MATERNAL MORTALITY, POPULATION CONTROL, AND THE WAR IN WOMEN'S WOMBS: A BIOETHICAL ANALYSIS OF QUINACRINE STERILIZATIONS

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Quinacrine hydrochloride is a drug that was developed in the late 1920's to prevent and treat malaria.[1] It is also used to treat several other diseases including giardiasis, lupus, and rheumatoid arthritis.[2] Given its history, it is hard to imagine how this drug became notoriously known as a female sterilization agent.[3] In the past three decades, two American doctors, Elton Kessel[4] and Stephen Mumford,[5] have been the main proponents of a worldwide quinacrine sterilization crusade.[6] As a result of their crusade, approximately 104,410 women in nineteen developing countries have already been subjected to quinacrine sterilizations.[7]

This article raises questions regarding the ethics of promoting quinacrine sterilizations even though quinacrine has not been approved for sterilization purposes by any government agency in the world. Specifically,

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1 During the second World War, quinacrine was used as an anti-malarial agent. It was administered orally to millions of U.S. soldiers and sailors serving in the South Pacific. According to Jack Lippes, a professor of Gynecology and Obstetrics at the State University of New York, more than three million servicemen took "100 milligrams daily." Thalif Deen, *Population: Group Seeks Review of Suspect Sterilization Drug*, INTER PRESS THIRD WORLD NEWS AGENCY, (Mar. 29, 1999) *available at* http://www.quinacrine.com/news-99.html#ips. *See also* Jack Lippes, *Quinacrine Sterilization (QS) – Safety and Efficacy*, remarks made at the American Public Health Association annual meeting held in Chicago, Illinois, on November 8, 1999.

2 Deen, *supra* note 1. A comprehensive overview of the history and clinical trials related to quinacrine is *available at* http://www.quinacrine.com/archive.

3 For brief history of quinacrine use in sterilizations, *see* note 8.

4 A brief description of Dr. Elton Kessel's background is (visited May 5, 2001) *available at* http://www.quinacrine.com/bio-kessel.html.

5 A brief description of Dr. Stephen Mumford's background is (visited May 5, 2001) *available at* http://www.quinacrine.com/bio-mumford.html.

6 Mumford and Kessel are the only distributors of quinacrine in the world.

7 Stephen Mumford has reported that 50,000 women were sterilized with quinacrine in Vietnam; 26,000 in India; 15,000 in Pakistan; 5,000 in Chile; 4,700 in Bangladesh; 900 in Indonesia; 700 in Costa Rica; 700 in China; 250 in Iran; 235 in Colombia; 200 in Venezuela; 200 in Romania; 200 in Egypt; 170 in Croatia; 100 in the Philippines; 30 in Morocco; 25 in Malaysia; and 0 in the United States. *Quinacrine Sterilization: A Response Prepared by Stephen Mumford* Dr. P.H. To A December 1999 Petition Prepared by Shree Mulay, Marlene Fried, Judy Norsigian and Jael Silliman Addressed to the Members of the Board of Directors of The Planned Parenthood Federation of America, Attachment #11, p. 23 (copy on file with author).

this article examines the reasons for promoting chemical sterilization of poor and politically powerless women in developing countries.

Section 1 of this article provides an historical background on the use of quinacrine as a sterilization agent. Section 2 examines three international codes of ethics governing human experimentation - the Nuremberg Code, the Helsinki Declaration, and the International Ethical Guidelines for Biomedical Research Involving Human Subjects. Although these codes of ethics have been violated, they are either unenforceable or historically unenforced and therefore have marginal utility in this case. In Section 3, I use three generally accepted principles of bioethics - autonomy, beneficence/non-maleficence, and distributive justice - to shed further light on the unethical nature of the quinacrine campaign. I conclude that because the quinacrine campaign fails to conform to any of these basic bioethical principles, it should be denounced, particularly by doctors and lawyers, as an unethical and unacceptable medical experiment.

I. BACKGROUND AND HISTORICAL INFORMATION ABOUT QUINACRINE STERILIZATIONS

Quinacrine was first used for sterilization in the early 1970s by Dr. Jaime Zipper, a Chilean researcher.[8] Dr. Zipper performed approximately four thousand sterilizations of Chilean women until the Chilean government banned the procedure in 1998, after reports of its cancer causing potential and alleged misuse.[9]

In his earliest phase of experimentation, Dr. Zipper injected quinacrine into women's uteruses in liquid form. This quinacrine concoction

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[8] In the 1970s, Family Health International (then the International Fertility Regulations Program) authorized financing for Dr. Jaime Zipper's research with quinacrine pellets in Chile. Zipper apparently began exploring the chemical's uterine-scarring potential after noting that quinacrine is frequently used by doctors to produce intentional scarring in the pleural cavities of victims of advanced lung cancer. After realizing the schlerosing quality of quinacrine, Zipper began experiments related to female sterilization in rats and rabbits. Zipper had previously experimented with agents such as formaldehyde and phenol as Nazi doctors had tried in their experiments with sterilization. J. Zipper, M. Medel, and R. Prager, *Alterations in Fertility Induced by Unilateral Instillation of Cytotoxic Compounds in Rats*, 167 AM J. OBST. & GYNEC. 1203-1207, (1992); J. Zipper, M. Medel, L. Pasten, and M. Rivera, *Intrauterine Instillation of Chemical Cytotoxic Agents for Tubal Sterilization and Treatment of Functional Metrorrahagias*, 12 INT'L J. FERTILITY, 280-84 (1969); Fawn Vrazo, *New Sterilization Method Prompts Safety Concerns*, THE TIMES-PICAYUNE, Dec. 5, 1993, at A39; J. Zipper, et al, *Quinacrine Hydrochloride Pellets: Preliminary Data on a Nonsurgical Method of Female Sterilization*, 18 INT'L. J. GYNAECOL. OBSTET. 275 (1980) *available at* http://www.quinacrine.com/archive/zipp80.pdf.

[9] Deen, *supra* note 1.

was referred to as the quinacrine slurry.[10] Due to its high failure rate (approximately 35%)[11] and because three women died as a result of exposure to quinacrine slurries,[12] Dr. Zipper developed the quinacrine pellet.[13] In pellet form, quinacrine is inserted through the vagina into the uterus with a tool similar to that used to insert intra-uterine devices (IUDs).[14] Within thirty minutes, the quinacrine pellets dissolve and liquid quinacrine then travels through the fallopian tubes, causing an injury similar to a chemical burn.[15] Over the next six to twelve weeks, the burn-like injury in the fallopian tubes turns into scar tissue,[16] which in turn blocks anything from getting in and out of the uterus, thereby causing permanent sterilization.[17] Although the procedure is often painful and uncomfortable, quinacrine sterilizations are performed without anesthesia.[18] Many women faint as a result of the pain.[19]

Although the long-term side effects of quinacrine sterilizations are not yet known, what has been reported is that this nonsurgical form of sterilization has caused burning and irritation of the vaginal walls, cervical stenosis (a narrowing of the cervical opening), uterine adhesions,[20] excitation

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[10] J. Zipper, E. Stachetti, & M. Rivera, *Human Fertility Control By Transvaginal Application Of Quinacrine On The Fallopian Tube*, 21 FERTILITY AND STERILITY, 581-589 (1970) *available at* http://www.quinacrine.com/archive/zipp70.pdf.

[11] *Id.*

[12] *Chile Quinacrine Banned*, WOMEN'S HEALTH JOURNAL 22 (Mar. 1998); Ambereen Choudhury, *The Row Over Chemical Sterilization*, THE INDEPENDENT (Sept. 10, 1998). *See also* Alix Freedman, *Exporting Sterilization (Part 2)*, NEWS & OBSERVER, June 19, 1998, explaining how Zafrullah Choudhury a public health doctor in Bangladesh, injected liquid quinacrine into a twenty-eight year old woman and two to three minutes later watched her die. He is quoted as saying that using quinacrine is like performing cold-blooded murder.

[13] Zipper, *supra* note 10.

[14] Dr. Zipper is also known for inventing the copper IUD. *See generally Sterile Arguments*, THE ECONOMIST: SCIENCE AND TECHNOLOGY, Mar. 9, 1999, at 99-100.

[15] Sydney P. Freedberg, *A New Chemical Sterilization Technique Sparks Global Debate*, THE HOUSTON CHRONICLE, Nov. 18, 1998, at A1. *See also* Choudhury, *supra* note 12; *Sterile Arguments*, *supra* note 14, at 99.

[16] For a detailed and scientific explanation of how quinacrine causes sterilization, *see Quinacrine Non-surgical Sterilization FAQ* (visited May 5, 2001) *available at* http://www.quinacrine.com/qs-faq.html.

[17] The concept of inducing sterility by scarring the female organs is far from new – early scientific studies of such procedures are recorded in the history of Germany, just prior to the rise of Hitler. In a comprehensive study of Nazi medicine author Robert N. Proctor writes: "Anticipating the importance of mass sterilization among [hated racial groups] physicians developed techniques that would allow more rapid sterilization on an outpatient basis. In the late 1920's the gynecologist Felix Mikulicz-Radecki perfected a method of operationless sterilization of women involving the scarification of fallopian tube tissue through injections of carbon dioxide." ROBERT PROCTOR, RACIAL HYGIENE: MEDICINE UNDER THE NAZIS 109 (1998)

[18] Hema Shukla, *Quinacrine: Population Control Miracle or Dangerous Drug?*, CHARLESTON GAZETTE, Feb. 15, 1999, at 1D. *See also* Lippes, *supra* note 1.

[19] Alix Freedman, *Exporting Sterilization (Part 1)*, NEWS & OBSERVER, June 19, 1998, at A1.

[20] Rajani Bhatia & Anne Hendrixson, *The Quinacrine Controversy*, NETWORK NEWS, Vol. 24, Sec. 3, 3, May 1, 1999 (copy on file with author).

of the central nervous system,[21] toxic psychosis,[22] and perforation of the uterus.[23] Abnormal menstrual bleeding,[24] backaches, fever, lower abdominal pain and headaches have also been reported.[25] In addition, if the quinacrine sterilization is not properly performed,[26] incomplete blockage of the fallopian tubes could occur, thereby causing an ectopic pregnancy - a life-threatening emergency,[27] particularly in areas with no emergency medical facilities for surgery.[28]

The risks associated with fetal exposure to quinacrine are also unknown. There is, however, one reported case of an anencephalic[29] infant conceived two and a half months following intrauterine insertion of quinacrine in a Vietnamese woman,[30] and one reported case of a hydrocephalic[31] infant being born to a woman who had previously undergone a quinacrine sterilization.[32] In addition to birth defects, there is concern

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21 *Unasked Questions*, BUSINESS LINE, July 28, 1997, at A18; H. Chandra & H.V. Maraviya, *Toxic Effects of Quinacrine Hydrochloride in Rhesus Monkeys*, 24 CONTRACEPTION 269, 269-274 (1981); *See also* L.A. Ciaccio, J.L. Hill & F.A. Kincl, *Observation of Toxic Effects of Quinacrine Hydrochloride in Rodents*, 17 CONTRACEPTION 231, 231-236 (1978) concluding that quinacrine could cause central nervous excitation leading to convulsions and even death.

22 Toxic psychosis is a form of chemically induced insanity. *See* Harper and Rowe, FEMALE TRANSCERVICAL STERILIZATION (1983). (Summary in POPLINE abstract no. PIP 019774) concluding that high-dose quinacrine treatment can cause nervousness, nervous system disorders, hallucinations and psychotic episodes.

23 Lippes, *supra* note 1.

24 Shukla, *supra* note 18; H. Arshat, A.E.-Suan & Kim, *Nonsurgical Female Sterilization with Quinacrine Pellets: Maylasian Experience*, 5 MALAYSIAN JOURNAL OF REPRODUCTIVE HEALTH 61, 61-69 (Dec. 1987).

25 Deen, *supra* note 1. *See also* Freedman, *supra* note 19.

26 A proper quinacrine sterilization requires the insertion of fourteen pellets of quinacrine which are supposed to be administered in two doses a month apart. CBS News with Morley Safer, *"Quinacrine: Questions Surround the Use of A Drug for Chemical Sterilization in the Third World, When It Has Not Been Approved in the U.S."* (CBS television broadcast, Oct.18, 1998) Unfortunately, many of the health care workers that perform quinacrine sterilizations fail to insert the second dose of quinacrine pellets. *See* www.quinacrine.com.

27 J.L. Tenore, *Ectopic Pregnancy*, 61 AM. FAM. PHYSICIAN 4, 1080-88 (2000); J. Abbott, et. al. *Ectopic Pregnancy*, 8 AM. J. EMERG. MED.6, 515-22 (1990).

28 In an area where there are no emergency medical facilities for surgery, an ectopic pregnancy would mean certain death. *Id.*; *See also* Shukla, *supra* note 18.

29 Anencephaly is a fatal condition involving an absence of formation of the brain and spinal cord. AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 68 (4th ed. 2000).

30 Memorandum *Controlled Correspondence Response* from Susan Allen, MD, MPH to Lisa Rarick, MD (Aug. 26, 1998) at 4 (copy on file with author).

31 Hydrocephaly is an abnormal accumulation of fluid in the brain that causes enlargement of the skull and compression of the brain. AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 860 (4th ed. 2000).

32 Memorandum, *supra* note 30. In a retrospective study of pregnancy rates among Chilean women, 120 pregnancies were recorded among 1,492 women who underwent the quinacrine sterilization procedure. 40 of those 120 pregnancies went to term or near term. There were nine adverse outcomes: one fetal death at 18 weeks gestation; three infants born prematurely, one stillbirth, and four infants with birth defects. *See* PJ Feldblum, M. Hays, J. Zipper, R. Guzman-Serani, and DC Sokal, *Pregnancy Rates Among Chilean Women who Had Non-surgical*

regarding the excretion of quinacrine hydrocholoride into breast milk because the effects of quinacrine on breastfed infants are also unknown.[33]

Studies show that between two and five of every one hundred chemically sterilized women become pregnant after one year.[34] Consequently, there is a need for follow-up studies to be done in order to track the effects of quinacrine on infants and developing fetuses.

Quinacrine pellets have not been adequately tested or approved for use as a sterilization agent anywhere in the world. Many major family planning organizations and foreign governments,[35] as well as the World Health Organization, oppose its use for sterilization.[36] Despite this fact, quinacrine is being distributed worldwide by two U.S. organizations - a North Carolina organization called the Center for Research on Population and Security and the International Federation for Family Health, run by Stephen Mumford and Elton Kessel respectively. These organizations are the only distributors of quinacrine in the world.[37]

A. THE KESSEL AND MUMFORD QUINACRINE CRUSADE

Dr. Elton Kessel is a Harvard and University of Chicago trained medical doctor and public health consultant from Carlton, Oregon[38] and is

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Sterilization with Quinacrine Pellets Between 1977 and 1989, CONTRACEPTION, 61(6): 379-84 (2000).

33 Memorandum, *supra* note 30, at 6.

34 REUTERS NEWSWIRE, citing LANCET (United Kingdom; *Vietnamese Doctors Test Quinacrine as Sterilizer*, (July 23, 1993) (reporting 800 pregnancies during the Vietnamese trials, giving the method a failure rate of between two to three percent); Sydney P. Freedberg, *New Way to Sterilize Women at Issue*, THE MIAMI HERALD Oct. 4, 1998 (visited May 5, 2001) *available at* http://www.quinacrine.com/news-miami4oct98.htm. *But see* Praful Bidwai, *South Asia-Health: Harmful Contraceptive Trials on Women*, INTER PRESS SERVICE (May 22, 1997) (citing a fourteen percent failure rate in quinacrine study in Bangladesh); Laxmi Murthy, *Population: Indian Court Sides With Activists on Quinacrine Ban*, INTER PRESS SERVICE (Mar. 18, 1998) (citing fifty percent failure rate as the reason for the Indian Council for Medical Research abandoning its clinical experiments in 1994).

35 Bangladesh, India, Chile and Vietnam have all banned the use of quinacrine sterilizations. Alix M. Freedman, *Chile Bans Quinacrine Sterilizations In Latest Setback to U.S. Distributions*, N.Y.TIMES, July 10, 1998, at A4; Jonathan Karp & Alix Freedman, *India Outlaws Sterilization by Quinacrine*. WALL ST. J. EUR., August 18, 1998, at 2.

36 Shukla, *supra* note 18. In 1993, the WHO declared that pending further lab research, quinacrine should not be used to sterilize women in any country. *See also* Freedman, *supra* note 19. The Association for Voluntary Surgical Contraception and the Population Council have also recommended against human trials of quinacrine sterilization until further animal studies are conducted. Alix Freedman, *FDA Tells Two Researchers To Stop Distribution on Drug For Sterilization*, WALL ST. J., Oct. 19, 1998, at C17; Giuseppe Benagiano, Letters to the Editor, *Quinacrine Family Planning Method*, THE LANCET, June 6, 1994, at 1425.

37 Choudhury, *supra* note 12; Freedman, *supra* note 19.

38 Catherine Clabby, *Birth-control Zealot Unfazed by the FDA Order* (Oct. 22, 1998) *available at* http://www.news-observer.com/daily/1998/10/22/nc07.html.

eighty years old.[39] He is the former director of Family Health International (FHI), a non-profit agency that funded Dr. Zipper's quinacrine research in Chile during the 1970's.[40] News reports indicate that he left FHI over differences about both the reporting and the conduct of quinacrine sterilization clinical trials.[41] His partner, Stephen Mumford, was also an employee of FHI at one point. Three years after Kessel was fired, Mumford was dismissed for writing a string of articles blaming the Vatican for the United States' failure to adopt a policy classifying population growth in the Third World as a threat to the national security of the United States.[42]

Mumford is not a medical doctor. He is fifty seven years old and holds a doctorate in Health Sciences Administration and Population Studies. He began his career promoting contraception and population control. For the past two decades, Mumford's fervor has focused on female sterilization through the use of quinacrine.[43] Mumford and Kessel joined forces in 1984 after Mumford incorporated the Center for Research on Population and Security.[44] Together, Mumford and Kessel have distributed quinacrine in nineteen countries including Bangladesh, Chile, China, Colombia, Costa Rica, Croatia, Egypt, India, Indonesia, Iran, Morocco, Pakistan, the Philippines, Venezuela, Vietnam, the United States, Malaysia and Romania.[45]

In a remarkably quiet crusade, Mumford and Kessel have paid for the manufacture of quinacrine in Switzerland,[46] arranged for its distribution in about twenty countries and mobilized a network of doctors, nurses and midwives to administer it.[47] Most of the sterilizations are a result of free donations or gifts of quinacrine given by Mumford and Kessel to doctors and health practitioners all over the world. In 1997, the worldwide efforts of Mumford's center cost only $156,000.[48] Apparently, neither Mumford nor

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39 Marie McCullough, *Polarization on Sterilization*, PHILA. INQUIRER, Feb. 28, 2000, at F1.

40 Clabby, *supra* note 38.

41 Alix Freedman, *A Mission To Sterilize The Poor Quinacrine Campaign Offers A Painful, Possibly Dangerous Drug To The World*, WALL ST. J., July 3, 1998, at A1.

42 STEPHEN D. MUMFORD, THE LIFE AND DEATH OF NSSM 200. For a detailed explanation of Mumford's theory on the Vatican's role in shaping U.S. population control policy, *see How The Destruction Of Political Will Doomed The U.S. Population Policy* (published by The Center for Research on Population and Security 1996).

43 Emery Dalesio, *Drug's Advocate Fights Regulators, Charges Double Standards*, THE DESERT NEWS, May 31, 1999.

44 *Id.*

45 Mumford, *supra* note 7.

46 Sipharm Sesseln AG, a small Swiss company, manufactured quinacrine pellets for Mumford and Kessel until 1998 when an article published in the Wall Street Journal revealed various abuses of the quinacrine pellets. *See also* Stephen D. Mumford, *A Response to Alix Freedman's Wall Street Journal article on Quinacrine Sterilization*, (visited May 5, 2001) *available at* http://www.quinacrine.com/news-wsj.htm.

47 Freedberg, *supra* note 15.

48 *Id.*

Kessel seek financial gain from this endeavor. In fact, Mumford draws a salary of only $37,500 a year from his research center, and Kessel reportedly lives off less than $30,000 from Social Security and income from small investments.[49] As Morley Safer, co-host of *60 Minutes* pointed out: "[f]or them, quinacrine is not a job, it's a crusade."[50]

B. FUNDING OF THE QUINACRINE CAMPAIGN

Private funding from the Leland Fikes Foundation[51] and the Scaife Family Foundation,[52] have made it possible for Mumford and Kessel to provide quinacrine free of charge to researchers, clinicians, and government health agencies worldwide. Mumford and Kessel's gifts of quinacrine are made possible not only through the right-wing Leland Fikes and Scaife Family Foundations[53] but also through the financial support of individuals such as Sarah G. Epstein and Donald Collins, both board members of the Federation for American Immigration Reform (FAIR),[54] a conservative, anti-immigrant organization.[55]

Like his financial supporters, Mumford also embraces an anti-immigration agenda. He is quoted as stating: "This explosion in human numbers, which after 2050 will come entirely from immigrants and the offspring of immigrants, will dominate our lives. There will be chaos and anarchy."[56] He has also been quoted as saying that quinacrine is "essential to population-growth control"[57] and that "overpopulation is a gravely serious national security issue, even more serious than the nuclear threat."[58]

Mumford's promotion of quinacrine is also steeped in the belief that quinacrine is an ideal method of population control because it is a cheap

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[49] *Id.*

[50] CBS News, *supra* note 26.

[51] For information on the Fikes Foundation, *see* note 201.

[52] For information on the Scaife Family Foundation, *see* note 199.

[53] Christine McConville, *Quinacrine Crimes*, IN THESE TIMES, Mar. 21, 1999, at 14.

[54] Ruth Coniff, *The Right Calls the Shots*, THE PROGRESSIVE, Oct. 1993. FAIR uses economic, environmental, and social arguments against immigration and calls for drastically reducing the total number of immigrants allowed into the United States every year to 300,000, *see FAIR's Purpose* (visited May 5, 2001) *available at* http://www.Fairus.org/html/fair.htm.

[55] Bhatia, *supra* note 20. Collins is also on the board of the Scaife Family Foundation which has donated $160,000 to the quinacrine effort since 1994. Another key backer lined up by Collins is Lee Fikes, son of a Dallas oil magnate; Fikes' Family Foundation has provided about $320,000. Fikes and Scaife are also big contributors to FAIR. *See also* Freedman, *supra* note 12, at A1.

[56] Freedman, *supra* note 41.

[57] Alix Freedman, *Two Americans Export Chemical Sterilization to the Third World*, WALL ST.J., June 18, 1998, at A1.

[58] Freedman, *supra* note 41.

nonsurgical sterilization method that requires no operating room, no anesthesia, no expensive equipment and no lengthy training.[59] In fact, Mumford claims that quinacrine is the best contraceptive for the world's poorest women because it costs less than one dollar[60] and is so simple a procedure that it can be performed in very modest settings by trained "nonphysicians."[61] He claims that quinacrine is safer than surgical sterilization in countries where hospitals and clinics are poorly equipped.[62] For this reason, quinacrine supporters often refer to it as the most revolutionary birth control development since the pill. They say it has the potential for curbing rampant population growth in developing countries, and they claim it can save the lives of millions of women who cannot obtain contraceptives or safe surgical sterilizations and would otherwise die as a result of unwanted childbearing.[63] According to Elton Kessel, quinacrine "will save more lives of women of reproductive age around the world than anything else we have."[64]

C. QUINACRINE ABUSE AND SAFETY CONCERNS

Opponents of quinacrine, however, point out that the potential for abuse is horrifying because quinacrine is simple to administer, irreversible, and inexpensive. In an article in the May 29, 1989, edition of the *International Journal of Gynecology and Obstetrics*, Elton Kessel acknowledged that one of the most intriguing features of quinacrine is that it can be used to accomplish sterilization on a massive scale.[65] Kessel argued that if the method were introduced in India's national family planning program, one million additional sterilization procedures could be performed there every year.[66] Approximately one year after the *International Journal of Gynecology and Obstetrics* had predicted quinacrine's potential for abuse, *actual* abuse of quinacrine sterilizations in India, as well as several other countries, was reported.[67]

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59 Elton Kessel, MD MPH, *Overview of First 100,000 Quinacrine Sterilization Procedures* (Aug. 7 1997) *available at* http://www.quinacrine.com/medicine/gynecology/kess.htm. *See also* Deen, *supra* note 1.

60 Mumford, *supra* note7 at Attachment #11, p. 19.

61 Elton Kessel, *Cost-effectiveness of Interventions To Lower Maternal Mortality: The Role of Quinacrine Pellet's in Nonsurgical Female Sterilization*, article prepared for presentation at the Pan African Maternal & Child Health Int'l Conference, May 25-27,1994 in Cairo, Egypt, *available at* http://www.quinacrine.com/archive/kess94.pdf. *See also* Deen, *supra* note 1.

62 *Id.*

63 Elton Kessel, *Prospects for Nonsurgical Female Sterilization*, 29 INT. J. GYNAECOL. OBSTET. 1 (1989) *available at* http://www.quinacrine.com/archive/kess89.pdf.

64 *See generally*, Vrazo, *supra* note 8.

65 *See* Kessel, *supra* note 63.

66 *Id.*

67 For more information on involuntary quinacrine sterilizations, *see* C. Autonomy, pp. 142-148.

The Indian government eventually banned quinacrine, claiming that after six years of "illegal" clinical trials,[68] the government was concerned about the complications caused by quinacrine sterilizations, including fetal abnormalities and cancer of the uterus.[69] The Indian government was not alone in expressing concern regarding the side effects and toxicity of quinacrine. In fact, many doctors expressed concern that quinacrine may be a carcinogenic.[70] The concerns regarding carcinogenicity are based on laboratory studies indicating that quinacrine causes cells to mutate.[71] According to some scientists, mutagenicity is circumstantial evidence of cancer.[72] In addition, other studies indicate that quinacrine causes DNA damage to bacteria, which is a prima facie case that quinacrine may cause cancer in human beings.[73] The FDA has indicated that because intrauterine administration of quinacrine pellets will result in significant tissue damage in the presence of a known mutagen, "serious concerns exist that such exposure could result in development of cancer of the reproductive tract."[74] This concern appears to be valid, particularly in light of the fact that a retrospective study of 421 Chilean women who had undergone quinacrine sterilization between 1977 and 1982 revealed a cluster of nine cases of cancer.[75] A second retrospective study of 1,492 Chilean women revealed that there were a total of seventeen cases of invasive cancer, including higher than expected numbers of breast and cervical cancer for that population.[76] Despite the fact that questions of safety and effectiveness have not been resolved,[77] and despite the fact that quinacrine sterilizations have not been approved by the FDA, Kessel and Mumford have solicited abortion providers in the United

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[68] McConville, *supra* note 53.

[69] *See* Kaiser Family Foundation Reproductive Health Report, *India: Bans Use of Quinacrine for Sterilization Purpose*, INTERNATIONAL NEWS, (Aug. 8, 1998) *available at* http://report.kff.org/archive/repro/1998/08/kr980818.6.html.

[70] Choudhury, *supra* note 12. *See also* Kaspar Stoffelmayr, *Products Liability and "Off-Label" Uses of Prescription Drugs*, 63 U. CHI. L. REV. 275, (1996).

[71] In late 1994, Family Health International (FHI) and the U.S. Agency for International Development (USAID) sponsored the conduct of four genetic toxicology tests by Microbiologic Associates. The tests confirmed quinacrine's mutagenicity. *See* Leonard E. Laufe, et.al., *Phase I Prehysterectomy Studies of the Transcervical Administration of Quinacrine Pellets*, 54 CONTRACEPTION 181 (1996).

[72] Freedberg, *supra* note 15 at A1.

[73] *Sterile Arguments*, *supra* note 14 at 99. *See also* Memorandum, *supra* note 30 (In this memorandum, the author concludes that quinacrine is a known mutagen, that its mutagenicity correlates with positive results in rodent carcinogenicity, and thus there is concern regarding the potential risk of cancer development in humans).

[74] *Id.* at 2.

[75] *Id.* at 3.

[76] *Id.*

[77] Studies conducted in developing countries over the last two decades, most "in consultation" with Mumford and Kessel, are too varied and flawed to conclude the method is safe and effective. *See generally* McCullough, *supra* note 39.

States to perform quinacrine sterilization.[78] According to Kessel, official government approval through the FDA would have been "desirable but not necessary"[79] because the FDA permits approved drugs to be used "off-label."[80] Kessel argues that since quinacrine is an approved drug for treating malaria, doctors should be free to prescribe quinacrine for any purpose, including sterilization.[81] Thus, Mumford concludes that it is "legal for clinicians to perform this procedure on American women as an off-label use of an approved drug."[82]

The FDA, however, disagreed. In October 1998, it ordered Kessel and Mumford to destroy their existing supply of quinacrine tablets and to immediately stop all export and distribution of the drug.[83] The FDA stated that quinacrine used for sterilizations was an "unapproved new drug and a misbranded drug in violation of the Federal Food, Drug, and Cosmetic Act."[84] It also indicated that quinacrine pellets used for non-surgical female sterilizations was an "unsafe use of this drug product."[85] Finally, the FDA stated that it was "very concerned about the safety risks associated with the

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78 *See* BSS International (visited May 5, 2001) *available at* http://www.drbenjamin.com (where Dr. Michael Benjamin announces his intention to perform quinacrine sterilizations in his Ft. Lauderdale, FL abortion clinic); *See also* CBS News, *supra* note 26 (where Dr. Mildred Hanson endorsed the quinacrine sterilization procedure).

79 Quinacrine Alert Network, *Stop Unethical Use of Quinacrine Sterilization* (visited Sept. 7, 2000) *available at* http://www.quinacrine.com/qs-faq.html. Quinacrine has been approved by the FDA for use in female sterilization.

80 It is estimated that at least one quarter of all U.S. prescriptions are for off-label drug uses. In fact, the American Medical Association Vice President of Science and Education estimated this figure to be between forty and sixty percent. Stoffelmayr, *supra* note 70, at 278.

81 Quinacrine: Non-surgical Method of Voluntary Female Sterilization Newsletter 2000, *Quinacrine Sterilization in the USA* (visited on Mar. 12, 2001) *available at* http://www.quinacrine.com/newsletter_2000_1.html.

82 Stephen Mumford, *Quinacrine Sterilization: Safe And Effective*, NEWS & OBSERVER, July 21, 1998, at A9. For further support of this assertion, Mumford claims that while the FDA approves drugs for specific uses, the United States Pharmacopeia (USP) is the highest authority in the land on accepted uses. According to Mumford, since 1996, the USP has taken the position that quinacrine sterilization has been sufficiently tested and its safety and efficacy adequately demonstrated to be listed by the USP as an accepted use of this drug for American women. Mumford also states that about forty percent of all prescriptions written in the United States are written for uses not approved by the FDA but which are nevertheless accepted uses. *See also* Bradford W. Williams, *FDA Warning Letter*, Oct. 14, 1998 (visited on Aug. 30, 2000) *available at* http://www.fda.gov.

83 *Id.*

84 *Id. See also* Food, Drug, and Comestic Act, 21 U.S.C.A. 321(3)(p) defining "new drug" to mean "any drug...the composition of which is such that such drug is not generally recognized....as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof...."

85 As an unapproved new drug, Mumford and Kessel would have to file either an Investigational New Drug Application with the FDA or apply for an exemption before marketing it in the United States. *Id. See also* Food, Drug, and Comestic Act, 21 U.S.C.A. 321 et al.

use of this drug and its effects on women and the fetus if a woman is or becomes pregnant."[86]

The FDA warned Kessel and Mumford that if they did not "immediately halt" distribution of the quinacrine pellets, they could face possible seizure of the pellets[87] or criminal prosecution.[88] In addition to forbidding the marketing of quinacrine in the United States for sterilization purposes, the Warning Letter forbade the import of the drug into the United States under sections 301(a) and (d) of the Food, Drug, and Cosmetic Act (FDCA).[89] The FDA also warned Dr. Mumford that under section 801, a product may only be exported to another country if it complies with the laws of that country and has valid marketing authorization by the appropriate authority.[90] The letter concluded that since quinacrine is not approved for use in non-surgical sterilizations in any country listed under the Act, exporting the drug would violate the Act.[91]

On September 24, 1998, during a telephone conversation between Mumford and the FDA, a FDA agent asked Mumford to identify the location of his remaining inventory of quinacrine, consisting of approximately 290,000 quinacrine pellets and 1,536 filled inserters.[92] Specifically, the FDA requested that Mumford "immediately halt all distribution of any and all quinacrine ... identify its location, and voluntarily destroy it under FDA supervision."[93] Mumford chose not to provide the FDA with the location of the products.[94] He also announced that, if necessary, he would escape the jurisdiction of the FDA by finding someone outside of the United States to distribute it.[95]

From September 1998 until December 1999, little was written about Mumford and Kessel's quinacrine escapades. The future of quinacrine

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[86] Freedman, *supra* note 36.

[87] Civilly, the FDA has the right to inspection under sections 703 and 704 of the FDCA, to send warning letters requiring response within 15 days, issue voluntary recalls, create publicity, and order seizures through the U.S. Marshall's service so long as the drug is in interstate commerce.

[88] The FDA can also impose criminal sanctions for gross violations in which there are unsafe conditions, obvious and continuing violations, life threatening violations, or deliberate attempts to circumvent the law. Under section 303(a)(1) for a misdemeanor, the penalty is up to one year in jail and a fine of up to $1,000. For felonies, section 303(a)(2) authorizes a penalty of up to three years imprisonment and up to $10,000 in fines.

[89] Williams, *supra* note 82.

[90] *Id.*

[91] The principal provision authorizing the exportation of unapproved new drugs is section 802(b)(1)(A) of the Act, providing that a drug "may be exported to any country, if the drug....complies with the laws of that country and has valid marketing authorization." Food, Drug and Cosmetic Act, 21 U.S.C.A. 802(b)(1)(A). Williams, *supra* note 82.

[92] *Id.*

[93] *Id.*

[94] *Id.*

[95] Clabby, *supra* note 38.

sterilizations laid in abeyance until Warren Buffet, the self-made billionaire investment guru, revived quinacrine research by donating two million dollars to FHI.[96] With this two million dollar donation, FHI will resume animal testing and begin human testing of quinacrine sterilizations in preparation for FDA approval. Planned Parenthood Federation of America, the largest reproductive health-care organization in the United States, has defended quinacrine sterilizations, indicating that they are willing to test quinacrine on their patients.[97] Commentators predict that large scale human clinical trials of quinacrine may begin as early as 2002 in the United States.[98] In the meantime, Jack Lippes,[99] Professor Emeritus at the University of Buffalo Medical School, has received approval from the Children's Hospital of Buffalo to conduct quinacrine sterilization on ten women.[100]

II. ETHICAL STANDARDS GOVERNING HUMAN EXPERIMENTATION

Unfortunately, the quinacrine sterilization campaign is just one of several examples of human experimentation[101] where poor women particularly women of color have been used as guinea pigs in the name of advancing reproductive technology. In the early stages of developing the oral contraceptive pill, for example, women in Puerto Rico were used as subjects to determine the pill's safety and effectiveness.[102] Many of the 132 women in Puerto Rico who were part of the early experiment died as a direct result of using the pill.[103] Those who did not die suffered a variety of side effects, including cancer, urinary infections, weight loss or gain, depression,

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96 McCullough, *supra* note 39.

97 *Id.*

98 *Id.*

99 Jack Lippes is the inventor of Lippes loop IUD, *supra* note 1.

100 Letter from James B. Lee, M.D., University of Buffalo, State University of New York, to Betsy Hartman, Director, Population and Development Program, Hampshire College (Oct. 26, 2000) (copy on file with author); Letter from Betsy Hartman, Director, Population and Development Program, Hampshire College, to Dr. Theodore Putnam (Nov. 3, 2000) (copy on file with author).; Letter from Mark Shields, M.D. Chief Medical Officer, Kaleida Health, to Betsy Hartmann, Director, Population and Development Program, Hampshire College (Dec. 20, 2000) (copy on file with author); Conversation with Dr. Jack Lippes on April 23, 2001 at a conference entitled "The Quinacrine Debate and Beyond: Assessing the Future of Female Non-Surgical Sterilization" held at the Lansdowne Resort in Lansdowne, Virginia.

101 Human experimentation can be broadly defined as anything done to an individual to learn how it will affect him or her. Its main objective is the acquisition of new scientific knowledge. M. Cheriff Bassiouni, Thomas G. Baffes & John T. Evrard, *An Appraisal of Human Experimentation in International Law and Practice: The Need for International Regulation of Human Experimentation*, 72 J. CRIM. LAW & CRIMINOLOGY 1597 (1981).

102 BARBARA SEAMAN, THE DOCTOR'S CASE AGAINST THE PILL vii (1980).

103 *Id.*

irritability, nausea, vomiting, and unexplained changes in menstrual periods.[104]

In the early clinical trials for Norplant,[105] women of color living in Asia, the Pacific, Latin America and Africa reported that they were not adequately informed of side effects.[106] Many of the doctors participating in the clinical trials assured women that Norplant was "totally" safe, even though the doctors did not know the long-term side effects and the effects that Norplant would have on women who were breast-feeding.[107] In one study, where primarily poor Egyptian women were test subjects, women reported that they experienced severe depression, weight loss, headaches and heavy bleeding.[108] After the clinical testing was concluded and Norplant was approved by the FDA, many women requested that their doctors remove Norplant from their bodies due to various side effects. They were told, however, that removal was not an option.[109] Due to the long list of health complications and the difficulties associated with having Norplant removed, several women filed class action lawsuits in Texas, Illinois, and Florida.[110] Over 50,000 women eventually filed complaints.[111]

Like the pill and Norplant, doctors first tested the Dalkon Shield (an intrauterine device designed in 1968) on poor women of color.[112] This time, the women of choice were African-American women from Baltimore. Many of the women involved in this experiment contracted a serious life-threatening uterine infection known as pelvic inflammatory disease.[113] By 1975, women filed several hundred lawsuits against the Dalkon Shield manufacturer

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[104] *Id.*

[105] Norplant is a contraceptive that consists of six silicone capsules, each about the size of a matchstick, filled with a synthetic hormone called Levonorgestral. The tubes are surgically implanted under the skin of a woman's upper arm. Once implanted, Norplant prevents pregnancy for up to five years by gradually releasing a low dose of the hormone into the bloodstream. When the FDA approved Norplant in 1990, it was considered to be the first major breakthrough in contraception since the pill. DOROTHY ROBERTS, KILLING THE BLACK BODY: RACE REPRODUCTION, AND THE MEANING OF LIBERTY, 105 (1997).

[106] BARBARA MINTZES, et. al., NORPLANT UNDER HER SKIN 84-109 (The Women's Health Action Foundation 1993).

[107] *Id.*

[108] *Id.* at 89-109.

[109] *Id.*

[110] ROBERTS, *supra* note 105.

[111] The complaints allege that Wyeth-Ayerst, the manufacturer of Norplant, negligently designed and actively promoted the device without adequately warning women about its potentially dangerous consequences. The complaints also allege that doctors were not properly trained in inserting and removing Norplant. Complaints filed in Missouri and New Mexico also claimed that Norplant was specifically marketed to minority and low-income women. ROBERTS, *supra* note 105.

[112] RICHARD B. SOBOL, BENDING THE LAW: THE STORY OF THE DALKON SHIELD BANKRUPTCY 1 (1991).

[113] *Id.*

claiming a long list of injuries including death related to spontaneous septic abortion, perforations of the uterus, ectopic pregnancies and pregnancies associated with birth defects.[114] By 1984, over 7,000 Dalkon Shield lawsuits had settled at a cost of $260 million while 3,500 cases were still pending.[115] Eventually, the manufacturer of the Dalkon Shield filed for bankruptcy in order to avoid paying the costs associated with litigation.[116]

The history of women as human subjects in experiments involving reproductive technology indicates that the rights of women are often abused. Women are told very little about the potential side effects of the drugs or devices that are being used in their bodies. Doctors provide very little, if any, information regarding alternatives to the new drugs and devices. Often doctors approach women who "choose" to use new reproductive technologies when they are at their most vulnerable. In Namibia, for example, in the 1980s, Depo-Provera was the most accessible contraceptive.[117] Women interviewed in the black townships of Katatura, Ovamboland, and Kavango indicated that hospital personnel gave them injections immediately after childbirth regardless of their medical history and sometimes against their will.[118] Similarly, young black women in South Carolina and Chicago, Illinois reported that immediately after giving birth, they were pressured into "consenting" to use either Norplant or Depo-Provera.[119]

In the case of quinacrine, women from all over the developing world have been sterilized by a drug whose long-term side effects and effects on fetuses are unknown. In many cases informed consent[120] was not obtained or honored; and therefore, these women were subjected to quinacrine sterilizations against their will. When one looks at this issue in combination with the history of sterilization as a form of population control,[121] it is difficult

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114 *Id.*

115 *Id.* These lawsuits were filed by women who used the Dalkon shield after the human experiments had been concluded and the Dalkon shield was being marketed to the general public.

116 *Id.*

117 Jenny Lindsay, *The Politics of Population Control in Namibia in* WOMEN AND HEALTH IN AFRICA 143-167 (Meredeth Trushen ed., 1991).

118 *Id.*

119 ROBERTS, *supra* note 105 at 127-128.

120 For more information on informed consent discussion, *see* C. Autonomy, pp. 142-48.

121 Birth control and population control are two different concepts. Birth control allows individual women to have control over whether and when they will have children. Population control, on the other hand, is a philosophy which states the belief that for the good of society, in light of overpopulation, certain groups (usually the least powerful and the poor) should reduce their birth rates. Coercion is often implemented in population control programs. Sterilization is viewed as only one tool of population control – immigration restriction and denial of services are other methods utilized by population control advocates. Sterilization, however, is a permanent solution to the challenges and consequences of unwanted population growth. In the United States, by the 1970's, so many women, particularly Black and Puerto Rican women, have been

to simply discard the quinacrine campaign as an unfortunate but necessary occurrence for the advancement of gynecological science.

With such serious allegations of violations of informed consent, as well as other ethical breaches, it seems as if something should be done to ensure that further abuse in quinacrine research does not occur. Although international codes of ethics governing human experimentation exist, none of these codes are regularly enforced. The codes are useful only in so far as they set standards articulating basic principles of bioethics. At this juncture, their utility as legal tools to force researchers to respect the rights of human subjects is minimal at best.

The three most prominent codes - The Nuremberg Code,[122] The Helsinki Declaration[123] and The International Guidelines for Biomedical Research Involving Human Subjects[124] are discussed below.

A. THE NUREMBERG CODE

The Nuremberg Code created the first internationally acceptable set of legal guidelines regulating research on human beings.[125] It was developed at the end of World War II, after the International Military Tribunal prosecuted twenty-three Nazi scientists and physicians who had designed experiments contemplating the death and dissection of human subjects for war crimes and crimes against humanity.[126] This tribunal, commonly referred

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involuntarily sterilized by doctors that several organizations against sterilization formed, including, the National Conference on Sterilization Abuse and the Committee to End Sterilization Abuse. The movement eventually passed legislation that set guidelines for sterilizations performed in municipal hospitals. *See generally* THOMAS SHAPIRO, POPULATION CONTROL POLITICS: WOMEN, STERILIZATION, AND REPRODUCTIVE CHOICE (1985).

[122] NUREMBERG CODE, *reprinted in* TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW, No. 10, Vol. 2, at 181-182 (Washington, D.C.: U.S. Government Printing Office, 1949).

[123] DECLARATION OF HELSINKI I (18th World Medical Assembly 1964), *reprinted in* THE NAZI DOCTORS AND THE NUREMBERG CODE 331 (George J. Annas & Michael A. Grodin, eds. 1992).

[124] INTERNATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS (Council For International Organizations of Medical Sciences 1983) (visited May 5, 2001) *available at* http://www.cioms.ch/frame_1993_texts_of_guidelines.htm.

[125] Although Nuremberg marked the beginning of regulations related to human experimentation, the history of human experimentation dates back to some of the oldest writings on earth. For example, the Chinese of the Sung dynasty in 590 B.C studied the effects of inoculation. In ancient Persia, the King consigned condemned criminals to scientific experimentation. The Ptolemies in Egypt and Renaissance Pisa also permitted this practice. In the 17th century experiments were conducted on both human beings and animals to demonstrate that blood circulates through the heart and lungs. In the 18th century, human beings were the subjects of experiments demonstrating that citrus fruits cure scurvy, vaccinations help reduce smallpox, and that anesthesia can control pain. Bassiouni, *supra* note 101, at 1599.

[126] The prosecutions took place in the International Military Tribunal which was established by the Allied nations (United States, French Republic, United Kingdom, and the Union of Soviet

to as the Nuremberg Trial, focused the world's attention on the worst possible consequences of unethical and uncontrolled human experimentation.[127]

The guidelines, hereinafter referred to as the Nuremberg Code,[128] established ten principles to ensure the moral, ethical, and legal practice of human experimentation.[129] The best known and perhaps the most frequently

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Socialist Republic). Twelve war criminal trials were conducted under the auspices of the International Military Tribunal. The eight-month trial of the twenty-three medical doctors and scientists began on July 19, 1947. This trial is often referred to as the "Doctor's Trial" or the "Medical Case." The defendants in this trial were accused of crimes conducted during scientific and medical experiments on concentration camp prisoners. These experiments included mass sterilization through castration doses of x-rays and through intrauterine injections of silver nitrate; immersion in tanks of cold water for periods up to fourteen hours to develop resuscitation techniques; mutilation of prisoners as experimental surgical subjects for training of German surgical students; infliction of bullet wounds and incisions and introduction of bacteria into the wounds to study and treat infections; shooting of prisoners with poisonous bullets to study the effects of aconite poisoning; execution and dismemberment of prisoners to furnish skeletons for an anthropological museum; and injection of malaria to test malaria immunity. The trial concluded with the conviction of fifteen defendants for committing war crimes and crimes against humanity. Seven of them were sentenced to death, five were sentenced to life imprisonment, two were sentenced to twenty years imprisonment, and one was sentenced to fifteen years imprisonment. *See* Bassiouni, *supra* note 101, at 1639-40; SOURCE BOOK IN BIOETHICS: A DOCUMENTARY HISTORY 5-11 (Albert R. Jonsen, et. al. eds, 1998); *See also* Karl Brandt v. United States, 333 U.S. 836 (1948); GEORGE J. ANNAS, LEONARD H. GLANTZ & BARBARA KATZ, INFORMED CONSENT TO HUMAN EXPERIMENTATION, 6-9 (1977); Kevin M. King, *A Proposal for The Effective International Regulation of Biomedical Research Involving Human Subjects*, 34 STAN. J. INT'L LAW 163, 167 (1998); Jonathan Todres, *Can Research Subjects of Clinical Trials in Developing Countries Sue Physician-Investigators for Human Rights Violations?*, 16 N.Y.L. SCH. J. HUM. RTS. 737, 742, (2000).

127 Bassiouni, *supra* note 101, at 1641.

128 The International Military Tribunal included the Nuremberg Code in its decision in the case of United States v. Karl Brandt. *See* 5 ENCYCLOPEDIA OF BIOETHICS, at 2763 (Warren T. Reich ed., rev. ed. 1995). *See also* SOURCE BOOK IN BIOETHICS, *supra* note 126; ALBERT R. JONSEN, A SHORT HISTORY OF MEDICAL ETHICS 5 (1999)

129 The following is a complete list of the ten principles known as the Nuremberg Code: (1) The voluntary consent of the human subject is absolutely essential; (2) The experiment should be conducted for the good of society and should not be random or unnecessary in nature; (3) The experiment should be designed and based on the results of animal experimentation; (4) The experiment should be conducted so as to avoid all unnecessary physical and mental suffering and injury; (5) No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects; (6) The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment; (7) Adequate facilities must be provided to protect the experimental subject against even remote possibilities of injury, disability, or death; (8) The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment; (9) The human subject should always have the option of choosing not to continue in the experiment if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible; and (10) During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject. NUREMBERG CODE, *supra* note 123.

articulated principle of the Nuremberg Code is the first principle which states that "voluntary consent is absolutely essential."[130] Under the Nuremberg Code, it was deemed impossible for an individual to consent to participate in an experiment without first being fully informed by the researcher about the nature and purpose of the experiment, as well as the risks, hazards and inconveniences to expect. The concept of consent refers to both the subjects' capacity to give consent as well as the researchers' obligation to provide information to their subjects.[131] Consequently, the process of obtaining consent is just as important as the actual giving of consent, and it is the duty and responsibility of each individual who initiates, directs, or engages in an experiment to ensure that the consent of the subject is valid.[132]

Although consent is essential, the Nuremberg Code makes it clear that all of the other nine points of the Nuremberg Code must be satisfied prior to obtaining consent.[133] In essence, the other nine points require that experiments involving human beings should be: (i) designed and based on the results of animal experimentation; (ii) conducted in a manner that avoids unnecessary physical and mental suffering and injury as well as death; and (iii) conducted for the good of society. The Code also requires that only scientifically qualified persons have authorization to conduct experiments on human beings.[134]

B. THE HELSINKI DECLARATION

The World Medical Association[135] enacted the Helsinki Declaration[136] in 1964. Like the Nuremberg Code, the Helsinki Declaration embraces

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[130] *Id.* at Principle 1.

[131] Jay Katz, *Human Sacrifice and Human Experimentation: Reflections at Nuremberg*, 22 YALE J. INT'L L. 401, 413 (1997).

[132] NUREMBERG CODE, *supra* note 122.

[133] George J. Annas, *Menegele's Birthmark: The Nuremberg Code in the U.S. Courts*, 7 J. CONTEMP. HEALTH L. & POL'Y 17, 21 (Spring 1991). For a complete statement of the 10 principles of the Nuremberg Code, *see supra* note 129.

[134] *Id.*

[135] The World Medical Association (WMA) is the first international medical organization. It was founded in 1946 to promote closer ties among medical organizations and doctors of the world. Thirty-two national medical associations were represented at the first WMA meeting. The WMA seeks to (1) maintain the honor and protect the interests of the medical profession; (2) study the problems which confront the medical profession in different countries, and (3) assist all peoples of the world to attain the highest possible level of health. *See* T.C. Routley, *Aims and Objects of the WMA*, WMA Bulletin 18 (1949); World Medical Association, *Human Experimentation*, 2 WORLD MED. J. 14, 14-15 (1955); *See also* George Annas, *Medical Ethics and Human Rights: Legacies of Nuremberg*, 3 HOFSTRA L. & POL'Y SYMPOSIUM 111, 115 (1999).

In 1948, the WMA incorporated some of the Nuremberg principles into its Hippocratic Oath. In the WMA Oath, individuals entering the medical profession pledge to devote their lives to the service of

informed consent and the need for experimentation to be conducted by scientifically qualified individuals. It also prescribes that animal and laboratory experiments should precede research on human beings, and it mandates a risk/benefit analysis in which the interest of science should not outweigh the health and safety of the subject.[137]

The Declaration, however, has two additional requirements not provided for by the Nuremberg Code. First, the Declaration provides that researchers who fail to fulfill their ethical obligations should be penalized by having their research rejected for publication.[138] Second, it requires an independent ethical committee[139] to provide researchers with comments and guidance on their research protocol. The committee also has the responsibility of verifying that (1) researchers are qualified to conduct the experiment, (2) experiments are properly designed, (3) test subjects have been equitably chosen, (4) privacy of the subjects will be respected, and (5) the potential humanitarian benefits arising from the experiment justify the risk to the individual subjects.[140] The concept of the independent ethical committee represents a significant advancement over the Nuremberg Code because it alleviates the need for investigators to rely solely on their own consciences to

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humanity, to practice medicine with conscience and dignity, to make the life and health of their patients their first consideration; and to never allow considerations of race, or religion, nationality, party politics or social standing to intervene between their duty to their patient. *See* King, *supra* note 126, at 179.

In 1954, the WMA created Principles for Those in Research and Experimentation. These five basic principles state that (1) experimentation should be conducted only in a scientific manner by qualified individuals who adhere to general rules of respect for individual rights; (2) publication of the first results of experimentation should be done with prudence; (3) the researcher bears primary responsibility in human experimentation for fully informing the human subject; (4) in desperate cases, the doctor's conscience must guide him in determining whether operations or treatment of a daring nature should be performed but informed consent can not be sacrificed; and (5) informed consent must be obtained in writing. World Medical Association, *Principles for Those in Research and Experimentation*, 2 WORLD MED. J. 14 (1955); *See also* http://csep.iit.edu/codes/coe/World_Medical_Association_Principles_for_Those_in_Research_1954.html. In essence, the five principles focus on the significance of informed consent, emphasizing the need for experimentation to be conducted by scientifically qualified individuals and for the results of research to be published in a responsible manner.

136 The Declaration was enacted in 1964 at the WMA conference in Helsinki. It was later amended at conferences in Tokyo (1975), Venice (1983) and Hong Kong (1989), South Africa (1996) and Scotland (2000). Alterations made after 1975, however have been minor. SOURCE BOOK IN BIOETHICS, *supra* note 126, at 13.

137 King, *supra* note 126, at 180. *See also Declaration of Helsinki: Recommendation for Conduct of Clinical Research* (visited May 5, 2001) *available at* http://www.bioscience.org/guides/declhels.htm.

138 HELSINKI DECLARATION, *supra* note 123, at Principle 27.

139 Bassiouni, *supra* note 101, at 1646.

140 HELSINKI DECLARATION, *supra* note 123, at Principle 13.

guide them in determining whether research is in compliance with basic ethical standards.[141]

Both the ethical review committees and the provision regarding the rejection for publication as a penalty for conducting unethical experiments creates a system of checks and balances that is not present in the Nuremberg Code. The provisions are an attempt at not only setting ethical standards but an attempt to establish a mechanism for monitoring and enforcing ethical requirements in human experimentation.

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[141] In the United States, ethical review committees govern all entities that receive financial support from the federal government to conduct research involving human subjects. These committees are institutional review boards or IRBs. *See generally* 45 CFR 46 (1998). An IRB reviews and/or approves research by examining research records, requiring reports from investigators, soliciting information from subjects, and observing the recruitment of subjects and the conduct of research. In addition, IRBs in the United States determine (1) whether research methods are appropriate to their stated objectives; (2) whether selection of subjects is equitable; (3) whether risks are reasonable in relation to the anticipated benefits that the subject will receive and/or the importance of the knowledge to be gained; and (4) whether informed consent has been obtained. If a research proposal disproportionately affects racial or ethnic minorities or persons of low socio-economic status, the IRB can evaluate whether the investigator's reasons for designing the research in this manner are justified. There are an estimated 3,000 to 5,000 IRBs in the United States. Most of these boards are associated with academic institutions or hospitals. *Institutional Review Boards (IRBs): A System in Jeopardy?* Testimony of George Grob Deputy Inspector General for Evaluation and Inspections, U.S. Dept. of Health and Human Services, (visited Mar. 22, 2001) *available at* http://www.forhealthfreedom.org/Publications/Children/hr61198/grob.html.

In addition to the United States, several other countries now use independent review committees as a means of regulating human experimentation. For a general discussion of research ethics committees in the United States, Britain, Ireland, Australia, New Zealand, Canada, France, the Netherlands, Belgium, Switzerland, Scandinavia, Germany, and Japan *see* PAUL MCNEILL, THE ETHICS AND POLITICS OF HUMAN EXPERIMENTATION 53-115 (1993). *See also* ALBERT JONSEN, et al., THE ETHICS OF RESEARCH WITH HUMAN SUBJECTS: A SHORT HISTORY 5, 8 (1998).

The effectiveness of IRBs in the United States has been challenged, however, because critics claim that these committees review too much too quickly without enough information and consequently the committees generally fail to provide protection to human subjects. June Gibbs Brown, Office of the Inspector General, U.S. Dept. of Health and Human Services, *Institutional Review Boards: A Time for Reform* (1998) OEI-01-97-00193, at ii. The critics also argue that many of the committee members employed by or closely affiliated with the institutions that are sponsoring the research proposals experience a conflict of interest because committee members are caught between a need to protect subjects and a desire to promote the interests of the institution by supporting innovative medical practices and research. *See* MCNEILL *supra*, at 4. The conflict of interest is particularly relevant to institutions where there is a direct correlation between funding and research. In such circumstances, protecting a human subject may mean that proposed research can not proceed. Once research is halted and funding is reduced, salaried employees serving on these committees will be faced with making a decision that could negatively impact their own financial resources.

C. THE INTERNATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS

Besides the Nuremberg Code and the Helsinki Declaration, there is one other international ethics document that provides ethical guidance to medical professionals conducting human research. In 1982, the Counsel for International Organizations of Medical Sciences (CIOMS),[142] in collaboration with the World Health Organization (WHO),[143] released the Proposed International Ethical Guidelines for Biomedical Research Involving Human Subjects (Guidelines).[144] These proposed guidelines, based on the 1975 version of the Helsinki Declaration, were offered to countries as a model for national standards.[145] The Guidelines stressed the need for informed consent, special protection for vulnerable populations,[146] equitable distribution of burdens and benefits associated with research, and the need for independent ethical review committees. The Guidelines were also designed to provide strategies on how to effectively apply the principles of the Helsinki Declaration, particularly in developing countries.[147]

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[142] CIOMS is an international association that maintains collaborative relations with the United Nations and its agencies. It was founded in 1949 under the auspices of WHO and UNESCO. It has national members from 30 countries (academies of medical sciences and medical research councils) and 72 international members (nongovernmental medical organizations). *See generally* Council For International Organizations Of Medical Sciences (CIOMS) (visited May 5, 2001) *available at* http://www.who.int/ina-ngo/ngo/ngo011.htm.

[143] The World Health Organization (WHO) is one of four specialized agencies of the United Nations that has a special interest in human rights matters. It was established by treaty in 1948. Ninety-one countries are members of the WHO which is funded by contributions from both its member states and other voluntary sources. The preamble to the Constitution of WHO declares that the enjoyment of the highest attainable standard of health is a fundamental right of every human being and that governments have a responsibility for the health of their peoples which can be fulfilled only by the provision of adequate health and social measures. DEP'T OF PUBLIC INFORMATION OF THE U.N., THE UNITED NATIONS AND HUMAN RIGHTS 19 (1984). *See also About WHO: Mission Statement* (visited May 5, 2001) *available at* http://www.who.int/aboutwho/en/mission.htm.

[144] Z. Bankowski and R. J. Levine, Council for Int'l Org. of Med. Sci. and the World Health, *International Ethical Guidelines For Biomedical Research Involving Human Subjects* (Geneva 1993).

[145] George Annas, *The Changing Landscape of Human Experimentation: Nuremberg, Helsinki and Beyond*, 2 HEALTH MATRIX: JOURNAL OF LAW-MEDICINE 119,124 (Summer 1992).

[146] The term vulnerable populations refers to individuals who are particularly susceptible to exploitation in research due to their age, their inability to give informed consent free from coercion, and/or mental disability. Vulnerable populations include children, mentally disabled adults, prisoners, individuals living in state institutions, pregnant women, and members of less developed communities who may be easily exploited due to their economic status and lack of knowledge about modern medicine. *See generally* BARUCH BRADY, THE ETHICS OF BIOMEDICAL RESEARCH: AN INTERNATIONAL PERSPECTIVE 49-51 (1998).

[147] Bankowski, *supra* note 144, at 8.

The final version of the Guidelines, published in 1991, constituted the most extensive treatment of issues related to human experimentation.[148] Unlike the Declaration and the Code, the Guidelines provide that subjects involved in medical research who suffer injury as a result of their participation in an experiment are entitled to financial compensation for any temporary or permanent disability.[149]

Another remarkable aspect of the Guidelines is that it is the first document to address issues arising from the internationalization of scientific research. In this regard, there are provisions in the Guidelines that specifically address research in developing communities. For example, Guideline 8 requires that research subjects from developing communities not be used in research that could be carried out reasonably well with subjects from developed communities.[150] It attempts to prevent the exploitation of socially and economically disadvantaged communities in developed countries as well.[151]

Guideline 15 addresses externally sponsored research, defined as "research undertaken in a host country that is sponsored, financed, and sometimes wholly or partly carried out by an external or international or national agency with the collaboration or agreement of the appropriate authorities... of the host country."[152] It requires that all externally funded research must meet not only the ethical standards of the host country, but also the ethical standards of the initiating country.[153]

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[148] The fifteen Guidelines include provisions for (1) individual informed consent; (2) essential information for prospective research subjects; (3) obligations of investigators regarding informed consent; (4) inducement to participate; (5) research involving children; (6) research involving Persons with mental or behavioral disorders; (7) research involving prisoners; (8) research involving subjects in underdeveloped communities; (9) informed consent in epidemiological studies; (10) equitable distribution of burdens and benefits; (11) selection of pregnant or nursing (breast-feeding) women as research subjects; (12) safeguarding confidentiality; (13) right of subjects to compensation; (14) constitution and responsibilities of ethical review committees; and (15) obligations of sponsoring and host countries. INT'L GUIDELINES, *supra* note 124.

The Guidelines were distributed to ministries of health, medical research councils, medical faculties, non-governmental organizations, research-based pharmaceutical companies, developing countries, and medical journals. Consequently, comments and suggestions for amendments were received from many sources and were incorporated in the 1991 edition of the Guidelines. *Id.*

[149] *Id.* at Guideline 13.

[150] King, *supra* note 126, at 183.

[151] INT'L GUIDELINES, *supra* note 124, at Guidelines 8 and 10.

[152] *Id.* at Guideline 15.

[153] King, *supra* note 126, at 183; Annas, *supra* note 145, at 125.

These Guidelines served as the inspiration for more than fifty-five countries that adopted legislation or enacted other measures to regulate human experimentation between 1980 and 1992.[154]

D. PROBLEMS WITH NUREMBERG/HELSINKI/CIOMS

The Nuremberg Code, the Helsinki Declaration and the International Ethical Guidelines for Biomedical Research Involving Human Subjects are all based on moral or ethical values rather than legal mandates. Although it may be argued that each document has some degree of influence over the conduct of researchers, ultimately these regulations create ethical duties that are only advisory in nature. Moreover, the Guidelines are clearly not intended to be legally binding and must be voluntarily enacted by national legislatures or adopted by a court of law in order to be enforceable.[155]

Although many countries have adopted enforceable legislation modeled after the Guidelines, the Nuremberg Code, or the Helsinki Declaration, each country is free to adopt whatever standards it desires. Some countries have very detailed regulations, while others have very lenient standards or no standards at all.[156] This lack of uniformity, combined with a general lack of enforcement, allows unethical research to be conducted with impunity. Despite the availability of both civil and criminal sanctions for unethical experimentation, there has never been a reported criminal case citing the Nuremberg Code. Furthermore, even though the Code became part of international customary or common law,[157] and could technically be used as the basis for both civil and criminal cases, a review of the case law in the United States indicates that there are very few American court decisions involving human experimentation in which either the Nuremberg Code or the Helsinki Declaration has ever been cited.[158] In fact, it took twenty-five years

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[154] RICHARD J. KELLY et al., THE REGULATION OF RESEARCH ON HUMAN SUBJECTS: A DECADE OF PROGRESS, ETHICS AND RESEARCH ON HUMAN SUBJECTS: INTERNATIONAL GUIDELINES 127 (Geneva: CIOMS 1993).

[155] King, *supra* note 126, at 184.

[156] *See generally* BRADY, *supra* note 146. *See also* MCNEILL, *supra* note 141.

[157] For a general discussion of the Nuremberg Code and its status in international law, *see* ANNAS, supra note 126, at 21.

[158] The court alluded to Nazi doctors in a pre-1975 dissenting opinion in Strunk v. Strunk, 445 S.W.2d 145 (Ky. 1969). This case involved the removal of a kidney from an institutionalized mentally retarded adult for transplant into his brother. In his dissent, Judge Steinfeld indicated that he was troubled in reaching a decision in this case because of his "recollection of a government which, to the everlasting shame of its citizens, embarked on a program of genocide and experimentation with human bodies." *Id.*, 445 S.W. 2d at 149.

In Karp v. Cooley, 493 F.2d 408, 423-24 (5th Cir. 1974). The U.S. District Court ruled that the Nuremberg Code was not relevant to a malpractice case involving the first artificial heart because the

after the Code was promulgated for a United States court to use the Nuremberg Code as guidance in a decision.[159] The United States Supreme Court has mentioned the Nuremberg Code in only one dissent.[160] Similarly, there are no reported cases from any international court or human rights agency which cite to the Helsinki Declaration or the Nuremberg Code.

This lack of reliance on the Nuremberg Code and the Helsinki Declaration may be due to the fact that often people injured as a result of human experimentation simply do not have the economic resources to pursue

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artificial heart was implanted to save Karp's life and was therefore not experimental but therapeutic.

In Pierce v. Ortho Pharmaceutical Corp., 417 A.2d 505, 516-18 (N.J. 1980), Judge Pashman of the New Jersey Supreme Court stated in his dissent that he believed that the plaintiff should have had the opportunity to present to a jury "recognized codes of medical ethics" including the Nuremberg Code, in her wrongful discharge lawsuit against a pharmaceutical company that she resigned from because she believed they requested her to act contrary to medical ethics.

In Jaffee v. United States, 663 F.2d 1226, 1229 (3d Cir. 1981), *cert. denied*, 456 U.S. 972 (1982), U.S. soldiers alleged that they were ordered to stand in a field without protection from radiation while a nuclear device exploded in the Nevada desert. The dissenting judges found that the military was conducting a dangerous "human experiment upon soldiers subject to their control, without their knowledge, permission or consent," and that this action violated the Nuremberg Code as well as the International Covenant on Civil and Political Rights, the Geneva Convention, the Torture Convention and the Universal Declaration of Human Rights. *Id.* at 1248. The majority, however, made no finding in regards to the Nuremberg Code because they declared that the issue was whether the plaintiffs were entitled to money damages.

In Begay v. United States, 591 F. Supp. 991 (D. Ariz. 1985), *aff'd*, 768 F.2d 1059 (9th Cir. 1985), the court found that a U.S. Public Health Service decision not to inform research subjects of the risk of continued exposure to uranium was justified "based on considerations of political and national security feasibility factors." *Id.* at 1012. In discussing this matter, the court treated the Nuremberg Code as if it did not have any legal force in the United States.

In Whitlock v. Duke University, 637 F. Supp. 1463 (M.D.N.C. 1986), *aff'd*, 829 F.2d 1340 (4th Cir. 1987), a nontherapeutic experiment was conducted in which deep sea dives were done as part of research into high pressure nervous syndrome. The plaintiff was an experienced diver who signed an informed consent form advising him of the risks. After the dive, the plaintiff suffered permanent organic brain damage. The court granted the defendant's motion for summary judgement after finding that the Nuremberg Code was authoritative on the issue of informed consent in the nontherapeutic context. However, the case was dismissed because the plaintiff failed to provide any evidence that there was a foreseeable or known risk of organic brain damage.

For a more detailed account of these court cases *see* Annas, *supra* note 133, at 29-36.

[159] Kaimowitz v. Michigan Dep't of Mental Health, No. 73 Civ. 19434-AW (Mich. Cir. Ct., Wayne County, July 10, 1973) (unreported) *cited in* Annas, *supra* note 126, at n.33. The court used the Nuremberg Code as guidance in deciding that involuntarily confined individuals who could not give voluntary, competent, informed, or understanding consent could never legally consent to experimental brain surgery designed to alter aggressive behavior; and that given the current state of knowledge, no one could consent to such a procedure.

[160] United States v. Stanley, 483 U.S. 669, 710 (1987). (Brennan, J. dissenting). *See also* Annas, *supra* note 126. *See* e.g. Jonathan Moreno, *Reassessing the Influence of the Nuremberg Code on American Medical Ethics*, 13 J. CONTEMP. HEALTH L. & POL'Y 347 (1997).

legal remedies. Some may not even know that pursuing a legal remedy is an option. Many individuals who do choose to pursue their legal rights may base their claims on local tort theories of battery, intentional infliction of emotional distress, medical malpractice or negligence, rather than on international law.[161]

Although the failure to apply, monitor and enforce the terms of the codes undermines the significance of these ethical guidelines which purport to regulate human research, these codes do provide significant evidence of international agreement on medical experimentation.[162] Thus, the codes provide an ethical framework for questioning the appropriateness of human experimentation. A detailed examination and analysis of how the provisions of the Nuremberg Code, the Helsinki Declaration and the Guidelines apply to the quinacrine campaign is beyond the scope of this article. Instead, this article seeks to emphasize that all three of these Codes articulate three commonly accepted principles of bioethics: beneficence (obligation to benefit others)/non-maleficence (obligation not to do harm),[163] autonomy (respect for persons),[164] and distributive justice (obligation to distribute benefit and harm fairly).[165]

In the next section, these three ethical principles will be used to provide a bioethical analysis of the quinacrine experiment.

III. QUINACRINE: A BIOETHICAL ANALYSIS

The Nuremberg Code, the Helsinki Declaration and the International Ethical Guidelines for Biomedical Research Involving Human Subjects all place great emphasis on the principles of beneficence, distributive justice, and autonomy. In bioethical analysis, all three of these principles are important to resolving the ethical problems presented by human experimentation.[166] In

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161 ANNAS, *supra* note 126, at 27-55.

162 Todres, *supra* note 126, at 749.

163 NUREMBERG CODE, *supra* note 122, at Principles 2, 4, 5, 7 and 10. *See ALSO* HELSINKI DECLARATION, *supra* note 123, at Principles 3, 5, 17, and 19; INT'L GUIDELINES, *supra* note 124, at Guidelines 5 (research involving children), 6 (research involving subjects in underdeveloped communities), and 11 (reflection of pregnant or nursing women as research subjects).

164 NUREMBERG CODE, *supra* note 122, at Principles 1 and 9. *See also* HELSINKI DECLARATION, *supra* note 123, at Principles 8, 21, 22, and 23; INT'L GUIDELINES, *supra* note 124, at Guidelines 1 and 3.

165 HELSINKI DECLARATION, *supra* note 123, at Principles 8 and 19. *See also* INT'L GUIDELINES, *supra* note 124, at Guidelines 8, 10 and 15.

166 Principalism represents just one approach to bioethics. The leading account of principalism is BEAUCHAMP AND CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS. The principles emerged from the work of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which was created by Congress in 1974. It was part of the Commission's charge to develop

this section, these three principles will be used to examine the questions raised by the quinacrine campaign.

A. BENEFICIENCE/NON-MALIFICIENCE

Beneficence and non-maleficence refer to the ethical obligation to maximize benefits and to minimize harms and wrongs.[167] These principles require that the risks of research must be reasonable in light of the expected benefits, that the research design must be sound, and that the investigators must be competent both to conduct the research and to safeguard the welfare of the research subjects.

To begin this analysis, it is necessary to point out that many of the quinacrine sterilizations that have already been performed were done without regard to an established research agenda. Mumford and Kessel believe that quinacrine is not a "new drug,"[168] and that its safety has already been established. Therefore, they often failed to conduct themselves as if they

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broad ethical principles to provide the basis for formulating, criticizing and interpreting rules. The Commission articulated these three ethical principles as (1) the principle of respect for persons, (2) the principle of beneficence, and (3) the principle of justice.

There are many critics of principalism who argue that principalism is mistaken about the nature of morality and is misleading about the foundation of ethics. *See* e.g. BERNARD GERT, et al., BIOETHICS: A RETURN TO FUNDAMENTALS (1997). Critics argue that the principles are not action guides but instead function as checklists which remind the researcher to "consider this....consider that...remember to look for this...." Thus, they argue that the principles do not embody an established and unified moral system capable of providing useful guidance. In addition, critics argue that principalism blurs the distinction between what is morally required and what is morally encouraged.

[167] MCNEILL, *supra* note 141, at 145-148.

[168] When the FDA approves a new drug, it is approved for the specific purposes associated with the clinical trial findings that supported the drug's application. Off-label use of a drug occurs whenever the drug is used in a manner that varies in some way from the instructions in the drug's labeling. Courts have repeatedly recognized the propriety of off-label use. However, off-label use of a drug is a legal determination, not a medical one. Consequently, the FDA through its regulatory process can determine that certain off-label uses of a drug are inappropriate and therefore forbidden. When this occurs, the FDA directs the doctor to refrain from using the drug for the off-label use in question, and the doctor is therefore required to apply for an investigational new drug application (IND). The IND process requires that a clinical testing plan be submitted to the FDA and that an institutional review board (IRB) supervise the clinical investigation. If the IND testing successfully demonstrates a drug's safety and effectiveness, the manufacturer can submit a new drug application (NDA) to the FDA. This application requires detailed chemical information about the drug, summaries of clinical testing and conclusions, a summary of risks and benefits or the drug (including a discussion of why the benefits exceeds the risks), and proposed labeling. After the FDA approves the NDA, the drug can be marketed for the uses for which it was investigated and labeled. For a detailed discussion of off-label use of drugs *see generally* James Beck and Elizabeth Azari, *FDA Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 FOOD & DRUG L.J. 71 (1998); *see also* Steven Salbu, *Off-Label Use, Prescription, and Marketing of FDA-Approved Drugs: An Assessment of Legislative and Regulatory Policy*, 51 FLA. L. REV. 181 (1999).

were involved in experimental research on human beings. From their perspective, quinacrine had been used to treat malaria and other diseases for over fifty years without any serious side effects. They therefore concluded that quinacrine sterilizations would also be safe and effective. No consideration was given to the possibility that quinacrine administered intrauterinely for sterilization purposes would most likely have a different effect on one's body and overall health than quinacrine administered orally as a prophylactic for disease. No consideration was given to the fact that quinacrine administered intrauterinely (as opposed to orally) was being used as a schlerosing agent to create scar tissue in a woman's reproductive tract.[169] Despite this obvious difference, Mumford and Kessel claim that quinacrine is "an approved drug in virtually every country of the world"[170] and that the sterilizations are not experimental[171] because they are a legitimate "off label" use of the drug.[172]

By removing quinacrine from the "experimental" category, the doctors believe that they are free to ignore all guidelines governing human experimentation. Consequently, many of the women who have been subjected to quinacrine sterilizations are not being monitored for either long-term or short-term effects, are not being provided with any type of follow up care, and are not being informed that there are potential unknown risks associated with quinacrine sterilizations. In essence, these women are not given the same consideration that is normally given to human subjects participating in medical experiments.

In those cases where women are clearly being treated as if they are "subjects" of a medical study,[173] there is a lack of uniformity in the manner in which the research is conducted. For example, in many instances, the dose of quinacrine administered from woman to woman varied.[174] In other cases, the skill of the health worker performing the sterilizations also varied.[175] Even the informed consent protocol varied from site to site, if it existed at all.[176] In a document published by Mumford and Kessel, they state:

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[169] For a discussion of the FDA's concerns regarding mutation and carcinogencity, *see supra* note 73 and p. 111.

[170] Mumford, *supra* note 7, at 7.

[171] *Id.* *See also Id.* at Attachment #6, p. 4.

[172] *Id.* at 7.

[173] For a list of quinacrine sterilization studies, *see* http://www.quinacrine.com.

[174] For a discussion of the lack of uniformity in administering quinacrine, *see supra* pp. 105-12 and *supra* note 26. *See also* Kessel, *supra* note 59.

[175] *Id.*

[176] For a discussion of the lack of informed consent see discussion of clinical trials in Vietnam and India, *see* Mumford, *supra* note 7.

> our decades of experience in working in countries around the world have led us to recognize that our form and our view of informed consent is not always applicable everywhere. We have learned that we must rely on the judgment of our collaborators to decide what is best for their patients.[177]

One interpretation of this statement is that Mumford and Kessel and the clinicians whom they have enlisted to assist them in performing quinacrine sterilizations do not share a common understanding of informed consent. On the other hand, the statement may also be interpreted to mean that in certain circumstances, doctors using quinacrine do not deem informed consent necessary.

The lack of informed consent, combined with unreliable research design, and inadequate follow-up in the quinacrine research trials, make it highly unlikely that the results of this "research" will be valid. Without valid results, research utilizing human subjects is not only valueless but probably unethical as well.[178]

To obtain a better understanding of the bioethical questions raised by the quinacrine campaign, however, it is helpful to more closely examine the motivations and alleged benefits of quinacrine sterilizations.

What are the potential benefits of quinacrine sterilization?

Mumford and Kessel claim that they are promoting quinacrine in order to decrease the world's population rate.[179] They claim that since women in developing countries have a high risk of dying from childbirth, sterilization will prolong their lives.[180] They argue that the more sterilizations there are in developing countries, the less maternal mortality there will be.[181] Ultimately, Mumford and Kessel claim that this will benefit not only women of childbearing age but society as a whole. They reason that the more sterilized women there are in developing countries, the fewer children there will be to feed and concomitantly the fewer people there will be to populate the earth - which in Mumford's opinion is a matter of survival.[182] Mumford warns that

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[177] Stephen D. Mumford, Responses to Articles by Shree Mulay in Quinacrine Sterilization (Jan. 6, 2000)(unpublished manuscript on file with author).

[178] Benjamin Freedman, *Scientific Value and Validity as Ethical Requirements For Research: A Proposed Explication*, IRB: A REV. HUM.SUBJECTS RES., vol. 9, no. 6, 7-10 (1987).

[179] Freedman, *supra* note 57.

[180] Kessel, *supra* note 61.

[181] *Id.*

[182] It is estimated that the world population will reach 6.2 billion people this year. Some scientists, sociologists, philosophers and politicians believe that population growth threatens the existence

"the world's population is growing too fast...and no one is doing enough to stop it."[183] He states that if population rates continue to rise, "[i]n time, all nations will be overrun by violent masses."[184] Both Mumford and Kessel have been quoted as stating that chemical sterilization will play a very important role in maintaining peace and security through out the world.[185]

This sentiment connecting national security to the need for population control is not new. In fact, twenty-five years ago, the Central Intelligence Agency, the Agency International Development, and the United States' Departments of State, Defense, and Agriculture produced confidential *National Security Study Memorandum 2000* in which the United States government supported population control as a way to stem radical dissent and protect U.S. access to strategic minerals in developing countries.[186] More recently, top State Department officials have indicated they believe overpopulation was a major cause of political strife in Haiti, Rwanda, and Chiapas, Mexico.[187] Similarly, in 1996, the White House announced in the preface to its National Security Strategy report that "large-scale environmental degradation, exacerbated by rapid population growth, threatens to undermine political stability in many countries and regions."[188] One year later, the Rockefeller Foundation embraced this notion and explained the conflict as follows:

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of the planet. They argue that overpopulation creates ethnic conflicts; warring nations; poverty; food, housing and employment shortages; and a host of environmental concerns including air and water pollution, and depletion of limited natural resources. U.N. CHRONICLE, vol. 31, no.2, ISSN:0251-7329, June 1, 1994 *available at* 1994 WL 13634803. CF. BETSY HARTMANN, REPRODUCTIVE RIGHTS & WRONGS: THE GLOBAL POLITICS OF POPULATION CONTROL (1995) which discusses the myth of overpopulation and explains how the philosophy of population control not only restricts reproductive choice, but helps to perpetuate poverty and heighten racial and ethnic tensions.

183 Catherine Clabby, *Triangle Maverick Says Aim is to Stem Population*, THE NEWS & OBSERVER, June 20, 1990, at A1 (visited Apr. 11, 2000) *available at* http://www.newsandobserver.com/daily/1998/06/20/tri00.html.

184 *Id.*

185 Mohan Rao, *Quinacrine Sterilization Trials: A Scientific Scandal?*, ECONOMIC AND POLITICAL WEEKLY, March 28, 1998, at 4 (visited Apr. 11, 2000) *available at* http://www.hsph.harvard.edu/Organizations/healthnet/SAsia/suchana /9999/quinacrine.html.

186 For a detailed analysis of this now declassified memorandum *see* Elizabeth Soto, *Why Washington Cares*, THE PROGRESSIVE, Sept. 1990, at 28; *See also* MUMFORD, *supra* note 42 (explaining how "destructive feminists" and the Vatican have mounted a successful opposition to international population policies that equate population growth in developing countries to national security interests)'.

187 *See* e.g., Warren Christopher, *American Diplomacy and the Global Environmental Challenges of the 21st Century* (1996), speech presented at Stanford University, Palo Alto, CA, Apr. 9. Reprinted in Wilson Center, Environmental Change and Security Project Report, 81-85, (Spring 1996).

188 1996 U.S. National Security Strategy of Engagement and Enlargement. Excerpted from Wilson Center, *Environmental Change and Security Project Report*, 72-76, (Spring 1996).

> Resource scarcities, often exacerbated by population growth, undermine the quality of life, confidence in government, and threaten to destabilize many parts of the globe.... Once a resource becomes scarce, a society's "haves" often seize control of it, leaving an even smaller share for the "have nots." Since population growth rates are highest among the have-nots, this means that an even larger number of people are competing for a smaller share of resources - and violent conflict is often the result.[189]

This alleged nexus between population, violence and political instability in developing countries has spawned a movement that preaches fear and hatred of people from developing countries. Its most recent manifestation is the coalition-building which is occurring between anti-immigration groups, population control groups and environmental organizations.[190] Their shared agenda is a dangerous resentment of immigrants as well as a targeting of immigrant women's fertility. It is at this crossroad that Mumford and Kessel appear.

Mumford, in particular, has been very open in espousing his concern for controlling immigration into the United States. He stated:

> Immigration is much too high. We have 1.2 million legal immigrants annually and who knows how many illegal.... Every environmental indicator in America is in decline, so immigration already is affecting our quality of life.... This

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[189] Rockefeller Foundation, *High Stakes: The United States, Global Population and Our Common Future*, (visited May 5, 2001) *available at* http://www.rockfound.org/display.asp?context=1&Collection=3&DocID=156.

[190] The Political Ecology Group (PEG) has documented a well-funded campaign by anti-immigration and white supremacist organizations to persuade the Sierra Club to support United States immigration restrictions. The campaign includes mass mailings, videos, magazine advertisements, and other public relations activities. A group called Population-Environment Balance (PEB) was one of the organizations that lobbied the Sierra Club and provided instructions to their membership on how to join the Sierra Club to a pack the vote for anti-immigrant policies. PEB has a history of advocating population control on environmental grounds, but in the last five years, their focus has shifted to an all-out campaign for immigration control. Their honorary chairman, Garrett Hardin is the former Vice President of the American Eugenics Society who advocates ending non-European immigration. Mr. Hardin has expressed alarm about "the next generation of breeders, now reproducing uncontrollably in Third World countries." The problem according to Mr. Hardin, is not simply that there are too many people in the world, but there are too many of the wrong kind of people. As he puts it: "It would be better to encourage the breeding of more intelligent people rather than the less intelligent.' *Exposing The Greening of Hate, Wooing The Sierra Club: Anti-Immigration Groups Make Unlikely Suitors*, A Special Report From the Political Ecology Group (copy on file with author).

> overpopulation bomb is going to drive terrorism in the United States.[191]

Mumford has also stated on film that: "If we don't control our borders, we will certainly become a Third World country. I mean, more than a billion people would like to emigrate here today."[192] Comments such as these, in addition to Mumford's membership in several anti-immigration groups,[193] have lead many people to believe that the motivation behind the quinacrine sterilization campaign is to reduce the number of poor uneducated immigrants to the United States.[194] This belief is also fueled by the fact that Mumford and Kessel's quinacrine campaign is primarily funded by donors who are also avid anti-immigration sponsors.[195] In 1998, Alix Freedman of the *Wall Street Journal* reported that the most dedicated fundraisers for the quinacrine sterilization campaign were Donald Collins and Sally Epstein, a couple from Washington D.C., who are both on the board of the Federation for American Immigration Reform (FAIR).[196] This organization advocates for a sharp reduction in immigration to the United States.[197] Also among Mumford and Kessel's contributors are the Scaife Family Foundation[198] (contributing

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191 McCullough, *supra* note 39.

192 CBS News, *supra* note 26.

193 Mumford's curriculum vitae indicates that he is a member of Americans for Immigration Control, the Federation of American Immigration Reform, Negative Population Growth, and Zero Population Growth. *See generally* Mumford Background, *supra* note 5.

194 *See* Betsy Hartmann, Women's Health Advocates *Win a Victory in the Fight Against Quinacrine Chemical Sterilizations, ZNET Commentaries* (Dec. 2, 1999) *available at* http://www.zmag.org/ZSustainers/ZDaily/1999-12/02hartmann.htm (where author states that Mumford and Kessel are population control and anti-immigration extremists).

195 Committee on Women Population & Environment (CPWE), Political Environments #5, Fall 1997, at 24 (copy on file with author).

196 Freedman, *supra* note 41.

197 Ruth Coniff, *The Right Calls the Shots*, THE PROGRESSIVE, October 1993. FAIR receives substantial funding from the Pioneer Fund, whose original founder advocated sending blacks back to Africa and supported the work of Nazi eugenicists. The Pioneer Fund still finances most eugenics research in North America. Pioneer Fund Director Harry Weyher has reported that the Fund makes large donations to FAIR because they are concerned "about who's coming in" to America.

198 The Scaife family is one of the richest families in America. Their fortunes are listed among the top eight. Richard Mellon Scaife (a great grandson of the founder of the Mellon empire) is cited as having done more than any other individual to influence the way in which Americans think about their country and the world. He has dedicated his wealth to influencing the formation of public opinion. His generous donations sometimes exceeding one million dollars have helped launch conservative think-tanks like The HERITAGE FOUNDATION and AMERICAN SPECTATOR, a conservative monthly magazine. It is reported that Scaife gives away over half a million dollars each *week*. He was the key funder of the $2.4 million Arkansas Project which was formed to discredit President Clinton. The Arkansas Project has been accused of paying money to David Hale, the key Whitewater witness and allegedly bankrolled the Paula Jones' sexual harassment case against President Clinton. The Scaife family foundations have also provided millions of dollars to as many as two dozen "New Right" organizations. Richard Scaife's

$160,000 to the quinacrine sterilization campaign since 1994)[199] and the Leland Fikes Foundation,[200] both of which are linked to FAIR.[201] Both of these organizations espouse the belief that the United States must limit immigration or be "overwhelmed with immigrants who [will] turn this nation into another third world country."[202]

In essence, Mumford and Kessel appear to be driven by three incentives in their sterilization crusade: (1) the need to reduce maternal mortality in developing countries in order to save women's lives; (2) the desire to control or reduce the population in Third World countries in order to secure world peace; and (3) the need to prevent immigrants from flooding United States borders in order to prevent chaos and destruction. From Mumford and Kessel's perspective, all three of these incentives are based on their desire to make the world a better place and to "do good."

Assuming for the sake of argument that Mumford and Kessel really are motivated by a desire to "do good," we must now determine how effective the quinacrine experiment is at achieving its allegedly "beneficent" goals. This is one of the key questions in bioethical analysis.

How effective is quinacrine at achieving its goals?

1. Chemical Sterilization Will Reduce Maternal Mortality

In terms of a risk/benefit analysis for quinacrine sterilization, Kessel states:

> A simple guide to determining benefits is the estimate for rural areas of South countries that each sterilization prevents two births. If maternal mortality is, say 3.8 per 1,000 live births as estimated for Vietnam, then each 1,000 sterilizations done by a new method such as quinacrine pellets will prevent

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mother, Sarah Scaife is best known for her charitable donations to population control type organizations. *See The Man Behind the Mask* (visited 11/10/00) *available at* http://www.salon.com/news/1998/04/07news.html. *See also* Karen Rothmyer, *Citizen Scaife – Part 6*, COLUMBIA JOURNALISM REV. (July/Aug. 1981) *available at* http://www.cjr.org/year/81/4/scaife_sidebars.asp.

[199] Freedman, *supra* note 57.

[200] CWPE, *supra* note 195. The Leland Fikes Foundation in Dallas gave Mumford's Center for Research on Population and Security $25,000 in 1993 for a quinacrine project in Chile. *See* Betsy Hartmann and Nalini Visvanathan, *A Risky Business? Quinacrine Used To Sterilize Women Worldwide Has Yet To Be Proved Safe*, BOSTON SUNDAY GLOBE, Aug. 3, 1997 at D1.

[201] Freedman, *supra* note 57.

[202] The Human Laboratory, (Horizon Entertainment 1995) (documentary video produced by Deborah Cadbury).

> 7.6 maternal deaths. No one has suggested that the method could kill that number of women.[203]

In making this statement, Kessel is trying to reinforce the notion that quinacrine sterilizations are good because they will reduce maternal mortality and save lives. Kessel's analysis regarding the relationship between sterilization and maternal mortality, however, is fatally flawed. The problem is that the analysis assumes that all women at risk of maternal death in developing countries - i.e. pregnant women - do not want to be pregnant and that they want to be sterilized. His analysis fails to account for the many women who consciously choose to be pregnant. For these women, sterilization is not a desired option. His analysis also ignores the many women who, although they seek to prevent pregnancy, would deliberately reject sterilization as an acceptable form of contraception and instead choose to use other less invasive forms of contraceptives that are not permanent.

Several of these other forms of contraceptives are also arguably more beneficial[204] than quinacrine sterilizations because they have a higher effectiveness rate in preventing pregnancy and/or providing protection against HIV.[205] Use of condoms, for example, would promote male responsibility for sexual conduct, in addition to providing protection against HIV. Other contraceptive alternatives which may be more effective at preventing pregnancy include the female condom, the pill, the IUD, the diaphragm used with spermicide, Norplant, and Depo-provera. Since there are so many other alternatives to prevent pregnancy besides quinacrine, it is simply scientifically inaccurate to juxtapose the risks of maternity with the benefits of quinacrine sterilization. As Marge Berer has pointed out, risks and benefits of quinacrine sterilization are appropriately compared only with those of other sterilization methods.[206] When, however, quinacrine is compared to surgical sterilization, it does not fare particularly well: quinacrine has a higher failure

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[203] Elton Kessel, *Commentary, Quinacrine Sterilization Revisited*, LANCET 344: 698-700; Sept. 1994.

[204] MCNEILL, *supra* note 141, at 145 (in the context of medical research on human subjects, researchers have a duty to minimize the risk of harm).

[205] According to the JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION, surgical sterilization for women is 99.5%- 99.9% effective in preventing pregnancy; Norplant is 99.95% effective; Depo-Provera is 99.7% effective; IUDs are 97.4%-99.2% effective; The pill is 97% - 99.9% effective; male condoms are 86%-98% effective; female condoms 79-95% effective; and Diaphragms are 80%-94% effective. Both the male and female condoms provide protection against HIV and sexually transmitted diseases. *Your Contraceptive Choices* (last modified Jan. 2000) *available at* http://www.ama-assn.org/special/contra/support/ppfa/choices.htm.

[206] Marge Berer, *The Quinacrine Controversy One Year On*, 4 REPRODUCTIVE HEALTH MATTERS 99 –106 (Nov. 1994).

rate[207] and presents unknown risks to fetuses and infants who are conceived post-sterilization.[208]

Although in developing countries, complications in childbirth literally kill hundreds of thousands of poor women every year[209] and pregnancy-related deaths desperately need to be reduced,[210] it is not true that quinacrine sterilizations are the most beneficial way of addressing this public health problem. Studies indicate that maternal mortality is caused by unhealthy lifestyles, poor nutrition, a lack of access to health care in general[211] and less access to prenatal care specifically.[212] Prescriptions to reduce maternal mortality should therefore address at least one of the root causes of the problem. Quinacrine sterilization, however, do not address any of these root causes.[213] This casts significant doubt on Mumford and Kessel's claim that quinacrine will benefit women who are at risk of maternal death.

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[207] Less than 1% of surgical sterilizations result in pregnancy as compared to the 3-50% failure rate for quinacrine sterilizations. *See supra* note 31 for quinacrine sterilization failure rates. *See also How Effective is Female Sterilization?, available at* http://www.who.int/rht/documents/FPP94-2.htm.

[208] Memorandum, *supra* note 30 (subject matter Health Hazard Evaluation Summary of a Kit for Intrauterine Insertion of Quinacrine Hydrochloride pellets for female sterilization).

[209] Maternal mortality rates in excess of 500 per 100,000 live births are not uncommon in many Third World countries, compared to an average of 26 in the industrialized world. Put another way, the complications of pregnancy account for between 10 and 30 percent of all deaths of women of reproductive age in Asia, Africa, and Latin America, but less than 2 percent in the United States and Europe. HARTMANN, *supra* note 182, at 50-51.

[210] Of the 600,000 maternal deaths that occur annually, 98 percent occur in the developing world. Four UN Agencies Announcing Joint Effort to Reduce Maternal Mortality, Press Briefing, Oct. 28, 1999, 1 (copy on file with author). Most maternal deaths occur in Asia (55%) and Africa (40%). *See Unicef, Children and Adolescents in Latin America the Caribbean – Maternal Mortality*, (visited Mar. 26, 2001) *available at* http://www.unicef.org/lac/ingles/infancia/mortma.htm.

[211] Marsen Wagner, *Maternal Mortality in the United States: Where Are the Doctors?* (visited Aug. 8, 2001) *available at* http://www.geocities.com/Wellesley/5510/wagner.html (discussing how maternal mortality is a direct function of the quality of health care that is available).

[212] In addition, a major cause of maternal death in Third World countries is unsafe, illegal abortions. Somewhere between one and two hundred thousand women die each year in developing countries due to unsafe abortions. In Latin America, where abortion is outlawed in most countries because of opposition from the Catholic Church, one fifth to one half of all maternal deaths are due to illegal abortion. Thus, making abortion safe, legal and accessible would also alter the maternal death rate, as well as reduce the number of births resulting from contraceptive failure. RUTH DIXON-MUELLER, POPULATION POLICY AND WOMEN'S RIGHTS: TRANSFORMING REPRODUCTIVE CHOICE 163 (1993).

[213] Although one could argue that making quinacrine available to women at risk to maternal mortality increases their access to health care, the experience of many of the women who have been subjected to quinacrine experimentation is that their access to health care was increased by only one contact – the appointment necessary to perform the sterilization. In many instances, no follow-up care was provided by doctors. As Dr. Mullick, a Mumford colleague, has been reported as stating "What do you mean by monitoring the woman patients? ... If the women have any problems, they will come to me. I have not received a single complaint in the last ten years. Moreover, I don't have the money to do any follow-up." SHREE MULAY, FORCED STERILIZATION OF WOMEN IN BANGLADESH, COVERT TRIALS, OVERT VIOLATIONS, ALTERNATIVES HOUR, Apr. 1997 *reprinted in* Stephen D. Mumford, Quinacrine

2. Chemical Sterilization Will Limit Immigration to the United States and Prevent Chaos and Destruction of Third World Countries Thereby Securing World Peace

According to Mumford and Kessel, reducing maternal mortality is not the only benefit of quinacrine sterilization. According to them, chemical sterilization will also (a) reduce third world populations thereby decreasing political chaos and promoting world peace, and (b) limit immigration to the United States thereby preventing further terrorism in and destruction of this country. The problem with these objectives is that they articulate a political rather than a medical objective.

If the doctors involved in this experiment actually attempt to achieve these political objectives, there is a great risk that the autonomy of the women subjected to quinacrine sterilizations will be severely curtailed. The doctors, when faced with the choice of focusing on what the women need or focusing on the so called "needs" of society, will be placed in an untenable position. They will need to weigh the importance of their own political objectives against the health interests of the women to whom they are providing services.

In this scenario, women in developing countries are viewed as a means rather than an end in themselves. Kantian principles of ethics maintain that "we should treat others as autonomous ends and never as means to our own ends"[214] because people should be valued in and of themselves. In the quinacrine campaign, women are being treated as a means to achieve lower third world population rates, not because it is in the best interest of the women to have fewer children, but because it will allegedly benefit the world and "American culture." This type of philosophy subjugates women's interests to a political agenda which is steeped in xenophobia, racism, and classism.

This desire to limit the population of a certain segment of society is hauntingly similar to traditional eugenics philosophy which calls for the elimination of those who are deemed to be "undesirable" or "unfit" individuals.[215] The political objectives of the proponents of quinacrine

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Sterilization A Response Prepared, Attachment #6, 9 (Jan. 6, 2000 unpublished manuscript on file with author.

[214] MCNEILL, *supra* note 141, at 145.

[215] Eugenics is an alleged "science" that argues for the selective encouragement or prevention of births for social, racial, or political ends. Eugenicists believe that diseases, idiocy, and socially deviant characteristics are all hereditary. They also believe that persons who are "socially deviant" reproduce at a greater rate than the "normal" population. Accordingly, compulsory sterilization was legitimized on a medical and social basis for people with epilepsy, mental

sterilization make it clear that the chemical sterilization campaign is not designed to save lives by decreasing the rate of maternal mortality. Instead it is designed to prevent the creation of new lives by eliminating the capacity of certain women to reproduce.

B. DISTRIBUTIVE JUSTICE

> *[T]he evidence clearly establishes that throughout the ages and down to the present, the people used as unknowing or unwilling subjects of experimentation are the poor; the racially or nationally oppressed; the imprisoned or the institutionalized; the very young or the very aged; and women more often than men.*[216]

Generally speaking, distributive justice refers to the ethical obligation to treat each person fairly or in accordance with what is morally right.[217] More specifically, it requires the equitable distribution of both the burdens and the benefits of participation in research. This principle dictates that no one group - socio-economic, gender, racial, ethnic, or geographic - should bear the burden or be denied the benefits of research.[218] Thus, beneficial research should not be offered only to favored individuals. Nor should "undesirable" or "disadvantaged" persons be the only ones selected for risky research.[219]

In terms of quinacrine, it is clear that most if not all of the women subjected to quinacrine sterilizations are disadvantaged: they are low income rural women with very little education living in developing countries.[220] It is

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illness, mental retardation, criminal histories, physical deformities, and communicable diseases. Involuntary eugenic sterilization was advocated to save civilization. In the 1930s and 1940s scientific research discredited many of the premises upon which eugenics was based. Research now conclusively shows that a majority of inheritable deficiencies are transmitted by parents who are considered normal; that undesirable characteristics are affected by nonhereditary factors such as trauma and the environment; and that many "classified" individuals are able to function quite well in society, both with and without special education and training. *See generally* Elyce Zenoff Ferster, *Eliminating the Unfit—Is Sterilization the Answer?*, 27 OHIO ST. L.J. 591 (1966); Beverly Horsburgh, *Schrodinger's Cat, Eugenics, And the Compulsory Sterilization of Welfare Mothers: Deconstructing An Old/New Rhetoric and Constructing the Reproductive Right to Natality For Low-Income Women of Color*, 17 CARDOZO LAW REVIEW 531 (1996).

[216] Herbert Aptheker, *Racism and Human Experimentation*, 54 POL. AFF. 46, 51 (1974).

[217] TOM BEAUCHAMP & LEROY WALTERS, ETHICAL THEORY AND BIOETHICS IN CONTEMPORARY ISSUES IN BIOETHICS 32 (4th ed. 1994).

[218] *Id.*

[219] Ruth Macklin, *Justice in International Research*, *in* BEYOND CONSENT, 131-146 (Jeffrey Kohn et. al., eds., 1998)

[220] Kateryna Fedoryka, *Sterilization by Acid Burns Denounced*, (visited May 5, 2001) *available at* http://www.hli.org/publications/hlir/1998/hr089801.html. *See also* Advisory Committee on

also clear that quinacrine research may be categorized as "risky" since quinacrine has not been tested adequately on animals and nothing is known about (a) its long term side effects, (b) its potential to cause cancer, or (c) the potential harm that fetuses exposed to quinacrine and infants exposed to quinacrine through breast milk will experience. Given these facts, we must question why women in developing countries are the sole target for the quinacrine sterilization campaign.

Socially and economically disadvantaged people have historically been disproportionately represented as subjects of human experimentation.[221] It is no secret that groups such as prisoners,[222] institutionalized persons,[223] and

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Human Radiation Experiments Final Report (visited May 5, 2001) *available at* http://tis.eh.doe.gov/ohre/roadmap/achre/report.html.

221 McNeill, *supra* note 141, at 149.

222 There is a long history of prisoners being used as subjects in various medical studies, including poison experiments and vivisection. JONATHAN MORENO, KAHN, MASTROIANNI, SUGARMAN, *Convenient and Captive Populations*, BEYOND CONSENT, *supra* note 216, at 111,113. In the eighteenth century, European physicians exposed prisoners to venereal disease, cancers, typhoid, and scarlet fever. *Id.* During World War II in the United States, many prisoners "agreed" to participate in studies in exchange for payment, the possibility of early parole, a break in the incessant boredom of incarceration, and often better food and living conditions. *Id.* at 113-114. The United States is one of the only countries that continues to use prisoners in clinical trials. ALLEN HORNBLUM, ACRES OF SKIN; HUMAN EXPERIMENTS AT HOLMESBURG PRISON (1998) Doctors are motivated to conduct biomedical experimentation on prisoners because it is an extremely lucrative endeavor. For example, Dr. Austin Stough, an Oklahoma physician, is estimated to have earned approximately $1 million a year by selling blood plasma extracted from prisoners and by using the prisoners for drug testing. Walter Rugaer, *Prison and Plasma Projects Leave Fatal Trail*, N.Y.TIMES, July 29, 1969 at A1 (visited May 5, 2001) *available at* http://www.guerrillacampaign.com/blood.htm. Throughout the 1960s, drug companies competed for access to prison populations. HORNBLUM, *supra*. In 1964, Upjohn and Parke-Davis contributed over a half million dollars to build a state-of-the-art laboratory inside the State Prison of Southern Michigan at Jackson which was the largest walled penitentiary in the world. *Id.* Between 1963 and 1973, the federal government through the Atomic Energy Commission, funded a radiation study in Oregon and Washington state prisons which was designed to determine how much radiation U.S. astronauts could tolerate during space flights. *Id.* Prisoners were required to undergo radiation exposure to their testicles. *Id.* Test subjects suffered painful, lasting effects, and almost half of them died. *Id.* In Philadelphia's Holmesburg Prison, Dr. Kligman of the University of Pennsylvania, in conjunction with the U.S. Army, tested mind-altering substance known as EA 3167 on prisoners in an effort to determine whether it should be added to the Army's chemical warfare stock HORNBLUM, *supra*. Inmates suffered confusion and hallucinations for up to three weeks. In addition, Klingman tested radioactive isotopes at the prison despite having little education or experience in radioactive medicine. *Id.* Since the 1990s, however, federal regulations have limited research on prisoners to four types of research: (1) research regarding incarceration and criminal behavior, (2) studies of prisons as institutions and prisoners as incarcerated persons, (3) research regarding conditions that particularly affect prisoners as a class. *Id.* (for a detailed account of human experimentation on prisoners in the United States.)

223 Patients in mental hospitals have often been exploited in biomedical experimentation. In the late 1940's and early 1950's, Quaker Oats sponsored research at a school for disabled adolescents in Massachusetts. *MIT, Quaker Oats to Settle Radiation Experiment Suit*, ASSOCIATED PRESS, Dec. 31, 1997, *available at* http://www.cnn.com/US/9712/31/radioactive.oatmeal/index.html. In these experiments radiation was introduced into the meals of male residents. *Id. Parents* who

military personnel,[224] in addition to historically disadvantaged groups, such as African Americans in the United States,[225] have been exploited by medical researchers. Like all of these groups, women in developing countries are more easily coerced and manipulated into participation in human experimentation by virtue of their lack of economic, political, and social status.[226] This lack of status often correlates with illiteracy, a reluctance to question those of "greater" status and an inability to access legal or governmental agencies that are capable of providing recourse for harm suffered. These conditions make the economically and socially disadvantaged prime candidates for exploitation in human experimentation. For this reason, close scrutiny of the quinacrine campaign is even more important.

To justify their decision to focus the distribution of quinacrine in developing countries, Kessel and his associates argue that using a riskier sterilization method is justified because women's lives in developing countries are more at risk not only in pregnancy[227] but in general. One of Mumford and Kessel's medical associates in Bangladesh framed the issue as follows: "[W]e have a mortality rate of forty to forty-five for women. These

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consented were told that their children would be in a "science club" that would include special meals, extra milk and field trips. MORENO, *supra* note 222, at 119. Radiation was not mentioned. *Id.* In addition, children in orphanages and reformatories have been used in studies involving tests for sexually transmitted diseases, scarlet fever, diphtheria, tuberculosis, mumps, chicken pox and whooping cough. Susan E. Lederer and Michael Grodin, HISTORICAL OVERVIEW: PEDIATRIC EXPERIMENTATION IN CHILDREN AS RESEARCH SUBJECTS: SCIENCE, ETHICS AND LAW 3-28 (Michael A Grodin and Leonard H. Glantz eds.1994).

224 Although the Department of Defense has adopted the Nuremberg Code to govern human experimentation by the military, experimental drugs are allowed to be administered to military without informed consent. Katherine A. Tuthill, *Human Experimentation: Protecting Patient Autonomy Through Informed Consent*, 18 J. LEGAL MED. 221, 240 (1997). In addition, private law suits cannot be brought against the United States Military by injured military personnel.

In the 1950's, the Department of Defense conducted studies regarding the effects of exposure to radiation in which servicemen were not informed of the fact that they were beings used as subjects of a human experiment. MORENO, *supra*, note 222. In Fort Detrick, Maryland, thousands of soldiers were used in research to determine the effects of the psychoactive drug LSD. Tuthill, *supra.*

More recently, the Department of Defense dispensed experimental drugs to the military serving in the Gulf War. *Id.* The drugs were supposed to protect the servicemen in the event that the Iraqis used chemical and biological weapons against them. *Id.* Military personnel were not asked to consent to using the drugs, nor were they informed of any risks associated with these drugs. *Id.* Over twenty thousand servicemen suffered from symptoms associated with the experimental drugs. *Id.* at 242; MORENO, *supra* note 222, at 119-123.

225 Katherine Bankole, *Enslavement and Medical Practices in Antebellum Louisiana,* SLAVERY AND MEDICINE 99-108 (1998); JAMES H. JONES, BAD BLOOD (1981).

226 MORENO, *supra* note 222, at 111. (describing how "captive populations" are easily exploited and more attractive to researchers looking for human "subjects").

227 The complications of pregnancy account for between 10 and 30 percent of all deaths of women of reproductive age in Asia, Africa, and Latin America, but less than 2 percent in the United States and Europe. HARTMANN, *supra* note 182.

women are going to die anyway be it from malaria, diarrhea or some form of cancer. So, if there are long term complications with quinacrine it does not matter."[228] Another Mumford/Kessel associate in Bangladesh, gynecologist Naseem Rahman, stated the following:

> The developed world's cautious standards of medical ethics and safety have no place in the lives of women for whom repeated pregnancies bring nothing but deprivation and danger. ... As it is, they're going to die, so what do the long-term complications of quinacrine matter?[229]

If this simple equation is correct - higher risk in pregnancy justifies higher risk in contraceptive method - Kessel and his cohorts would have to conclude that it is also appropriate for African-American women to be subjected to greater contraceptive risks than white women in the United States because African-American women are four times more likely to die from pregnancy-related complications than white women.[230] Using this rationale, it would also be logical to conclude that it is appropriate for poor women in general to be subjected to greater contraceptive risk than wealthy women because poor women are at greater risk in pregnancy than wealthier women.[231] The problem with these arguments is that they promote a social theory that deems the lives and health of certain individuals to be more important and worthy of protection than others. Those who have resources and access to health care are worthy of all that is good including good health. Those who are poor in resources and health, on the other hand, are not worthy and are therefore deemed to be suitable for all sorts of health risks .

Categorizing human subjects as "less worthy" allows the researchers to construct psychological and emotional space between themselves and their

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[228] Choudhury, *supra* note 12.

[229] Freedman, *supra* note 19.

[230] In June 1999, the Center for Disease Control reported that the average maternal death rate for African American women is 19.6 per 100,000 live births — which is the same rate for women in Nicaragua and Vietnam. National Center For Health Statistics report on maternal mortality ratios, (June 18, 1999). The maternal death rate for white American women, however is 5.3 per 100,000 live births. *Id. See also* Wagner, supra note 212 which indicates that maternal mortality is four times higher for African American women than for other women in the United States because African American women as a group are more likely to be uninsured, are more likely to be served by hospitals that are greatly understaffed, and are more likely to be served by health care practitioners with less training.

[231] *Maternal Mortality - United States 1982-1996* (visited on May 5, 2001) *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/00054602.htm. *See also* KOONIN, MACKAY, BERG, ATRASH & SMITH, DIVISION OF REPRODUCTIVE HEALTH, NATIONAL CENTER FOR CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION, PREGNANCY-RELATED MORTALITY SURVEILLANCE - UNITED STATES 1987-1990, Vol. 46, No. SS-4, pg. 17-36 (Aug. 8, 1997).

subjects. Since most researchers maintain a status in society which affirms their "worthiness," they begin to view the human subject as something "other" than them. Once the subject is labeled "other," it is easier for the researcher to perceive the human subject as being less emotional (or simply unemotional) less capable of experiencing pain; and ultimately less valuable.[232] Being less worthy or valuable, the well-being of the socially and economically disadvantaged is deemed to be inconsequential, and concomitantly, their participation in experimentation that involves unknown health risks becomes acceptable.

Thus, in terms of quinacrine, women in developing countries are deemed to be expendable because they will either die from malnutrition, malaria, some form of cancer or from pregnancy.[233] Putting these women at risk is therefore viewed to be a relative concept in which poor health or health complications are viewed as simple nuisances which are always preferable to death. The rationale of the researchers then becomes - "you might not be healthy, but you won't be pregnant and dead." Options for women in developing nations do not include living a healthier life or maintaining a healthy pregnancy. Thus, Mumford and Kessel do not advocate strategies to make pregnancy safer for these women but instead call for the elimination of their ability to become pregnant. Rather than improve the health care systems that are failing to provide safe maternal options, these social strategists call

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[232] This process of objectification or "otherness" explains why, for example, Black people in the United States have often been used as specimens for clinical instruction and public display. TODD SAVITT, et al., THE DISEASES AND HEALTH CARE OF BLACKS IN ANTEBELLUM VIRGINIA, MEDICINE AND SLAVERY 18-41 (1978); ROBERT BLAKELY AND JUDITH HARRINGTON, EDS., BONES IN THE BASEMENT: POSTMORTEM RACISM IN 19TH CENTURY MEDICAL TRAINING (1997). "Otherness" also explains how human subjects who are perceived to be inferior or powerless can be easily exploited by researchers; and taken to its furthest extreme, "otherness" serves as the basis for believing that certain individuals are actually subhuman. *Id.* For example, Europeans often debated whether African people who the Europeans enslaved were human, subhuman or animal. Katherine Bankole, *Slave Medicine in Louisiana*, 5 RACE, GENDER & CLASS 3-11 (1998). For a general discussion of the concept of "otherness", *see* Z.D. Gurevitch, *The Other Side of Dialogue: On Making the Other Strange and the Experience of Otherness*, AM. J. SOC., Vol. 93, Issue 5, 1179-1199 (1998).

[233] Like the women in developing countries, African-American women are also faced with a panoply of fatal rather than healthy options. Disparities in health status between African-American and white women in the United States demonstrates that, while white women are enjoying the benefits of living in a developed country, African-American women exist in a reality that is similar to those of third world women. Like women in developing countries, African-American women have limited resources and limited choices of care. Consequently, they experience shorter life expectancy, higher levels of mortality at every age, the highest mortality rates from AIDS, higher rates of infant mortality, and the highest rates of death from breast cancer, cervical cancer, heart disease, liver disease, stroke and diabetes. *See e.g.* Marilyn Gaston, et al., *Health Care Needs of Medically Underserved Women of Color: The Role of the Bureau of Primary Health Care*, 23 HEALTH & SOC. WORK 86 (May 1, 1998). *Also generally* Karin Elliot Brown, et al., *The Well: A Neighborhood-based Health Promotion Model For Black Women*, 23 HEALTH & SOC. WORK 146 (May 1, 1998).

for the alteration of women's bodies. From their perspective, the problem is not the system, it is the women themselves.

Kessel and Mumford do not offer any persuasive reason why quinacrine is disproportionately offered to women in developing countries. The alleged potential benefits of quinacrine do not appear to outweigh the harm to women's bodies, emotions and their integrity. This inequitable distribution of burdens violates the basic principle of justice.

C. AUTONOMY

> *"The voluntary consent of the human subject is absolutely essential."*[234]

The principle of autonomy primarily focuses on the need to respect an individual's capacity for self-determination.[235] Thus, individuals who are capable of deliberating about their personal goals must be treated with respect. Respect for the autonomy of a human subject can be demonstrated by (a) providing information to human subjects about the nature of their research; (b) by informing them that there may be unknown risks associated with the process; (c) by revealing all known risks of injury; and (d) by discussing alternative treatments. It is only after all the risks and the alternative treatments have been explained in simple language capable of being understood by the individual that an individual can consent to participation in an experiment. In addition, the process of obtaining consent must be free of deception and coercion. These requirements are commonly referred to as the principles of informed consent. If a potential research subject has not been adequately informed, she cannot freely decide, in accordance with her own values, whether or not to participate in experimentation.[236] Thus, if decision making is inhibited by any actions of the researchers, the individual's self-determination has not been respected.

In the quinacrine controversy, it has been reported that many of the women who were sterilized did not know what was happening to them. For example, in 1989, after Vietnam's family planning program had performed more than thirty thousand quinacrine sterilizations, it was reported that women working at the Hoa Binh Rubber Plantation were involuntarily

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[234] NUREMBERG CODE, *supra* note 122, at Principle 1.

[235] Individuals with diminished capacity for making personal choices such as children, pregnant women and their fetuses, nursing women and their infants, prisoners and the mentally ill are referred to as "vulnerable populations" in bioethics literature. Autonomy requires that these individuals be protected. For more on vulnerable populations, *see supra* note 146.

[236] ROBERT J. LEVINE, ETHICS AND THE REGULATION OF CLINICAL RESEARCH 15 (1986).

sterilized.[237] According to Mumford, approximately one hundred and seven Vietnamese women employed by this privately-owned rubber plantation were sterilized without knowing or understanding that they were being permanently sterilized.[238] One of these women, Nguyen Thi, reported that on March 10, 1993, she went to the plantation health clinic, where she was told that she would receive a routine gynecological examination.[239] Instead, the clinic's doctor removed her IUD and performed a quinacrine sterilization.[240]

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[237] MUMFORD, *supra* note 7.

[238] *CNN Talkback Live*, (June 19, 1998, Fri. 3:00 p.m. Eastern Time) (Transcript #98061900V14, Headline: The Controversy Over Quinacrine: A Sterilization Drug Used Worldwide, Guests included Stephen Mumford, Elton Kessel, Adrienne Germaine, Kateryna Fedoryka, Byline: Bobbie Batista) (copy on file with author).

[239] MUMFORD, *supra* note 7.

[240] Recently, Mumford has stated that the press reports regarding the Hoa Binh Rubber Plantation are "sheer fabrication" because all one hundred and seven women allegedly signed consent forms. Mumford, *supra* note 58 (copy of text is on file with author). In literature regarding sterilization abuse, however, there is evidence that women often "consent" to sterilization under duress from their doctors. In 1973, for example, the Health Research Group in Washington, D.C. released a study in which it found that doctors were cavalierly subjecting women, most of them poor and Black to surgical sterilization without explaining either potential hazards or alternate methods of birth control. The study also implied that "informed consent" forms were demanded of the women regardless of whether they were truly informed. *Sterilization, Experimentation and Imperialism*, 53 POL. AFF. 37, 41 (1974). There is also ample evidence to suggest that when doctors deal with women, particularly women with little or no income and/or education, they are tempted to (and in fact do) make paternalistic decisions on behalf of these women. *See e.g.* PROTECTING THE VULNERABLE: AUTONOMY AND CONSENT IN HEALTH CARE 81 (Margaret Brazier and Mary Lobjoit, eds., 1991). This phenomena exists because many doctors feel that it is quicker and more convenient to make a decision on someone's behalf than to ensure that valid consent is actually obtained. The situation is complicated by the fact that in many third world countries, the poor, who represent the vast majority of the population, tend to submit to the will of anybody who appears more powerful than themselves – and both researchers and doctors appear to be quite powerful and authoritative. Zbigniew Bankowski, *International Ethical Considerations for Research on Human Subjects*, ETHICAL ISSUES IN RESEARCH 184 (Darwin Cheney, eds., 1993). Although the Nuremberg Code, the Helsinki Declaration, the International Guidelines, all make it clear that in order for consent to be valid, the doctors involved must fully disclose the side effects, discuss other alternatives to sterilization with the women, and must communicate with the women in a language that they are able to comprehend, there is good reason to believe that this does not always happen. *See also* Wendy Savage, *Taking Liberties With Women: Abortion, Sterilization and Contraception*", INT'L J.OF HEALTH SERVICES, 294. (1982) ("There is abundant evidence that some doctors continue to press their ideas upon women, and do not allow them the right to choose freely if and when to be sterilized."). ROSALIND PETCHESKY, ABORTION AND WOMEN'S CHOICE (1984) (women are particularly vulnerable to unwanted sterilization because family planning clinics and practitioners assume that women should be the target of contraceptive advice, "that they should take the pill or be fitted with an intra-uterine contraceptive device (IUCD) for several years, followed by a period during which they have all the children they desire, whereupon they should be sterilized. Accordingly, if a woman who has several children seeks a termination of pregnancy, it is not unlikely that she will be persuaded to have a concurrent sterilization."). In the case of quinacrine, women's experience in providing consent has not yet been researched or documented; consequently, there have been no reports of consent under duress. The reports that have surfaced, however, regarding involuntary quinacrine sterilization, are sufficient to conclude that obtaining women's informed consent was not a priority.

Although most of the details about the Vietnam sterilizations remain buried, a senior employee of the rubber plantation has stated that the doctor who performed the sterilizations did so to enhance his career by helping enforce Vietnam's two-child policy.[241] However, the doctor, who was not fired, insists he sterilized the women in accordance with orders from plantation officials.[242] No comment has been made by the Hoa Binh Rubber Plantation regarding this matter.[243] Other people speculate that the managers at the plantation orchestrated the campaign to keep productivity high. As a result of intense pressure from the World Health Organization, the quinacrine sterilization program in Vietnam was abandoned.[244]

Unfortunately, quinacrine sterilization abuse in Vietnam was not an isolated incident. In Pakistan, Dr. Bashir of the Faisalabad Mother and Child Welfare Association reported sterilizing two thousand one hundred women in 1990 alone.[245] An independent nurse-practitioner who went to Faisalabad in 1993 to observe Dr. Bashir's clinical work reported that some of Bashir's patients were recruited at "street camps" and were "given little information or time to fully understand and think about the implications of this type of procedure."[246] The nurse-practitioner reported that insertions were conducted by health workers who were unable to provide essential information regarding quinacrine due to their limited clinical skills. As for follow-up of clients who were sterilized, the nurse stated: "The patient is told to return if she has any problems. Those who do not return are assumed to have no problems."[247]

Similar problems regarding the failure to adequately inform women about the quinacrine procedure and the failure to provide follow-up care arose in India as well. In a documentary film entitled *The Yellow Haze*, produced in 1997 by students of the Jamia Millia University in India, thirty-three women who received quinacrine sterilizations were interviewed.[248] In one of the interviews, Indu Das, a twenty-seven year old mother of three reported that in 1995 when she sought contraceptive counseling from her doctor, he informed her that quinacrine could prevent childbirth for approximately ten

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241 Freedmen, *supra* note 41, at A1; For other articles related to Vietnam, *see* http://www.quinacrine.com/index-toc.htm.

242 *Id.*

243 *Id.*

244 *Id.*

245 A. Bashir, M. Mustansar, MA Cheema *et al*, *Quinacrine Nonsurgical Female Sterilization*, THE GYNECOLOGIST 129-36 Vol. 3 (1993).

246 Berer, *supra* note 206.

247 *Id.*

248 V.K. Shashikumar, *India Dlhi Durbar*, (Oct. 10, 1999) *available at* http://www.the-week.com/99oct10/life3.htm (indicating that filmmakers Suniti Singh, Craytri Prebhu and Pankay Seksaria were recognized at Toronto Human Rights Film Festival).

to fifteen years.[249] Das then signed, but did not read, an "informed consent" form.[250] She underwent one quinacrine procedure in which one dose of seven pellets of quinacrine (rather than the two doses of quinacrine that are required) were inserted through her uterus.[251] Immediately after this procedure, Indu experienced severe bleeding.[252] Two years later, she became pregnant and had to have an abortion.[253]

If it were not for the *Yellow Haze* documentary, this woman's story would never have been told since the doctor who performed the sterilization made no report of the incident.[254] Other women interviewed in this documentary also indicated that they, like Indu Das, were not told of the risks associated with quinacrine.[255] These women reported that they suffered side effects, including swelling of the feet, severe abdominal pain and depression.[256]

Following the release of *The Yellow Haze* documentary, the All India Democratic Women's Association and faculty members of the Center for Community Health at Jawaharlal Nehru University filed a lawsuit claiming that thirty thousand Indian women had been involuntarily subjected to quinacrine sterilizations without their knowledge or consent.[257] Shortly thereafter, the Indian government banned the import, manufacturing, sale, and distribution of quinacrine for use as a sterilizing agent.[258] Violators of the ban were subject to imprisonment for up to three years or a fine of up to Rs. 5,000 or both.[259]

All of these stories illustrate that deception and/or coercion were used as part of the process in recruiting women to be chemically sterilized. These are clear examples of experimentation that lack respect for autonomy.

There also appear to be more subtle ways in which women's autonomy in this chemical sterilization experiment may not have been respected. For example, it is doubtful that the doctors involved in this experiment have ever bothered to inform the women of the potential health

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249 *The Yellow Haze* (Suniti Singh, Gaytri Prabhu and Pankaj Seksaria - Jamia Millia University, India 1999)

250 *Id.*

251 For information describing "proper" procedures for quinacrine sterilizations, *see supra* note 26.

252 *Id.*

253 *Id.*

254 Freedman, *supra* note 41, at A1. *See also* Murthy, *supra* note 34.

255 *Id.*

256 Praful Bidwai, *South Asia - Health: Harmful Contraceptive Trials on Women*, INTER PRESS SERVICE (May 22, 1997).

257 Special Correspondent, *Use of Quinacrine as Contraceptive Banned*, THE HINDU, (Aug. 18, 1998). *See also* Laxmi Murthy, *Population Follies*, NEWS & OBSERVER June 28, 1998, at A24; Murthy, *supra* note 34.

258 *Id.*

259 Special Correspondent, *supra* note 257.

risks associated with quinacrine. One need only look at Mumford's response to a *Wall Street Journal* article to come to this conclusion.[260] In a letter to the *Journal*, Mumford states that he "firmly rejects the idea that there are any serious scientific concerns that quinacrine may cause cancer."[261] He also states rather defensively and unpersuasively that it is simply "a lie" that the safety and effectiveness of quinacrine sterilizations have not been resolved.[262] He offers no evidence that these issues have been resolved (perhaps because there is no evidence to support a claim that quinacrine sterilizations are safe and effective). Mumford simply states that he believes "quinacrine sterilizations offer women worldwide a safe, sure, non-surgical and inexpensive way to end childbearing."[263] He also claims that the concerns regarding carcinogenicity of quinacrine are the product of a "feminist conspiracy." This assertion is mind-boggling, particularly in light of the fact that well respected, non-feminist health organizations like the FDA, the WHO, the AVSC, FHI, and Planned Parenthood have all stated that they have serious concerns regarding quinacrine's safety and potential for causing cancer.[264] Statements such as these indicate that Mumford may not be capable of making a fair or balanced presentation of the facts associated with quinacrine's side effects.

Kessel's and Mumford's writings, as well as the writings of the doctors associated with them, downplay the significance of the potential side effects associated with quinacrine. None of the published medical reports on quinacrine mention that quinacrine slurries caused the death of three women.[265] In fact, Kessel brags that over "100,000 procedures have been performed in twenty countries without a case fatality."[266] Kessel criticizes those who mention these deaths because he claims that they were caused by quinacrine "slurries," not quinacrine pellets, which he claims is an entirely different method of sterilization. Nonetheless, when the tables are turned and Mumford attempts to prove that quinacrine is "safe," he makes two major claims: (1) that there are 20,000 published scientific papers on quinacrine, and (2) there are one hundred million people who have used this drug without harm. The 100,000,000 people and the 20,000 scientific papers he refers to

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260 Mumford, *supra* note 46.

261 *Id.* at 17.

262 *Id.*

263 *Id.* at 1.

264 In their warning letter to Mumford, the FDA expressed concern that quinacrine pellets caused abnormal lesions in the uterus, prolonged amenorrhea, and possible fetal exposure as well as increased the risk of reproductive-tract cancer. Williams, *supra* note 82.

265 As a result of these deaths, researchers discontinued sterilizations by quinacrine slurries and instead developed the quinacrine pellet. There have been no *reported* deaths resulting from the use of quinacrine pellets. Memorandum, *supra* note 30.

266 Kessel, *supra* note 59.

pertain not to women who have been sterilized with quinacrine but people who were using quinacrine to treat *malaria.* How Mumford can be upset by the comparison of one form of quinacrine sterilizations to another form of quinacrine sterilization but not be bothered by his own comparison of quinacrine sterilizations to use of quinacrine for non-sterilization purposes is a glaring example of hypocrisy and perhaps even deception.

Kessel has stated that all quinacrine side effects "are transient and easily treated."[267] Although it is true that most of the side effects[268] are not necessarily life-threatening, some could in fact be fatal. For example, perforation of the uterus and ectopic pregnancies are both potentially fatal conditions in areas where there are no emergency medical facilities.[269] Furthermore, many other side effects are not accurately described as "transient or easily treated." For example, women who become pregnant due to an incomplete blockage of the fallopian tubes subsequent to quinacrine sterilization have given birth to children with serious disabilities.[270] There is at least one reported case of anencephaly, being born without a brain, and another reported case of hydrocephaly.[271]

Due to the fact that no serious follow-up studies have been completed, it is impossible to determine the exact nature and severity of the side effects.[272] As the FDA has pointed out:

> Currently available information on the safety, efficacy and clinical experience with quinacrine sterilization is based upon clinical trials which lack appropriate study design, are poorly controlled, have incomplete follow-up on study participants and are not comparable due to differences in formulation, dose, dosing regimen and adjuvant therapies used.[273]

Based on this history, it is therefore doubtful that Mumford and his colleagues (those who were trained by him) would be able to clearly articulate the side effects and risks associated with quinacrine in a manner that would be consistent with the notion of informed consent. The diminishment of the significance of side effects and the lack of concern about the potential

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267 *Id.*

268 For complete list of side effects, *see* pp. 105-06.

269 Tenore, *supra* note 27; *see also* Abbott, *supra* note 27.

270 *See supra* notes 29-32.

271 For discussion of these cases, *see* p. 106.

272 Out of the 104, 410 women who have already been sterilized, only 1,800 of these women have been involved in a follow-up study. The 1,800 were part of the study involving 35,000 women sterilized in Vietnam. *CNN Talkback Live*, *supra* note 238.

273 Memorandum, *supra* note 30.

carcinogencity of quinacrine by the doctors involved in this experiment, in combination with willingness to conduct involuntary quinacrine sterilizations indicate that respect for the principle of autonomy is clearly lacking.

Even if autonomy were respected by obtaining informed consent from the women to be sterilized, the experiment would still be unethical. As Robert Burt points out in connection with the Nazi experiments, "the consent of the experimental subjects would not have justified the experiments"[274] because obtaining consent in clinical research is not the only requirement for ethical validity. The principles of beneficence/non-maleficence and distributive justice must also be considered. In the case of quinacrine, none of the principles of bioethics have been sufficiently respected.

IV. CONCLUSION

In November 2000, the FDA approved a clinical trial of quinacrine to be conducted by Dr. Jack Lippes at the Children's Hospital of Buffalo, in Buffalo, New York.[275] This trial will involve ten women as human subjects.[276] Although FDA clinical trials will provide an environment more conducive to respecting women's rights to obtain information and follow-up care, it is a double-edged sword. With United States backed quinacrine research, the research previously conducted in developing countries will be buried under this new found FDA "legitimacy." All of the questionable studies that were done will be overshadowed by the FDA approved experiments. Thus, the women in developing countries who were ill-informed and ill-treated will be forgotten and swept under the proverbial rug.

In addition to the amnesia regarding prior clinical trials, the introduction of quinacrine in the United States raises several other issues and concerns. How and to whom will quinacrine be marketed in the United States? Will there be the same type of population control politics at work? What assurances will there be that women "selected" for quinacrine sterilizations will have the opportunity to exercise their right to informed consent? Given the history of reproductive technology, as well as the stated objective of advancing quinacrine sterilizations, it is likely that low-income women will be the target of the quinacrine campaign in the United States. As one quinacrine advocate has stated, "the major advantage of quinacrine sterilizations in the USA and elsewhere is its increased access for women who

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[274] Robert Burt, *The Suppressed Legacy of Nuremberg*, HASTINGS CENTER REPORT 26:30-33; Sept.-Oct. 1996).

[275] Lippes, *supra* note 100.

[276] *Id.*

cannot afford surgical sterilization."[277] What this tells us is that women with little or no resources are prime candidates for quinacrine sterilizations. Like women in developing countries, women in the developed world with little or no resources are considered to be "expendable." They are not targeted as prime candidates because they volunteer for this position, nor because they have a demonstrated need for chemical sterilization. They are prime candidates for sterilization because they are thought to be the source of the world's population "problem." This desire to fulfill the political objective of controlling the population has led doctors involved in the quinacrine campaign to completely ignore the well-established principle that no one should be subjected to experimentation without their consent.[278] This lack of respect for autonomy is reprehensible but not new.

Historically, sterilization has been abused in low income and politically powerless communities.[279] Consequently, when sterilization is promoted as a means of preventing pregnancy, suspicion and scrutiny are warranted. And when a sterilization method such as quinacrine is being promoted as a weapon in the womb of women in developing countries, heightened scrutiny and suspicion are warranted. Should we allow quinacrine sterilizations to be advanced and perfected when there is clear evidence that this method has already been used to abuse the rights of women?

The Helsinki Declaration states that the "potential benefits, hazards, and discomfort of a new method should be weighed against the advantages of the best current diagnostic and therapeutic methods."[280] Presently, there are several other options available for preventing pregnancy that are safer than quinacrine.[281] There are also several other methods of preventing pregnancy currently under development, which would place a more equitable burden on

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[277] Mildred Hanson, MD, *Why US Women Deserve QS as an Option*, Quinacrine Non-surgical Method of Voluntary Female Sterilization Newsletter 2000, p. 2, (visited Sept. 16, 2000) *available at* http://quinacrine.com/newsletter_2000_2.html.

[278] The first principle articulated in the Nuremberg Code states that informed consent is absolutely essential. NUREMBERG CODE, *supra* note 122, at Principle 1. Basic Principle 9 of the Helsinki Declaration requires the physician-investigator to "obtain the subject's freely-given informed consent." HELSINKI DECLARATION, *supra* note 123, at Part I, Principle 9. Similarly, the International Ethical Guidelines for Research Involving Human Subjects also emphasize the importance of informed consent while establishing principles for doing research in "underdeveloped communities." INT'L GUIDELINES, *supra* note 124, at Guideline 8. See, in particular, Guideline 8 which states in pertinent part: "Before undertaking research involving subjects in underdeveloped communities, whether in developed or developing countries, the investigator must ensure that...every effort will be made to secure the ethical imperative that the consent of the individual subjects be informed." *Id.* at Guideline 8.

[279] For general discussion of sterilization abuse in the United States, *see* SHAPIRO, *supra* note 121.

[280] HELSINKI DECLARATION, *supra* note 123, at Part II, Principle 2.

[281] For more information, *see supra* note 205.

both men and women.[282] These forms of contraception may be more deserving of scientific resources than quinacrine sterilizations.

Although many people argue that scientific research is necessary to advance our knowledge as a society, we must keep in mind that not all advances in science are in the best interest of humanity. Quinacrine, in the best case scenario, may prevent unwanted pregnancies, but it does so without guarantees of protection against sexually transmitted diseases and with a failure rate that exceeds other contraceptives currently available. Although a pregnancy is not always desirable, it is not a disease. It does not beg for a cure at the cost of human dignity, autonomy, or justice. In biomedical research considerations related to the well-being of the human subject should take precedence over the interests of science and society.[283]

So far, there is no convincing evidence that the benefits of quinacrine research outweighs the risks to women[284] or fetuses.[285] Nor is there any evidence that women anywhere in the world are in need of chemical sterilizations as an option for preventing pregnancy. The fact that the doctors involved in this research claim that quinacrine sterilizations are safe and effective when no evidence exists to support this claim is outrageous and particularly alarming in light of the serious questions regarding quinacrine's mutagencity, carcinogenicity, and effectiveness at preventing pregnancy that have been raised by several entities, including the World Health Organization.[286] Quinacrine was presumed to be safe and then introduced outside of the avenues for "mainstream research."[287] This lack of precedent for declaring a medical procedure to be "safe" is testimony to the fact that the researchers involved in this campaign do not care about the well-being of the women who serve as their human subjects.

In spite of this, the doctors/researchers involved in this chemical sterilization campaign not only continue to publish their selected "findings," but they continue to have access to large audiences of doctors and public health officials.[288] Their access to publications as well as well-respected

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[282] Dorothy Bonn, *Male Contraceptive Research Steps Back Into Spotlight*, LANCET, Jan. 23, 1999, at 2; Elaine A. Lissner, *Frontiers in Nonhormonal Male Contraception: A Call for Research* (visited on Dec. 15, 2000) *available at* http://www.gumption.org/mcip/paper.html.

[283] HELSINKI DECLARATION, *supra* note 123, at Part III. "In research on man, the interest of science and society should never take precedence over considerations related to the well-being of the subject." *Id.* at Principle 4.

[284] For more information, *see* notes 20-28.

[285] For more information, *see* notes 29-32.

[286] *See supra* note at 71.

[287] R.N. Pine, A.E. Pollack, *Putting an Ear to the Ground: Where Now With Quinacrine?*, 69 INT'L J. OF GYNEC. & OBSTET. 55-65, 57 (2000).

[288] Mumford and Kessel have been invited to participate in a wide variety of international reproductive rights conferences. For example, they have attended the National Family Planning & Reproductive Health Association 27th Annual Meeting; Contraceptive Technology Conference;

audiences should be denied until retrospective studies of women who were already treated with quinacrine are completed. This would be consistent with the provisions of the Helsinki Declaration.[289]

Although medical experiments conducted on an international basis are not governed by any legally binding provisions that are actively enforced, health professionals and legal activists can insist that researchers respect the bioethical principles consistent with the Nuremberg Code, the Helsinki Declaration, and the International Ethical Guidelines for Research Involving Human Subjects. Unless we take a closer look at the ethical dimensions of the quinacrine campaign, the devaluation of women's lives in both developing and developed countries will continue. Health professionals and legal activists should emphasize the ethics or lack of ethics involved in the quinacrine campaign in order to set a threshold for what will be considered acceptable objectives and procedures for future experimentation. The history of abuse and lack of justice involved in the quinacrine experiments should not be tolerated or forgotten.

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the National Abortion Federation's 23th and 24th Annual Meeting; the American College of Obstetrics and Gynecology's (ACOG) 47th and 48th Annual Meeting; the American Society for Reproductive Medicine 1999; Nurse Practitioners in Women's Health (formerly known as NANPRH – National Association of Nurse Practitioners in Reproductive Health); American Public Health Association Annual Meeting; National Family Planning & American Association for the Advancement of Science; the 2000 Council on Resident Education on Obstetrics & Gynecology (CREG) and the Association of Professors of Gynecology & Obstetrics (APGO); the Fund for the Feminist Majority-Feminist Expo 2000; the American College of Osteopathic Obstetricians and Gynecologists 67th Annual Convention; the American College of Nurse-Midwives 45th Annual Meeting and Exhibit; the American Society for Reproductive Medicine; and the American College of Nurse Practitioners National Clinical Symposium. For a complete listing of conferences and meetings attended by Mumford and Kessel, *see Conferences At Which The Center for Research on Population & Security Have Participated in as Exhibitors Within The Past 12 Months* (visited Feb. 15, 2001) *available at* http://www.quinacrine.com/08-conferences_1999.htm.

[289] HELSINKI DECLARATION, *supra* note 124. *See also* Marcia Angell, *Editorial Responsibility: Protecting Human Rights by Restricting Publication of Unethical Research* in Ethics and Modern Medical Research.