxy consent except for exigent circumstances. *Id.*

¹¹¹ *Id.* guideline 14.

¹¹² *Id.*

¹¹³ See *id.* (this is inferred by the overriding objection capacity of parents and that consent is sought to the extent it can be understood).

¹¹⁴ *Id.* guideline 14.

¹¹⁵ See *id.* guidelines 10, 13.

¹¹⁶ *Id.* guideline 13.

¹¹⁷ *Id.* guideline 10.

¹¹⁸ World Health Org., *Communicable Disease and Response (CSR), Cerebrospinal Meningitis in Nigeria, Disease Outbreaks Reported* (Feb. 19 1996), at <http://www.who.int/disease-outbreak-news/n1996/feb/n19feb1996c.html>.

¹¹⁹ World Health Org., *Communicable Disease and Response (CSR), Cerebrospinal Meningitis in Nigeria - Update, Disease Outbreaks Reported* (Mar. 7, 1996), at <http://www.who.int/disease-outbreak-news/n1996/mar/n7mar1996b.html>.

website on a weekly basis.¹²⁰ This epidemic ultimately left more than 18,000 victims suffering from the disease and claimed more than 3,000 lives.¹²¹

After seeing the WHO reports, Pfizer came to Nigeria to test the experimental drug Trovan,¹²² which had never been tested on children.¹²³ Pfizer set up research headquarters next to an existing Doctors Without Borders ("DWB") facility, using some of DWB's bed space and part of DWB's treatment center in order to speed up the experimental trial process.¹²⁴ Pfizer researchers also hired out many of the physicians and medical assistants who were previously working with DWB and the local hospital in Kano to help translate and facilitate patient care.¹²⁵ The Pfizer doctors were not prepared for a city of more than two million people ravaged by pollution, disease and death.¹²⁶ With only two weeks in Kano, researchers treated just under two hundred children for spinal meningitis, with half the children using either an oral or intravenous form of Trovan.¹²⁷ The remaining half were treated with the antibiotic Ceftriaxone, a drug already approved for use on American children.¹²⁸

At first, the Pfizer doctors only wanted the most treatable children, but as the epidemic raged on, the researchers began treating any child arriving at their doors.¹²⁹ The ages of the children participating in the experiment ranged from a few months to eleven years; the severity of infection varied from early stages to partial paralysis to near death.¹³⁰ Many cases involved children who, despite showing progressing stages of infection, continued treatment from trial doctors using oral doses of Trovan and ultimately

¹²⁰ Compare *Communicable Disease and Response (CSR), Cerebrospinal Meningitis in Nigeria, Disease Outbreaks Reported*, *supra* note 118, with *Communicable Disease and Response (CSR), Cerebrospinal Meningitis in Nigeria - Update, Disease Outbreaks Reported*, *supra* note 119.

¹²¹ Warsh, *supra* note 2, at C1; *Families: Pfizer Hurt, Killed Kids*, *supra* note 2.

¹²² Stephens, *supra* note 3.

¹²³ *Id.* Trovan was not approved at the time of the outbreak for human experimentation in the United States. In fact, Trovan has been one of the few drugs in the last five years that has been withdrawn from the U.S. market due to known serious side effects. Washburn, *supra* note 17, at 18.

¹²⁴ Stephens, *supra* note 3.

¹²⁵ See *id.*

¹²⁶ *Id.*

¹²⁷ *Id.*

¹²⁸ *Id.*

¹²⁹ *Id.*

¹³⁰ See *id.* Some physicians argue that it is inappropriate to condemn Pfizer's researchers where the participating patients' cause of death is identical to the natural effects of the disease. See Eferaro, *supra* note 6.

succumbed to the disease.¹³¹ Due to the vast number of patients treated in such a short time and the high illiteracy rate in Kano, many of the patients did not sign consent forms.¹³² Using nurses as translators, many of the patients consented verbally; but often, the nurses did not translate all the details of the consent form to the families.¹³³ Pfizer's humanitarian venture resulted in the deaths of eleven of the ninety-nine children given one form of Trovan or another;¹³⁴ several more were left brain damaged, deaf or paralyzed.¹³⁵

III. Analysis of Current Standards Under Pfizer's Epidemic

A. Voluntary Consent

Article One of the Nuremberg Code requires that patients give consent to experimental research.¹³⁶ The patient's right to consent is absolute above all else, including any other humanitarian end that might be attained through the scientific knowledge derived from the trials.¹³⁷ The Code requires voluntary consent in experimental research to contain three independent but equally important elements: 1) that consent be voluntary and the patient be adequately informed of the nature of the experimentation and the risks involved in experimentation; 2) that voluntary consent be free from coercion or duress; and 3) that participants have the legal capacity to give voluntary consent.¹³⁸ The Code's strongest point, and greatest flaw, is that it is extremely definitive on the issue of voluntary consent.¹³⁹ The

¹³¹ Stephens, *supra* note 3. One case involved a seven year-old boy whose face had been partially paralyzed by the disease and was given fifty milligrams of the oral form of Trovan. *Id.* Within nine hours the child died from effects related to meningitis. *Id.*

¹³² *See id.*

¹³³ *Id.* (One of the Pfizer doctors explained, “[I]t was a general explanation. . . . It is very complicated for them. You explain to them it's a new medicine and you have a right to say no.”).

¹³⁴ *See Nigerian Doctor Says Pfizer Used Illegal Approval for Human Tests*, FLA. TIMES-UNION (Jacksonville, FL), Jan. 16, 2001, at A6, available at 2001 WL 6999948.

¹³⁵ Kevin Gopal, *FDA Stays Silent on Trovan Charges*, PHARMACEUTICAL EXECUTIVE, Oct. 1, 2001, at 24; ‘*Why we Sued Pfizer in US*’, *supra* note 11.

¹³⁶ “The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent. . . .” Nuremberg Code, *supra* note 40, at art. 1; *see* Sebring, Beals & Crawford, *supra* note 16, at 298.

¹³⁷ Sebring, Beals & Crawford, *supra* note 16, at 298-99.

¹³⁸ Nuremberg Code, *supra* note 40, at art. 1.

¹³⁹ The issue of voluntary consent was, in fact, one of the foremost in the minds of those participating in the trials of the Nazi physicians, as is evidenced by its placement in the Code. *See* Sebring, Beals & Crawford, *supra* note 16, at 298.

Code approaches voluntary consent through a moral approach, requiring absolute voluntary consent from subjects because of society's demands for personal autonomy.¹⁴⁰ The Declaration and the Guidelines similarly require voluntary consent of research subjects, but approach the matter in varying measures. The Declaration approaches voluntary consent through the doctor-patient relationship. The Guidelines view voluntary consent through the status of the patient and the surrounding circumstances.

i. Informed Consent

Article One of the Code not only requires that a patient know that the experimental research is experimental, but also requires that each patient comprehend the nature and extent of the experiment.¹⁴¹ Patients should be able to make an "enlightened decision" based upon information provided by researchers that explains the purpose of the experiment, duration, methods, and means involved.¹⁴² The Code places responsibility on the persons engaging, directing, or initiating the experiment to ensure comprehension by each patient taking part.¹⁴³ The Code does not acknowledge the difficulty in obtaining informed consent where the patient does not completely understand the complexities of experimental procedures. Where many of the patients are uneducated or unfamiliar with Western medicine, the Code would prohibit their involvement in experimental research if they are unable to understand the procedures involved or the nature and aims of the research.¹⁴⁴ In this way, the Code impedes medical progress on entire populations deemed unable to comprehend the research.

The Code fails to take into account cultural variations for what can be considered consent. In many developing countries, it is customary for community leaders to give consent on behalf of its citizens.¹⁴⁵ If strictly adhered to, the Code would not permit community consent to take the place of individual consent.¹⁴⁶ The Code mandates that only persons with legal capacity to give consent may participate in experimental research.¹⁴⁷ Some national cultures desire to preserve roles of decision-making affecting the

¹⁴⁰ *Id.*

¹⁴¹ Nuremberg Code, *supra* note 40, at art. 1.

¹⁴² *Id.*

¹⁴³ *Id.*

¹⁴⁴ See *id.*

¹⁴⁵ "At the individual level, what constitutes informed consent may vary by culture. A continuing practice exists in which people visiting a traditional healer show unquestioning trust in the healer's diagnosis and prescriptions for treatment. The contract between parties is based on this trust." Ankrah & Gostin, *supra* note 20, at 549.

¹⁴⁶ See Nuremberg Code, *supra* note 40, at art. 1.

¹⁴⁷ *Id.*

public good by only allowing leaders of the community to make consent decisions.¹⁴⁸ Some patriarchal cultures prohibit females from making important decisions affecting either themselves or their children.¹⁴⁹ While deference to some cultural practices may not seem acceptable to Western cultures, these countries may not desire to change custom¹⁵⁰ for a Western corporation's procedural requirement.¹⁵¹ Because of its rigidity in refusing to consider situations that warrant using community consent instead of individual consent,¹⁵² the Code is not highly favored by the medical community or by developing countries. Under the Code, Pfizer would have not been allowed to substitute the consent of the community for that of any individual.¹⁵³

The Declaration requires that individuals be informed of the aims, methods, benefits, and risks that experimental research may entail.¹⁵⁴ Where the Code failed to address the issue that additional information could be provided to the subject,¹⁵⁵ the Declaration explains that it is the duty of the physician to inform the patient of potential conflicts of interest on the part of the physician conducting the experiment and the institutional affiliations of the researchers.¹⁵⁶ This requirement addresses the need for

¹⁴⁸ “Except among the urban and educated, gaining the individual’s informed consent instead of being guided by the family’s wishes is new to many Africans. The potential for a conflictual interplay is generated between cultural practices instituted by preliterate societies and those introduced from more modern settings.” Ankrah & Gostin, *supra* note 20, at 549.

¹⁴⁹ See Macklin, *supra* note 68, at 251.

¹⁵⁰ “The ethical and legal issues raised with respect to consent in diverse cultures require an appreciation of the values held by a specific community, while at the same time upholding the universality of the right of all people to make decisions about their own bodies and health.” Ankrah & Gostin, *supra* note 20, at 549.

¹⁵¹ “People become confused when . . . emphasis is for the first time placed on individuals’ permission to receive a certain treatment or to have their blood tested. This transfer of decision-making power from healers to individuals may represent a departure from tradition.” *Id.* But see B.O. Osuntokun, *Individual Consent: A Perspective of Developing Countries*, in ETHICS AND RESEARCH ON HUMAN SUBJECTS: INTERNATIONAL GUIDELINES, PROCEEDINGS OF THE XXVITH CIOMS CONFERENCE 25, 29 (Z. Bankowski & R.J. Levine eds., 1993) (“The assertion that in some central African cultures the concept of personhood differs fundamentally from that in Western culture . . . is not true of most parts of Black Africa.”).

¹⁵² WHO-CIOMS Guidelines, *supra* note 39, guideline 4 cmt. (“In no case, however, may the permission of a community leader or other authority substitute for individual informed consent.”).

¹⁵³ See Nuremberg Code, *supra* note 40, at art. 1.

¹⁵⁴ Declaration of Helsinki, *supra* note 39, at 3044, para. 22.

¹⁵⁵ Because physicians created the Declaration, rather than judges, it identifies procedural problems and conflicts that arise in practice that judges would not be aware of until after the fact.

¹⁵⁶ Declaration of Helsinki, *supra* note 39, at 3044, para. 22.

clarity within the doctor-patient relationship when conducting experimental research in extreme circumstances. Patients who are informed of the institutional affiliations of researchers are given the ability to discern between institutions providing care and those conducting research. By providing the institutional affiliations of researchers, patients can base their decision on additional factors not directly related to the research, such as the local reputation of the company conducting ethical research.¹⁵⁷

Even though the researcher must reveal institutional affiliations, the informed requirement of consent should not end there. These requirements serve to clarify the doctor-patient relationship only if patients are made aware that the nature of the research is experimental.¹⁵⁸ The Declaration uses the word "aims" to describe the type of experimentation used. However, the word "aims" describes any aspirational ends that researchers seek to derive from the research; whereas a description that research is experimental alludes to the means used by researchers to achieve their aspirational ends. The Declaration's use of the word "methods" would lead a researcher to convey technical or procedural aspects of the research. It would not induce a researcher to convey the experimental nature of the research to the patient. There is no explicit requirement in the Declaration for doctors to reveal the experimental nature of the research to potential patients.¹⁵⁹

While not specifically addressing community consent, the Declaration does allow for doctors to follow national laws.¹⁶⁰ However, if a nation does not codify the concept of community consent within its laws, researching physicians are left without direction when dealing with communities that traditionally allow community consent. Similar difficulties arise in distinguishing between individuals who are part of a community that has

¹⁵⁷ This information becomes even more important as locals can become wary of institutions conducting research in their area. In Kano, for example, many locals are refusing to accept aid due to Pfizer's research problems. See *How Cholera Wreaked Havoc in Kano*, AFRICA NEWS, Nov. 28, 2001, available at LEXIS, News Library, Africa News File.

¹⁵⁸ When the nature of the research is not disclosed, there is a danger that locals will be wary of future efforts associated with the non-disclosing company, even if those efforts are purely charitable.

¹⁵⁹ See Declaration of Helsinki, *supra* note 39, at 3044, para. 22. It is interesting to note that the Declaration switches between "should" and "must" when addressing informed consent. A researcher "must" inform potential patients of aims, methods, etc; but a researcher "should" obtain freely-given consent after informing the patient. Researchers obtain consent from the community, inform each patient according to the requirements of the Declaration, and do not worry about whether individual consent was obtained. In this manner, according to the situation as described in this paper, patients "volunteer" for experimental procedures without ever realizing the nature of the research and without ever giving consent. It is through this very loophole that Pfizer slipped while in Kano.

¹⁶⁰ See *id.* at 3043, para. 9.

already given consent and from individuals whose communities have not rendered consent for treatment.

Community consent clashes with the Declaration's policy that individuals personally volunteer for the experimental procedure.¹⁶¹ The need for consent is only implied in the Declaration through the requirement that patients be volunteers.¹⁶² At first glance, consent for participation in research seems absolutely necessary. However, as in Pfizer's case, where experimental research sits side by side with charitable medical services without sufficient clarity or separation, a patient may "volunteer" as a subject for research without purposefully "volunteering."¹⁶³ A subject entering into facilities where medical treatment is being provided to those in need by charitable organizations could easily mistake the experimental research for treatment by the charitable organization and "volunteer" for the experimental research, thus disposing of the need for researchers to obtain consent.¹⁶⁴ In communities subscribing to community consent, doctors performing experimental research under the Declaration of Helsinki are not required to obtain consent from every individual. According to the Code¹⁶⁵ and the Guidelines,¹⁶⁶ in communities subscribing to community consent, physicians should seek to obtain the consent of every individual, allowing community consent to act as a supplement to consent, not as a substitute.¹⁶⁷ The Declaration fails to make this distinction clear.

The WHO-CIOMS Guidelines address informed consent with all of the same requirements as the Code and Declaration, but specify that patients be informed in language they are capable of understanding.¹⁶⁸ The Guidelines enhance the protection of subjects by requiring investigators to

¹⁶¹ *Id.* at 3044, para. 20.

¹⁶² *Id.*

¹⁶³ Pfizer set up research headquarters next to an already present Doctors Without Borders ("DWB") facility, using some of DWB's bed space and part of DWB's treatment center in order to speed up the experimental trial process. Stephens, *supra* note 3. Pfizer researchers also hired out many of the physicians and medical assistants who were previously working with Doctors Without Borders and the local hospital in Kano to help facilitate in translation and patient care. *Id.*

¹⁶⁴ This situation is not a hypothetical. This kind of conduct is the very type that Pfizer allegedly took part in while in Kano, Nigeria. Patients did not sign provided consent forms. *Id.* Several patients did not know that they were part of experimental research. *See id.* Many felt that they had been tricked into participating in the experiment because Pfizer set up its research tent in close proximity to the Doctors Without Borders tent. *Id.*

¹⁶⁵ *See* Nuremberg Code, *supra* note 40, at art. 1.

¹⁶⁶ *See* WHO-CIOMS Guidelines, *supra* note 39, guideline 4 cmt.

¹⁶⁷ Osuntokun, *supra* note 151, at 31.

¹⁶⁸ WHO-CIOMS Guidelines, *supra* note 39, guideline 5.

obtain community consent where local customs require such consent.¹⁶⁹ The burden of ensuring patient understanding is placed on the physician, who must verify the understanding of a patient by administering a test to the participant.¹⁷⁰ If the physician is to take the role of investigator in obtaining informed consent, the physician is required to inform the patient of this role to clarify the doctor-patient relationship.¹⁷¹ These requirements assure that the patient will understand the nature of the research and that patients are not somehow tricked into participation through misunderstanding or faulty communication.

The Guidelines do not directly address community consent, clearly stating that each individual participating in experimental research must give informed consent.¹⁷² The Guidelines' comments specifically provide that community consent can play a role in informed consent, particularly when dealing with difficult questions of public policy or research involving minimal risk.¹⁷³ Under the Guidelines, Pfizer would not have been allowed to substitute community consent for individual consent because the risks to the participants were so great.¹⁷⁴

ii. Coercion

Voluntary consent, as described in article one of the Code, requires patients involved in experimental research be free from "any element of force, fraud, deceit, duress . . . or other ulterior form of constraint or coercion."¹⁷⁵ The absolute nature of voluntary consent allows little room for variation. The Code fails to mention mitigating or exculpatory circumstances wherein consent need not be completely voluntary. The Code's strict demand that all consent be absolutely untainted by external influence rejects the possibility that some level of coercion could legally exist in drastic circumstances and still preserve the patient's right to remain free to choose. This view of experimental procedure ignores the inherent coercion involved in certain types of experimental research. Such black and white exclusion of all research involving any element of coercion

¹⁶⁹ *Id.* guideline 4 cmt. The commentary clarifies that only informed consent may be supplemental and that voluntary consent must be individual. *Id.*

¹⁷⁰ *See id.*

¹⁷¹ *See id.* guideline 5.

¹⁷² *Id.* guideline 4.

¹⁷³ Community consent is appropriate, if not necessary, where information is obtained that would subject a community to stigmatization. *See id.* guideline 8 cmt. Such studies include research in epidemiology, sociology, and genetics. *See id.*

¹⁷⁴ *See id.* guideline 4 cmt. (stating that an ethical review committee may waive certain or all provisions of informed consent if there is only a minimal risk posed to the participant).

¹⁷⁵ Nuremberg Code, *supra* note 40, at art. 1.

would only achieve the undesired result of eliminating a great quantity of safe, effective experimental research.

Experimental research is sometimes needed for the benefit of a patient whose life depends on the success of the researcher.¹⁷⁶ In such situations there is a degree of external coercion placed upon a patient who is faced with no other alternative than to suffer the effects of his or her malady or to participate in experimental medical procedures.¹⁷⁷ It is generally accepted that certain circumstances exist where voluntary consent might be waived.¹⁷⁸ These circumstances usually exist in the form of emergency experimental research. U.S. courts have held that "a physician should not subject patients to a 'mere experiment . . . save possibly when the patient is in extremis, and fatal results substantially certain unless the experiment may succeed.'"¹⁷⁹ Emergency research situations typically involve doctors performing experimental procedures or research only when no other known alternative exists and the patient's life hangs in the balance.¹⁸⁰ In such situations, the patient may not have the ability to enter into voluntary consent due to the required spontaneity of the research or the duty of the physician to save the patient's life, thus requiring the attending physician to forego consent and administer the treatment. Such medical necessity should be viewed as exculpatory for an omission to obtain voluntary consent.¹⁸¹

There exists in any therapeutic research¹⁸² an element of coercion where the patient suffers from disease or other maladies and the outcome or

¹⁷⁶ Norman Fost, *Waived Consent for Emergency Research*, 24 AM. J.L. & MED. 163, 183 (1998).

¹⁷⁷ See *id.* at 176 (discussing the reduction of efficacy of consent in emergency settings); see also, George J. Annas, *Questing for Grails: Duplicity, Betrayal, and Self-Deception in Postmodern Medical Research*, in HEALTH AND HUMAN RIGHTS: A READER 312, 317 (Jonathan M. Mann et al eds., 1999) (noting that researchers during the Cold War did not obtain consent from the terminally ill because they could not be further harmed).

¹⁷⁸ See generally Jesse A. Goldner, *An Overview of Legal Controls on Human Experimentation and the Regulatory Implications of Taking Professor Katz Seriously*, 38 ST. LOUIS U. L.J. 63 (1993).

¹⁷⁹ *Id.* at 72 (quoting *Allen v. Voje*, 89 N.W. 924, 932 (Wis. 1902)).

¹⁸⁰ *See id.* at 74.

¹⁸¹ The existence of one exculpatory circumstance for requiring voluntary consent begs for further investigation into whether other circumstances might possibly mitigate or further exculpate the absolute necessity for a patient's voluntary consent. In this respect, the Code falls short, and regulation is needed to clarify requisite behavior in clinical trials regarding voluntary consent.

¹⁸² I will define therapeutic research as research involving the treatment of an individual suffering from the malady under investigation.

ultimate effect of the treatment is unsure.¹⁸³ Coercion, however, is offset by assurances from the treating physicians of adequate alternate treatment pending failure of the experimental procedure. In non-therapeutic research, the coercive effect can be offset by financial means.¹⁸⁴ Such reassured and guaranteed coercive elements are seen as ethical under the laws of most countries when the benefits of the experimentation outweigh the risks.

Regardless of the nature of the research, the Code disallows any type of coercion or duress in obtaining consent or in participating in experimental research,¹⁸⁵ thus preventing doctors from entering into situations where they can not guarantee patients alternate treatment in spite of patients' participation in the research process.¹⁸⁶ This is especially relevant in developing countries where necessary medical treatment is not always available to every person. The lack of options available to the patient could be seen as unethical due to the external influence on the patients' decision to participate in research procedures,¹⁸⁷ and could result in the loss of an opportunity to conduct legitimate research. This outcome is drastic and harsh on medical progress.

The Declaration addresses coercion as it relates to the doctor-patient relationship but fails to address external sources of coercion, such as an epidemic, that could influence patients in their decision to participate in experimental research. The Declaration provides that "special attention is required for those who may be subject to giving consent under duress."¹⁸⁸ The "special attention" provision of the Declaration only provides a remedy for coercive circumstances within a doctor-patient relationship;¹⁸⁹ the Declaration does not address the possibility of externally coercive elements arising outside of the doctor-patient relationship. If a coercive situation arises within the doctor-patient relationship, a third party not participating in the investigation and not a party to the doctor-patient relationship may obtain consent to participate from the patient.¹⁹⁰

While requiring that all participants in experimental research be volunteers,¹⁹¹ the Declaration fails to address external sources of coercion

¹⁸³ For a more complete discussion on coercion in therapeutic research see Annas, *supra* note 177, at 312.

¹⁸⁴ In some respects, offering monetary compensation for participation in experimental research (especially in poorer populations) is coercive . . . much like holding a carrot in front of a horse.

¹⁸⁵ Nuremberg Code, *supra* note 40, at art. 1.

¹⁸⁶ *Id.* at art. 5.

¹⁸⁷ See WHO-CIOMS Guidelines, *supra* note 39, guideline 21 cmt.

¹⁸⁸ Declaration of Helsinki, *supra* note 39, at 3043, para. 8.

¹⁸⁹ *Id.* at 3044, para. 23.

¹⁹⁰ *Id.*

¹⁹¹ *Id.* at para. 20.

in the patients' decision-making process, thereby not sufficiently protecting patients. As one doctor working with Doctors Without Borders in Kano at the time of the meningitis outbreaks stated:

It's an emergency situation—an epidemic situation—and you are trying a drug that has not been tested. It raises a lot of moral and ethical questions, especially in an illiterate environment. Imagine coming to the hospital, a poor man hearing that there is this thing they want to give to your kid and it's free. At that time, you'll sign anything.¹⁹²

The failure of the Declaration to specify a physician's need to recognize external sources of coercion effectively disperses the physician's burden to protect the individual from coercion to participate in experimental research.

The Declaration carefully addresses the topic of therapeutic research, seeking to protect participants when their well-being is at stake. The Declaration clarifies that when therapy is combined with research, additional standards apply.¹⁹³ These additional standards are explicitly given to protect the rights of the patient.¹⁹⁴ According to the additional standards, researchers bear the burden of showing that the benefits of the research outweigh the risks as compared "against those of the *best current prophylactic, diagnostic, and therapeutic methods.*"¹⁹⁵ The Declaration also requires physicians conducting therapeutic research make available the best treatment to participants at the conclusion of the research.¹⁹⁶

Conducting therapeutic research during an epidemic presents the additional problem of conflicting objectives within the doctor-patient relationship.

[C]linical research is an activity designed to produce generalizable knowledge through the application of procedures of potential diagnostic or therapeutic value to those involved as patient-subjects; and *non-therapeutic research* is an activity designed to produce generalizable knowledge through the application of procedures without the intention of directly benefiting those involved as subjects.¹⁹⁷

¹⁹² Sam Eferaro, *supra* note 6.

¹⁹³ Declaration of Helsinki, *supra* note 39, at 3044, para. 28.

¹⁹⁴ *Id.*

¹⁹⁵ *Id.* at 3045, para. 29 (emphasis added). The standard for research without therapy takes into account the "predictable risks and burdens in comparison with foreseeable *benefits to the subject or to others.*" *Id.* at 3044, para. 16 (emphasis added).

¹⁹⁶ *Id.* at 3045, para. 30.

¹⁹⁷ Alexander M. Capron, *Different Compensation Approaches to Bad Outcomes from Standard Treatment, Innovative Treatment, and Research*, in MEDICAL INNOVATION AND BAD OUTCOMES: LEGAL, SOCIAL AND ETHICAL RESPONSES 145, 149 (Mark Siegler et al. eds., 1987).

The object of a doctor-patient relationship for the researcher in experimental research is "not the marketplace, but *the laboratory*. The object of . . . [the] visit . . . [is] not commerce but *research* on human beings."¹⁹⁸ The objectives of patients in developing countries during an epidemic are therapeutic. As one Nigerian doctor in Kano pointed out, "[t]he patients did not know if it was research or not . . . [t]hey just knew they were sick."¹⁹⁹ Because the ends to commercial research efforts are primarily for profit, and the ends for volunteers participating are therapeutic, volunteers participating in the experimental research in such drastic settings are bound to be confused where charitable efforts are working side by side with for-profit research.

The Guidelines acknowledge the need for researchers to provide participants with some sort of compensation to keep profit and therapeutic ends rigidly separate.²⁰⁰ "Researchers from developed countries who seek to conduct clinical trials in Africa instead of in their home countries should provide special justification. In particular, the research must meet all international ethical requirements and confer a benefit on the African community."²⁰¹

Research participants are usually given some sort of consideration for their participation, even when the research results may be therapeutic in nature. This consideration usually comes in the form of monetary compensation.²⁰² However, when applied to a situation in an impoverished, developing country, foreign money could be seen as an "undue influence" for participation.²⁰³ Many of the participants involved in the research in Kano were in poverty.²⁰⁴ Offers of foreign financial aid and a quick fix might induce those more in need of monetary than medical assistance to take part in the research, leaving out those who stand in real need.²⁰⁵ A

¹⁹⁸ Smith v. United States, 412 F.2d 791, 792-93 (9th Cir. 1969) (Hufstedler, C.J., dissenting) (emphasis added).

¹⁹⁹ Stephens, *supra* note 3.

²⁰⁰ See WHO-CIOMS Guidelines, *supra* note 39, guideline 7.

²⁰¹ Ankrah & Gostin, *supra* note 20, at 555.

²⁰² See WHO-CIOMS Guidelines, guideline 7.

²⁰³ See Declaration of Helsinki, *supra* note 39, at 3043, para. 13; see also WHO-CIOMS Guidelines, *supra* note 39, guideline 10 cmt. (stating the concern that countries with limited resources will be vulnerable to exploitation by wealthy countries).

²⁰⁴ See Sarah Boseley, *Ailing Ethics: A Clinical Trial Raises Disturbing Questions about Drug Companies' Activities in Africa*, THE GUARDIAN (London), Jan. 20, 2001, at 20. "It is unjust to selectively recruit impoverished people to serve as research subjects simply because they can be more easily induced to participate in exchange for small payments." WHO-CIOMS Guidelines, *supra* note 39, guideline 12 cmt.

²⁰⁵ The concept of overuse of patients for research is approached in the WHO-CIOMS Guidelines. The Guidelines recognize the need to diversify those used in research, so as not to place the burden of research entirely on one class. *Id.* It is suggested that offering large

better idea would be to provide additional medical care for those participating in the research. A staff dentist, optometrist, or general physician might accompany the group to perform routine physicals and other more basic medical procedures for those participating in the research activities.²⁰⁶ Care should be limited to basic medical needs. This is necessary to maintain the separation from other care-giving groups. Extra care given to those volunteers participating in the experimental research should be explicitly separate from the care given to others, so as not to confuse purely charitable efforts with for-profit research.

The WHO-CIOMS Guidelines require that “special justification” be given for the participation of vulnerable subjects in experimental research.²⁰⁷ The “special justification” provision in the Guidelines is similar to the Declaration’s “special attention,” but the Guidelines require that the rights and welfare of vulnerable patients be “strictly applied.”²⁰⁸ The rights of freedom from coercion for patient participants are clearly provided in the Guidelines, and the extra requirement of strict application of patient rights and welfare rightly places the burden on the physician to ensure the protection of vulnerable patients. Taking into account external sources of coercion and protecting patients in dire health or extreme poverty,²⁰⁹ the Guidelines not only require that physicians recognize potential economic coercion, but provide specific guidelines for physicians conducting research in these circumstances.²¹⁰ Physicians may provide compensation for patients’ participation in research, including free medical services, so long as it does not produce “undue inducement.”²¹¹ The Guidelines also stipulate that any reimbursements for participation be approved by an ethical committee.²¹² This limitation takes excessive discretion out of the exclusive control of physicians conducting the research.

The fact that the subjects of Pfizer’s research were children is one of the main concerns with Pfizer’s research in Nigeria.²¹³ The Code

amounts of money for compensation on a consistent basis would expose the community to overuse. *Id.*

²⁰⁶ See *id.* guidelines 7 cmt., 21 cmt (stating that unrelated health care services may be performed free of charge and, while not required, offering these services is “morally praiseworthy”).

²⁰⁷ *Id.* guideline 13.

²⁰⁸ *Id.*

²⁰⁹ For example, the Guidelines require that children consent to experimental research, but if the child is very young and immature the parents of the child can override the child’s refusal to participate when no other available treatments exist. *Id.* guideline 14 cmt.

²¹⁰ See *id.* guideline 7.

²¹¹ *Id.*

²¹² *Id.*

²¹³ See Stephens, *supra* note 3.

incidentally addresses research focused on vulnerable groups such as those lacking "legal capacity" to consent.²¹⁴ The Declaration does little to provide a clear definition of which persons are to be considered vulnerable. The only standard given to clarify the Declaration's coverage of persons to be afforded "special attention" is that of the economically disadvantaged: those who cannot give consent themselves; those giving consent under duress; or those involved in therapeutic research.²¹⁵ This application of "special attention" does not give much instruction on protection from coercion provided to these groups.²¹⁶ The Guidelines, on the other hand, specifically provide that children are considered vulnerable persons,²¹⁷ give specific actions for researchers to follow, and the mandate that procedures and protections for children be "strictly applied."²¹⁸

iii. Capacity to Understand

The Code fails to address the possibility of proxy consent for minors or other groups unable to comprehend informed consent. All subjects are required to understand the research in which they are participating and the consequences of their decision.²¹⁹ Because much research is complex and has potentially fatal consequences for the subject providing consent, it can be reasonably said that the Code prohibits experimentation on minors unable to comprehend their situations. Such an interpretation is hardly feasible if medical science is to progress in the area of pediatric medicine. In this sense, the Code is too strict and unbending to be of any practicable use for regulating experimental research on minors. The subject of proxy consent for minors is yet another reason why the medical community, as

²¹⁴ Nuremberg Code, *supra* note 40, at art. 1.

²¹⁵ Declaration of Helsinki, *supra* note 39, at 3043, para. 8 ("Some research populations are vulnerable and need special protection. The particular needs of the economically and medically disadvantaged must be recognized. Special attention is also required for those who cannot give or refuse consent for themselves, for those who may be subject to giving consent under duress, for those who will not benefit personally from the research and for those for whom the research is combined with care.").

²¹⁶ Another problem with the Declaration's broad definition of vulnerable groups is that the Declaration leaves ambiguous terms to national or local interpretation. Many developing countries do not legally recognize any group as vulnerable, giving the Declaration's "special attention" provision little, if any, effect.

²¹⁷ WHO-CIOMS Guidelines, *supra* note 39, guideline 13 cmt.

²¹⁸ See *id.* guidelines 13, 14. The Guidelines also delineate between ages of children as their ability to understand increases and susceptibility to coercion lessens. See *id.* guideline 14 cmt. (stating that older children who are more capable of giving consent should be selected before younger children).

²¹⁹ Nuremberg Code, *supra* note 40, at art. 1.

well as many developing nations, have refused to acknowledge the Code as anything more than suggestive.

The Declaration's focus on understanding and competency is perhaps its strongest point. The Declaration recognizes the vulnerability of groups of people who lack the ability to adequately understand the complexities of participation in experimental treatments, specifically minor children.²²⁰ Researchers seeking participants considered "vulnerable" are to give "special attention" for protecting participants' rights.²²¹ Researchers are instructed to obtain informed consent from each individual deemed vulnerable, including children.²²² With individuals lacking the capacity to give informed consent, the researcher is required to obtain informed consent from the legal guardian.²²³

The Declaration's policy of adhering to local law for legal standards governing vulnerable individuals is problematic because interpretation of ambiguity in the Declaration's standard is left to local laws.²²⁴ When conducting experimental research in developing countries, the Declaration requires doctors to conduct their research under the supervision of a national or local independent review board to ensure adherence to national and local standards. Oftentimes, however, developing nations lack guidelines for or even fail to provide an independent review board.²²⁵ Because national laws in developing countries are often much less stringent than those in developed nations, physicians conducting experimental research encounter very few laws providing definitions of legal competency for ethical research.²²⁶ This leaves researching doctors without adequate guidance while conducting research.

Many of the parents of the children participating in the Pfizer research claimed that they did not understand that their children were participating in experimental research.²²⁷ Perhaps Pfizer's doctors only obtained consent from the children participating in the research, failing to adequately inform

²²⁰ See Declaration of Helsinki, *supra* note 39, at 3044, paras. 24-26.

²²¹ *See id.*

²²² *See id.*

²²³ *Id.* at para. 24.

²²⁴ *See id.* at 3043, para. 13.

²²⁵ Such was the case with Pfizer. Several of the Nigerian doctors working with Pfizer later admitted that there was no ethical review board present at the hospital where Pfizer was conducting its experiments. In fact, the hospital's medical director later admitted that an ethical committee was created only after Pfizer had left and that the documents from the hospital's ethical committee permitting Pfizer to conduct its experimentation in Kano were created after Pfizer left Kano. Boseley, *supra* note 6.

²²⁶ *See* Stephens, *supra* note 3.

²²⁷ *See id.*

the parents of the nature of the research.²²⁸ Whether the ethical review board in charge of supervision failed in its capacity to inform Pfizer's doctors about local laws regarding competency of minors or whether local laws defining competency of minors simply did not exist at the time, the charge that Pfizer's doctors failed to recognize the need for supplemental consent serves to illustrate the Declaration's practical weaknesses. The Declaration adequately addresses theoretical issues of competency and understanding of the research subject, but fails in its practical application.

The Guidelines require "special justification" for including vulnerable individuals in experimental research, and require strict protection of vulnerable patients' rights and welfare once included.²²⁹ The Guidelines don't leave vulnerability questions open to interpretation by physicians, but provide specific categories of individuals considered "vulnerable,"²³⁰ and further subdivide vulnerable groups for clarification.²³¹

The Guidelines provide detailed requirements for physicians to follow to protect the rights and interests of the vulnerable patient. Ethical justification of the involvement of vulnerable subjects requires researchers to respond to an ethical review committees' inquiry regarding: (1) whether the research could not be carried out with less vulnerable subjects; (2) whether the research will lead to improved diagnosis, prevention, or treatment of diseases unique to the vulnerable class; (3) whether members of the vulnerable class will be assured access to diagnostic, preventive, or therapeutic products that will become available as a consequence of the research; (4) whether the risks attached to research will be minimal; and (5) whether researchers will obtain supplemental proxy consent from legal guardians.²³²

The Guidelines provide special protection for children as vulnerable subjects, requiring that each child consent to research and

²²⁸ See '*Why We Sued Pfizer in US*', *supra* note 11.

²²⁹ WHO-CIOMS Guidelines, *supra* note 39, guideline 13.

²³⁰ These include children, elderly, persons suffering from life-threatening diseases, persons interned in long-term care facilities, etc. *Id.* guideline 13 cmt.

²³¹ The subdivisions are: 1) Those who would be capable of informed consent but are not given the right to the necessary autonomy by their own society at large; examples are women, handicapped people, and prisoners; 2) those who might be unduly influenced or tricked into consent unless very special precaution is taken to present simple and clear information: examples are members of communities unfamiliar with modern medical concepts; 3) those who, under any circumstances, might not be capable of informed consent; examples are children, and many of the mentally ill; 4) those dependent upon the researchers for their livelihood or studies; examples are medical students. C. de Sweemer-Ba, *Informed Consent: Protecting the Vulnerable*, in ETHICS AND RESEARCH ON HUMAN SUBJECTS: INTERNATIONAL GUIDELINES, PROCEEDINGS OF THE XXVITH CIOMS CONFERENCE 36, 37 (Z. Bankowski & R.J. Levine eds., 1993).

²³² WHO-CIOMS Guidelines, *supra* note 39, guideline 13 cmt.

requiring that the purpose of the research be to obtain knowledge specifically relevant to the health needs of children.²³³ Additional issues addressed include: the maturity of the child; the age of the child; and the ability of parents to override a child's refusal to treatment when there is no available alternative.²³⁴ The Guidelines allow parental supplemental consent to be procedurally governed by the local government, but supplemental consent of the child's parents is essential, independent of local requirements.²³⁵ The Guidelines also provide that older children should be used for research before younger children.²³⁶

The Guidelines require, through the doctrine of "responsiveness"²³⁷ that any positive benefits received from the experimental research be provided to the community from which the information was extracted.²³⁸ The commentary to Guideline 10 further explains, "[t]his is especially the case when research is conducted in countries where governments lack the resources to make such products widely available."²³⁹ This requirement assures that while certain communities may be vulnerable to exploitation, abuse will be minimal by providing vulnerable communities with needed care. Part of the reason for outrage against Pfizer was that Pfizer came, conducted its research and left,²⁴⁰ leaving patients feeling that they had been used and had not been given sufficient care.²⁴¹

B. Enforcement

The Code seeks to punish criminal behavior,²⁴² but fails to set a standard for behavior that is not antisocial or even necessarily intentional. In many cases, civil liability may well suit the bill to serve the demands of justice. Where behavior by experimenting physicians leaves criminal jurisdiction and approaches medical malpractice is a line not clearly marked, and in fact, may not be even considered by the Nuremberg Code.

²³³ *Id.* guideline 14, cmt.

²³⁴ See *id.* guideline 14 cmt.

²³⁵ *See id.*

²³⁶ *Id.* This was one of Pfizer's problems in conducting their research. Patients seeking help began to pour into the hospital where Pfizer was camped. As the numbers rapidly grew, Pfizer stopped distinguishing patients on the basis of their age. See Stephens, *supra* note 3.

²³⁷ WHO-CIOMS Guidelines, *supra* note 39, guideline 10, cmt.

²³⁸ *Id.* guideline 10.

²³⁹ *Id.* guideline 10 cmt. The commentary further provides that if the benefits of the research are "used primarily for the benefit of populations that can afford the tested product, the research may rightly be characterized as exploitative and, therefore, unethical." *Id.*

²⁴⁰ See Stephens, *supra* note 3.

²⁴¹ *See id.*

²⁴² See Annas, *supra* note 177, at 314-16.

The Code does not address the need for supervision and enforcement of experimental research in developing countries. The need becomes apparent when faced with the facts of Pfizer's case. When confronted with accusations of abuse, the Pfizer researchers produced evidence of permission to conduct the research project from the local ethical oversight committee in the Kano regional hospital.²⁴³ However, one of the doctors at the hospital in Kano alleged that there was no ethical oversight committee at the hospital at the time Pfizer came to Kano and further alleged that Pfizer never had permission to conduct research in Kano.²⁴⁴ The doctor further alleged that Pfizer forged the evidence of permission and backdated individual consent forms.²⁴⁵ Finally, when doctors in Kano tried to report Pfizer's conduct to national authorities, their request for audience was dismissed without reason.²⁴⁶ Similarly, the suit brought in Nigeria has experienced recent publicity due to its problems in getting underway. Lawyers on both sides, judges, and clients have consistently failed to appear on the trial date.²⁴⁷ Recently, the lawyers handling the Pfizer suit explained their decision to bring suit in the U.S. was influenced by Pfizer's political influence in Nigeria and repeated procedural difficulties in Nigerian courts.²⁴⁸

The Declaration does not provide a legal standard for the enforcement of its provisions. The Declaration places enforcement of its standards on local ethical oversight committees.²⁴⁹ However, many developing countries do not have the ability,²⁵⁰ resources, or political will²⁵¹ to sufficiently

²⁴³ See Boseley, *supra* note 6; Joe Stephens, *Doctors Say Drug Trial's Approval Was Backdated*, WASH. POST, Jan. 16, 2001, at A1.

²⁴⁴ Boseley, *supra* note 6. The Nigerian government later acknowledged that Pfizer had obtained national permission to conduct experimental research, but no evidence has been given to show that permission was obtained in Kano or that any kind of national or local oversight was provided. See Sam Eferaro, *NAFDAC Okayed Pfizer's Trovan Trials*, AFRICA NEWS, Jan. 8, 2001, available at LEXIS, News Library, Africa News File.

²⁴⁵ Boseley, *supra* note 6; Stephens, *supra* note 243.

²⁴⁶ See Boseley, *supra* note 6; Stephens, *supra* note 243.

²⁴⁷ See *Absence of Victim's Lawyer Stalls Pfizer Drug Case in Nigeria*, AGENCE FRANCE PRESSE, Apr. 5, 2001, available at 2001 WL 2378421 (identifying travel problems for a victim's lawyer). See also *In Nigeria, Case Against Pfizer Over Meningitis Drugs Adjourned*, AGENCE FRANCE PRESSE, May 31, 2001.

²⁴⁸ 'Why We Sued Pfizer in US', *supra* note 11.

²⁴⁹ Declaration of Helsinki, *supra* note 39, at 3043, para. 13.

²⁵⁰ See Karen DeYoung & Deborah Nelson, *Latin America is Ripe for Trials, and Fraud: Frantic Pace Could Overwhelm Controls*, WASH. POST, Dec. 21, 2000, at A1 (discussing vulnerability of Latin America). Since April, when Pfizer's case was allowed in a Nigerian federal court, multiple demonstrations by thousands of Nigerians have taken place due to the common adjourning and rescheduling of the lawsuit against Pfizer. See *In Nigeria, Case Against Pfizer Over Meningitis Drugs Adjourned*, AGENCE FRANCE PRESSE, May 31, 2001, available at 2001 WL 2418513 (delaying of case due to a jurisdictional challenge).

maintain ethical oversight committees.²⁵² Moreover, local laws do not always prescribe the use of ethical oversight committees.²⁵³ This looseness of oversight—or non-existence thereof—further illustrates the Declaration's lopsided intent to protect physicians conducting experimental research abroad.

Another type of enforcement provided for in the Declaration is that of political enforcement. Researchers are required to preserve accurate records of their results,²⁵⁴ and are urged to publish both positive and negative results,²⁵⁵ as well as sources for funding and possible conflicts of

Nigerians are beginning to show distrust for the ability of their local courts to fairly try claims. See *Nigerian HIV/AIDS Drug Trial Delay*, MARKETLETTER, Dec. 17, 2001, available at 2001 WL 31103635 ("Pfizer's influence would have prevented justice."); see also 'Why We Sued Pfizer in US', *supra* note 11 (explaining that the reasons for choosing to file suit in the U.S. were because Pfizer had influence in the Nigerian government and was seeking to influence government decisions). Nigerians are beginning to show distrust in their local governments to protect them from abusive research. Recently, reports have arisen of the unwillingness of Nigerians to submit to experimental research, as well as other kinds of treatment, including vaccinations, fearing that Western corporations and local governments are not protecting the citizens. See *Nigerian HIV/AIDS Drug Trial Delay*, *supra*. Many Nigerians are afraid of another "Trovan" incident.

²⁵¹ During the 1990's, Nigeria's national government was overturned four times—once since the meningitis epidemic in 1996—and only recently emerged from dictatorial military rule. See *Nigeria: Chronology of the Struggle for Stability and Democracy* (Aug. 24, 2000), at <http://allafrica.com/stories/200008240352.html>. In such highly dynamic times, adequate governmental oversight and enforcement of ethical behavior can be difficult, if not impossible. *Id.* Governments in constant flux do not have the budget or ability to police every activity within its borders. Executive control is not the only problematic area during governmental flux; the judicial branch also suffers from dynamic, drastic governmental changes. In often-changing governments, there exists a greater potential for judicial corruption and lack of organization. Newly created judiciaries lack experience and often suffer from procedural difficulties, resulting in questionable behavior behind the bench. This is nowhere more obvious than in Pfizer's Nigerian case.

²⁵² Adding to the complexities of Pfizer's situation, default Islamic laws in Kano, in the absence of national regulation, prohibit performing autopsies, thereby preventing any inquiry as to the cause of death of patients involved in Pfizer's research. Yinka Olusanya & Lawrence Ndukwe, *Trovan: Records of 350 CSM Patients Vanish*, AFRICA NEWS, Jan. 3, 2001, available at LEXIS, News Library, Africa News File. But see Abdulziz Sachedina, *Islam*, in *ENCYCLOPEDIA OF BIOETHICS* 1289, 1291 (Warren Thomas Reich ed., 1995) (stating that Islamic law permits autopsies if necessary for research needed to cure a disease).

²⁵³ It is not clear whether an ethical oversight committee was required in Nigeria at the time of the Pfizer incident in Kano, but the allegations of the absence of an ethical oversight committee allow the inference that they are not required.

²⁵⁴ Declaration of Helsinki, *supra* note 39, at 3044, para. 27.

²⁵⁵ *Id.* Research language throughout the Declaration switches between 'must' and 'should,' varying with the degree of deference a doctor should give to the document. For

interest.²⁵⁶ The only suggested recourse against violations is that publishers should not publish reports of experimentation found not to have complied with the Declaration's standards.²⁵⁷ These remedies are hardly the makings of legal enforcement, but more closely resemble professional regulation of misconduct.

The WMA's Declaration of Helsinki appears to be solely interested in protecting doctors' rights and in protecting the advance of science. Because of its one-sided approach to regulation, the Declaration of Helsinki does not provide adequate legal guidance to companies, but more closely resembles a field manual for procedural policy. The loose, permissive language of the Declaration supports this conclusion.²⁵⁸

The Guidelines state that every patient suffering accidental injury from experimental research has the right to compensation. The Guidelines do not provide for criminal liability, but do clarify that ethical review committees do not have the power to impose sanctions on violations by researchers.²⁵⁹ The ethical review committee has the duty to report any significant violations to local or national governments or enforcement entities.²⁶⁰ The Guidelines state that certain methods of control are preferred, including the "cultivation of an atmosphere of mutual trust, and education and support to promote in researchers and in sponsors the capacity for ethical conduct of research."²⁶¹ In this respect, the Guidelines shift its focus from the rights of the patient to the benefit of scientific progress, doing much to deter abuse in experimental research, but little to aid enforcement of international standards.

example, the Declaration requires that a patient be a volunteer, using the language, "subjects *must* be volunteers and informed participants in the research project," leaving little wiggle room for guesswork. *Id.* at para. 20 (emphasis added). However, in other areas, such as possible remedies for coercion in a doctor-patient relationship, doctors are advised, "the informed consent *should* be obtained by a well-informed physician who is not engaged in the investigation and who is completely independent of this relationship." *Id.* at para. 23 (emphasis added).

²⁵⁶ *Id.* at para. 27.

²⁵⁷ *Id.*

²⁵⁸ Again, the Declaration uses the permissive 'should' in describing the researchers' duty to publish positive and negative results of their research. *See id.*

²⁵⁹ WHO-CIOMS Guidelines, *supra* note 39, guideline 2 cmt. The Guidelines adopt the sanctions from the Declaration of Helsinki, but are less stringent in the area of publication, finding that publication of results could benefit communities as well as science in general. *See id.* Sanctions available include "fines or suspension of eligibility to receive research funding, to use investigational interventions, or to practice medicine." *Id.*

²⁶⁰ *Id.*

²⁶¹ *Id.*

None of the standards, including the Code,²⁶² has been afforded the weight of binding international law,²⁶³ but carry only suggestive or persuasive weight in regulating conduct by doctors or in finding liability for individuals accused of unethical experimental research.

The Code was meant to prescribe physician conduct to certain minimums of ethical behavior as are required by universal moral, ethical and legal concepts, the violation of which would bring down the condemnation of society.²⁶⁴ Notwithstanding the intentions of the prosecutors and judges at the Nuremberg trials to curtail unethical behavior by doctors, application of the Code's standard has been nearly impossible. Because of the contextualized nature²⁶⁵ of these trials, most doctors conducting experimental research abroad worry little that their actions will be comparable to the brutal experiments performed by the Nazi doctors.²⁶⁶

Because the Code has been applied in a real world setting, it carries an air of authority that other international guidelines lack. The Code provides a broad, bright-line definition of what is universally needed to conduct ethical research in an international setting, but is largely inapplicable because of its failure to address outlying considerations.²⁶⁷

While the Code has provided direction in the past, modern circumstances require additional guidance to enlighten researchers. In comparing the Pfizer case to the international standards found in the Code, its shortcomings become more apparent. Patients in the Pfizer case were not given a choice whether they would be among the patients selected to take the drug already proven effective or those taking the experimental

²⁶² The Nuremberg Code has been proposed as an international standard, but the Tribunal was chiefly made up of American judges and lawyers. For this reason, many have argued that the Nuremberg standard has never been officially sanctioned as international law. See Miller, *supra* note 38, at 203.

²⁶³ *Id.* at 202. For an overview of treatment of Nuremberg's principles of international law in the U.S. see Harold Hongju Koh, *Transnational Public Law Litigation*, 100 YALE L.J. 2347, 2359-60 (1991) (analyzing the history of U.S. court treatment of transnational public law litigation).

²⁶⁴ Sebring, Beals & Crawford, *supra* note 16, at 297-98.

²⁶⁵ Many physicians feel that the Code only addresses human subject experimentation not involving therapeutic needs of a patient. Therefore, much of the research being conducted on patients actually suffering from the maladies being investigated was deemed as therapy, not experimental research, thereby exempting physicians from following its precepts. See Michelle D. Miller, *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 (1997).

²⁶⁶ See Ann E. Ryan, *Protecting the Rights of Pediatric Research Subjects in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use*, 23 FORDHAM INT'L L.J. 848, 869 (2000).

²⁶⁷ See Annas, *supra* note 177, at 315.

drug.²⁶⁸ Alternate methods of obtaining medical help were not guaranteed to those not participating in the test,²⁶⁹ tragically forcing patients to decide whether to participate in the experimental research or take the chance of not getting necessary treatment for their malady.²⁷⁰ Voluntary consent in this setting is no longer completely voluntary.²⁷¹ The substance of the patient's voluntary consent is diminished to a choice between the lesser of two evils.

When compared with the Nazi medical experimentation, however, Pfizer's conduct does not measure up.²⁷² While Pfizer's actions may have been unethical, undesirable, or even criminal, they can only compare to the Nazi experimental research in small degree. The Pfizer researchers arguably had some legitimate benefit to society in mind, whereas many of the Nazi experiments were conducted only for the pleasure of the treating physicians.²⁷³

Pfizer is not entirely free of guilt. Pfizer used an epidemic to conduct experimental research on children. Pfizer created ad hoc experimental trials to catch an epidemic while it still raged.²⁷⁴ Abandoning its patients after only six weeks of treatment, the patients were left before they received adequate help.²⁷⁵ It is difficult to even compare what was done by Nazi physicians with what happened with the Pfizer researchers in Nigeria.

²⁶⁸ See Stephens, *supra* note 3.

²⁶⁹ *See id.*

²⁷⁰ The patient's decision-making ability is severely limited by the consequences of their choice: death or permanent disability from lack of treatment, or an experimental treatment whose most drastic consequences are equal to suffering without treatment. A reasonable person may choose the experimental treatment over no treatment. As the lead doctor in charge of research at Pfizer stated, "That was kind of a desperate time for them—they were happy to have anyone come in and do just about any kind of work. . ." Stephens, *supra* note 3.

²⁷¹ A patient still has the right to choose, but the substance of their consent is taken away from them and transferred to the doctors conducting the experiment.

²⁷² Professor Goldner, in distinguishing negligence in experimentation from criminal intent in willfully causing harm, states, "[T]he physician was acting in relatively good faith for the benefit of the patient,' as opposed to the intentional antisocial malice that was seen as being at the root of the concept of battery." Goldner, *supra* note 178, at 76 (citing *Nathanson v. Kline*, 350 P.2d 1093, 1106 (Kan. 1960)).

²⁷³ Taylor, *supra* note 27, at 70.

²⁷⁴ For a more descriptive analysis of the ethical considerations surrounding ad hoc experimentation, see S. Rebecca Holmes-Farley & Michael A. Grodin, *Law, Medicine and Socially Responsible Research*, 24 AM. J.L. & MED. 153 (1998).

²⁷⁵ Administering experimental medicine to a suffering patient is not always better than nothing at all. A partial treatment creates the illusion for other physicians that some treatment has been provided, giving priority to other patients to receive proven treatment. This is especially true where numbers of cases are high and medicine is in short supply.

In the cases of the Nazi physicians and Pfizer, the Code fails to distinguish between a crime against humanity and a lesser evil. The only guidelines provided by the judges who created the Code are the conclusions as to the Nazi physicians' intent and purpose in conducting the experiments, stating: "We find from the evidence that in the medical experiments which have been proved, these ten principles were much more frequently honored in their breach than in their observance."²⁷⁶ Pfizer's conduct comes closer to reckless behavior than egregious, intentional destruction, as was the case with the Nazi physicians' experiments.

With an overriding interest in protecting researchers and their activities, the Declaration fails to address legal consequences for violations of its guidelines, either in adherence or enforcement.²⁷⁷ This is not to say that the Declaration does not have its place, but it is best suited as a policy guide for individual corporations within the industry, rather than a guide for entire nations or as an international regulation.

Because the World Medical Association, which is made up of officials elected or appointed by the healthcare industry, drafts the Declaration,²⁷⁸ the Declaration's principles are strongly influenced by a desire to advance the medical industry.²⁷⁹ Even when the ends of the industry appear to be humanitarian in nature, private entities do not have the inherent responsibility to humanitarian means that are typical of governmental organizations. Because the organization as a whole is not political, or subject to the will of the people, there is no oversight function to ensure protection of third-party interests.

The Declaration fails to effectively balance protection of the rights of individuals participating in experimental research and the protection of physicians and scientific progress. Because of this imbalance, the Declaration would not serve as an appropriate standard for experimental research conducted in an international setting. However, the Declaration would prove effective as a professional standard for physicians conducting experimental research abroad. Much like the American Medical Association, WMA and the Declaration provide ethical standards within the medical profession.

The Guidelines offer a more balanced approach between human rights and the protection of professionals and other entities engaged in international experimentation involving humans. Providing explicit remedies for injury to the patient and liabilities for doctors violating its

²⁷⁶ Sebring, Beals & Crawford, *supra* note 16, at 299.

²⁷⁷ In fact, the only consequences or attempts at enforcement of the Declaration can be found in paragraph 27, wherein the WMA advises that any violation of the standards created in the Declaration should result in the refusal of any entity to publish the results of the experimental research. *See* Declaration of Helsinki, *supra* note 39, at para. 27.

²⁷⁸ *See* WMA Policy, *supra* note 50.

²⁷⁹ *See id.*

standards,²⁸⁰ the Guidelines seem the most plausible as a ready-made international guide for corporations and professionals seeking to conduct experimental research on human subjects abroad. However, much like the Declaration, the Guidelines lack legal effect, and are only persuasive arguments for what international standards should be. The UN has yet to adopt or implement these Guidelines as binding law.²⁸¹ By limitation of the WHO Constitution, the UN has not given the WHO legislative capacity or binding regulatory power.²⁸² The WHO only has power to suggest its guidelines to individual countries for implementation.²⁸³ This limitation of power is an extremely sovereignty-cautious approach toward worldwide protection of health and is an inefficient means of obtaining the WHO's objective of ensuring governmental responsibility for maintaining the overall health of its population.

Universal adoption of any one of the standards as conclusive and binding on any country, let alone the international community, would not adequately serve to protect individuals or groups from abusive experimental research. The three standards cannot continue to co-exist in their current incarnations because each requires different procedures from researchers and each prohibits or allows different practices. Researchers attempting to follow all three simultaneously are left with no clear indication as to what measures to take when contradictions arise. For individual standards, researchers are given little direction as to which is the correct standard to follow, affording patients little protection from misconduct and unethical experimental procedures. In this respect, the moral underpinnings of individual autonomy are not safeguarded and are not substantively reflected in the three standards.

IV. Solutions

An international standard should provide guidelines to national and local governments regarding minimum standards to conduct, or participate in, international experimental research. It must also be enforceable, carrying with it the approval and application of developed and less developed nations to secure its integrity.

An international standard must also respect national government sovereignty by setting minimum requirements, allowing additional national

²⁸⁰ See WHO-CIOMS Guidelines, *supra* note 39, guideline 2 cmt. 19.

²⁸¹ See Ryan, *supra* note 266, at 863.

²⁸² See the enumerated powers of the WHO in the Constitution of the World Health Organization, *supra* note 75, at art. 2, 62 Stat. at 2681-82, 14 U.N.T.S. at 187-89; see also *What is CIOMS?*, *supra* note 83.

²⁸³ Constitution of the World Health Organization, *supra* note 75, at art. 23, 62 Stat. at 2685, 14 U.N.T.S. at 193.

governmental regulation and implementation of international standards. Individuals and companies failing to meet this standard should be held publicly accountable; violators should be brought before an appropriate court to preserve fairness and justice. A system for addressing criminal and civil violations of the international standard must be in place. Countries and people affected by abuse of the international standard should be given venue and an opportunity to publicly air their claims and seek legal redress.

An international standard regulating human experimentation should contain clear guidelines for researchers, governments, and patients to follow for protection and guidance. Voluntary consent should be expressly required, requiring specific international minimums for ethical behavior regarding all aspects of consent, coercion, and capacity. The international standard should provide for specific measures to be taken to protect patients and instruct doctors. Specifically, researchers should be required to clarify and distinguish experimental research from charitable aid. Special measures should be provided for exigent circumstances where issues of vulnerability or external coercion arise. Enforcement of the standard should be clear and binding on the parties.

In order to accomplish effective enforcement, an international agency should be created to oversee all experimental research throughout the world, providing an independent investigator to ensure that international standards are observed.²⁸⁴ Issues affecting the community being studied should be referred to the community leaders, preferably a national or local ethical oversight committee for approval. Community leaders, the independent investigator, and the individuals participating in the research should approve any departures from minimum standards. The international enforcement agency should have enforcement powers to bring questions and claims of abuse or violations before a binding decision maker.²⁸⁵

An international professional licensing agency should be created in order to promote ethical ideals among the profession. Researchers desiring to conduct research abroad should be subject to professional regulation. Included in these licensing standards should be requirements for education and training in international ethics.²⁸⁶

The international community should create awareness of the need to protect against human subjects experimentation,²⁸⁷ especially among

²⁸⁴ George J. Annas & Michael A. Grodin, *Medical Ethics and Human Rights: Legacies of Nuremberg*, 3 HOFSTRA L. & POL'Y SYMP. 111, 118 (1999).

²⁸⁵ The international decision making tribunal should be empowered to produce a common law to guide researchers in interpretation of the international standard.

²⁸⁶ In ethics training, the need to return benefits back to the community could be propagated.

²⁸⁷ Ankrah & Gostin, *supra* note 20, at 557.

developing countries.²⁸⁸ The international community should impress upon developed nations the need to return benefits to countries from which scientific information has been reaped.²⁸⁹

V. Conclusion

Universal adoption of any of the current standards would not adequately serve to protect individuals or groups from abusive experimental research. Regulation of human experimentation in developing countries is necessary to produce a single, binding standard to protect against future abuse.²⁹⁰ Binding regulation is important to provide for enforcement of uniform regulation.²⁹¹ International regulation is necessary to protect individuals and developing countries by recording acts committed into history to preserve justice and to serve to protect the basic human right to freedom of health.

Companies and individuals involved in experimental research in developing countries need protection if human subject research is to continue in the future.²⁹² If abuse continues to occur, scientific progress will be hindered by fear of participation from citizens of underdeveloped countries.²⁹³ The world cannot afford to disproportionately place a burden of experimentation on underdeveloped countries if current human rights standards are to remain intact.²⁹⁴

²⁸⁸ One approach is to disallow national marketing of products not conforming to international standards.

²⁸⁹ "The benefits should not just be scientific honors for scholars or profits for vaccine-producing companies. People in developing countries who have participated in trials must reap real benefits in terms of the future protection of the population. Scientific, financial, or administrative imperatives alone seldom provide an overwhelming justification for research." Ankrah & Gostin, *supra* note 20, at 555. See Phillips, *supra* note 15.

²⁹⁰ "Like ghosts from a dark past, the victims of research haunt the dream of biomedical progress, returning again and again to raise the harsh reality of dignity violated, integrity invaded, and lives destroyed." Alexander Morgan Capron, *Incapacitated Research*, HASTINGS CENTER REP. Mar.-Apr. 1997, at 25.

²⁹¹ See Osuntokun, *supra* note 151, at 33.

²⁹² See Phillips, *supra* note 15.

²⁹³ "The Pfizer experience is still haunting our people." *Kano Government Addresses Cholera Outbreak*, BBC WORLDWIDE MONITORING, Nov. 14, 2001, available at LEXIS, News Library, BBC Worldwide Monitoring File.

²⁹⁴ Ankrah & Gostin, *supra* note 20, at 555 ("People and communities cannot be used as merely a means to an end, regardless of how important the research goal may be.").

