Misguided Altruism:
Indian Health Service Physicians and Reproductive Control of Native-American Women

An Honors Paper for the Department of History

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I've been shocked at the comments. A physician recently said to me, "You know how your women are. They can't understand the information of informed consent." That's totally dishonorable and ridiculous. They just don't want to take the time to explain women's options to them.

—Charon Asetoyer, Executive Director,
Native American Women's Health Education Resource Center

Physicians are here because they want to serve the patients and would therefore not be out to harm them or deprive them of knowledge, information, or choice.

—Timothy Ryschon, M.D., Clinical Director,
PHS Indian Hospital Rosebud Service Unit

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CHAPTER 1

A Push to Control the "Oversexed" Gender: Physicians, Women, and the United States Eugenics Movement

Writing to the *Medical Tribune* in 1978, obstetrician David Priver, M.D., sought to convince his medical peers that they should ignore the fervor that the Department of Health, Education, and Welfare (HEW) had raised over its revised sterilization guidelines.[1] Based on charges that a federally-funded family planning program had sterilized teenage sisters Mary Alice and Minnie Relf without their consent, United States District Court, in *Relf v. Weinberger,* ordered the HEW to tighten its regulations on sterilizations. Priver resented this change in policy which limited the power of physicians to make individual decisions according to the financial status of their patients. He argued for a return to looser control, asserting that "poor women, be they black or Indian, will have little chance to escape from the poverty cycle if they do not have complete, unhampered access to fertility control." Priver urged readers of his letter to support his ideology, hoping "that all physicians who are concerned for the welfare of poor women will speak out on this issue." Otherwise, Priver lamented, "It will be a cold comfort for the impoverished Indian or black mother, unable to adequately care for her existing children, to be told that in order to protect her 'Rights', she can't have the fertility control that is readily available for the rest of society."[2]

Priver's letter represented the latest strains of a debate that had begun when prosecutors in *Relf v. Weinberger* presented evidence that federally-funded family planning programs had sterilized 100,000 to 150,000 low-income citizens annually during the early 1970s—possibly against their wills.[3] In the late 1960s, after Congress authorized funding for

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[1] Either men or women may undergo surgical sterilization, a procedure that disrupts part of the reproductive tract so sperm cannot unite with an ovum. Sterilization provides permanent and generally irreversible contraception (today, physicians are experimenting with reversal procedures). In males, the procedure is termed a vasectomy. Five procedures are performed on women, all grouped under the heading "tubal ligation": laparotomy, minilaparotomy, colpotomy, laparoscopy, and culdoscopy. These different methods block contraception by cutting, tying, crushing, or burning the fallopian tubes. On occasion, chemicals or occlusive devices may be used to block the tubes. Thomas M. Shapiro, *Population Control Politics: Women, Sterilization, and Reproductive Choice* (Philadelphia: Temple University Press, 1985), 7.

[2] David M. Priver, M.D., "Letter to the Editor: Sterilization Debate," *Medical Tribune,* 12 April 1978.

[3] *Relf v. Weinberger*, 372 F. Supp. 1196 (1974). At the time of the *Relf* decision, the Supreme Court had already determined in *Skinner v. Oklahoma*, 27 L. Ed. 2d 444 (1971), that "the power to sterilize, if exercised, may have subtle, far-reaching and devastating effects. In evil or reckless hands it can cause races or types which are inimical to disappear. There is no redemption for the individual whom the law touches. Any experiment which the State conducts is to his irreparable injury. He is forever deprived of a basic liberty." This decision determined that a

sterilizations in family planning clinics and the medical establishment abandoned its age-parity sterilization eligibility requirements, the number of poor, minority women undergoing sterilization procedures dramatically increased.[4] By expanding these poor women's access to birth control, *offering* them the option of sterilization rather than *forcing* them to undergo involuntary sterilization, the government and medical establishment appeared altruistic. However, hidden beneath the excitement over technological advances and emphasis on women's new choices regarding contraception lay the inevitable dilemma that physicians could use sterilization to control women's reproductive freedom. Physicians such as Priver believed that they should use their medical expertise to better the lives of poor, minority women whom they often assumed did not have the intellectual capacity to make autonomous decisions regarding contraception. While physicians may not have acted maliciously in sterilizing these women, female and minority group advocates questioned their behavior, suggesting a paradox existed between the intent of physicians and the consequences of their actions.

While historians have told the stories of African-American and Mexican-American women sterilized during the 1970s, few accounts investigate in-depth the Native-American experience and the role of physicians in it. Like the Relf sisters and other victims of involuntary or coercive sterilization, the majority of Native-American women relied on the public health care system—specifically, the Indian Health Service (IHS)—to monitor their reproductive health and provide them with contraception.[5] When Native-American physician Constance Redbird Uri, M.D, discovered that some IHS hospitals were sterilizing as many as one out of every four women admitted each year during the early 1970s, she demanded a

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statute mandating the sterilization of "habitual criminals" (convicted two or more times of felony crimes) in Oklahoma was unconstitutional. Although the court case dealt with the issue of criminals, primarily male criminals, it nonetheless articulated the danger to personal liberty that sterilization posed to *all* vulnerable citizens.

[4] Shapiro, *Population Control Politics,* 87. To meet the age-parity requirement when it existed, a woman's age multiplied by her current number of children needed to equal 120.

[5] The Indian Health Service, an agency within the United States Department of Health and Human Services (formerly known as the HEW), currently provides federal health services to approximately 1.5 million Native Americans belonging to more than 557 federally recognized tribes in 34 states. The IHS staff consists of nearly 850 physicians, 380 dentists, 100 physician assistants, and 2,580 nurses. Most Native Americans receiving care from one of the 12 regional service areas live on or near reservations.

government investigation.[6] Although the Government Accounting Office (GAO) produced a 1976 report that confirmed the alleged abuses, its limited scope led Uri to examine the situation more thoroughly herself. By interviewing over one thousand Native-American women, Uri concluded that only 100,000 women of child-bearing age remained fertile in 1977; if the IHS had continued to sterilize Native-American women at the rate it had maintained during the 1973-76 fiscal years, all pure-blooded races would have ceased to exist within 15 years. Most shocking was Uri's discovery that physicians convinced most women to undergo the procedure. "Doctors have assumed a God-like authority, and think they are helping women by sterilizing them. Very few Indian women ask to be sterilized. In almost every situation, the woman is talked into it in a very authoritarian, or coerced manner," Uri explained.[7]

Without question, the permanence of sterilization procedures adversely affected Native American women who underwent operations involuntarily; however, other forms of birth control more subtly threatened their reproductive freedom. Beginning in the 1980s, Depo-Provera, a provider-controlled hormonal injection that had gained Federal Drug Administration (FDA) approval *only* as treatment for endometriosis and endometrial cancer—*not* for contraception—presented IHS physicians with an apparently innocuous alternative to sterilization.[8] Because federal law gave physicians the authority to prescribe Depo-Provera for unapproved indications, IHS physicians dismissed reports of Depo-Provera's dangerous side effects and evidence that researchers had proven Depo-Provera

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Indian Health Service, "Comprehensive Health Care Program for American Indians and Alaska Natives, Introduction," ihs.gov/AboutIHS/IHSintro.asp and wysiwyg://323/http://www.ihs.gov/AboutIHS/ThisFacts.asp, (22 September 1999).

[6] Constance Redbird Uri, M.D., *Indians and medicine sterilization and genocide,* Pacifica Tape Library, 1974, cassette. At the time of her study, Uri claimed that the IHS had sterilized every pureblooded woman of the Oklahoma Kaw tribe. John Elliott, "Genocide Charged by Indian M.D. Investigator," *Medical Tribune*, 24 August 1977.

[7] "The Theft of Life," *Akwesasne Notes,* September 1977, 30.

[8] Upjohn Company manufactures Depo-Provera, a synthetic progesterone given in injection form. Unlike oral contraceptives, Depo-Provera does not contain estrogen. A health care provider gives the injection four times a year in the buttocks or upper arm. For birth control purposes, it is 99.7 percent effective in preventing pregnancy.
Pharmacia and Upjohn Company, "About Depo-Provera," http://www.depo-provera.com/about/index.htm (26 October 1999). Endometriosis is a disease that causes endometrial tissue (tissue that lines the uterus) to migrate and form growths in other areas of the body. It can cause extreme pain and eventually result in infertility. Endometriosis Association, "What is Endometriosis," http://www.ivf.com/endoassn.htm (26 October 1999).

highly carcinogenic in animal testing.[9] IHS physicians found Depo-Provera particularly appealing for use on mentally retarded patients because it stopped menstruation and therefore made personal hygiene easier for women who could not care for themselves. In a 1987 United States Congress hearing on the "Use of the Drug Depo-Provera By the Indian Health Service," evidence surfaced that IHS physicians had possibly misused their medical authority by administering Depo-Provera to mentally retarded Native Americans. While the alleged IHS misuse of Depo-Provera occurred more as an isolated incident than as a reflection of nationwide trends, it nonetheless raised questions also asked during the 1970s sterilization controversy. The debate over Depo-Provera focused on whether the IHS was at fault for its lack of oversight regarding the drug, or whether it acted appropriately in allowing individual physicians to practice autonomously according to their own medical discretion.

When the FDA approved Norplant in 1991, proponents of the long-term, implantable birth control method claimed that it offered the most significant improvement in women's contraceptive options since the 1960s introduction of birth control pills.[10] Although Norplant initially cost over $500 per insert, family planning advocates successfully lobbied Congress to lower the price of Norplant so poor women could enjoy the same access to it as more prosperous women did. In 1992, increased pressure from drug manufacturers led the FDA to approve Depo-Provera for contraceptive purposes; together, Depo-Provera and Norplant

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[9] Congress, House, Select Committee on Population, *The Depo-Provera Debate: Hearing before the Select Committee on Population,* 95th Cong., 2nd sess., 8, 9, 10 August 1978, 336. In 1960, the FDA approved Depo-Provera as a treatment for endometrosis and in 1972 as treatment for endometrial cancer; the FDA did not approve the drug for contraceptive purposes until 1992. In the United States, a physician does not violate the Federal Food, Drug, and Cosmetic Act if he or she wishes to prescribe or dispense an FDA drug "under conditions of use not specifically described in the FDA approved labeling for that drug (*The Depo-Provera Debate,* 21). On August 15, 1972, the Federal Register provided notice of proposed rule-making on the "Legal Status of Approved Labeling for Prescribing Drugs; Prescribing for Uses Unapproved by the Food and Drug Administration." This statement made clear that although drug manufacturers could not ship a prescription drug in interstate commerce for an unapproved use, once the drug arrived, physicians, by law, could prescribe it for an unapproved use. Charles C. Edwards, Commissioner of Food and Drugs at the time, said, "the Food and Drug Administration [did not intend] to interfere with medical practice . . . [and] regulate the practice of medicine between the physician and the patient. Congress, Senate, Subcommittee on Health of the Committee of Labor and Public Welfare, *Quality of Health Care—Human Experimentation, 1973: Hearing before the Subcommittee on Health of the Committee of Labor and Public Welfare,* 93rd Cong., 1st sess., 7 and 8 March 1973, 18.

[10] Sarah Samuels and and Mark D. Smith, eds., *Dimensions of New Contraceptives: Norplant and Poor Women* (Menlo Park, CA: Henry J. Kaiser Family Foundation, 1992), ix. Wyeth-Ayerst laboratories manufacture Norplant; the Population Council developed it. Norplant is a synthetic form of progesterone that provides protection against pregnancy for five years. It is administered in implant form; in a minor surgical procedure, a physician inserts six thin, flexible capsules in a woman's upper arm. Population Council, "Population Council

would provide IHS physicians the option of administering long term, provider-dependent birth control to Native-American women. When anti-welfare activists and several state governors began advocating compulsory Norplant for welfare mothers, the possibility that Depo-Provera and Norplant could restrict rather than expand the reproductive rights of minority women such as Native Americans became apparent. This question intensified when contraceptive researchers discovered that poor women used Norplant at a much higher rate than middle-class women, many of whom filed lawsuits against its manufacturer after suffering devastating side effects from the drug. Still, IHS physicians continued to prescribe both drugs for Native-American women, disregarding health risks and charges from Native-American rights organizations that the agency was violating women's control over their own bodies. With physicians succeeding in their efforts to promote the drugs and groups such as the Native American Women's Health Education Resource Center (NAWHERC) protesting the IHS's lack of informed consent policy, a heated battle raged.

The Native-American struggle to maintain reproductive freedom in the aftermath of widespread sterilizations and administration of long-term hormonal contraceptives involves complicated issues of physician responsibility. While the IHS failed to protect women by never establishing a clear-cut policy regarding sterilizations during the 1970s, or long-term hormonal contraceptives during the 1980s and 1990s, the agency also relied on its physicians to make ethical decisions according to their own medical discretion. Physicians did not respond to specific orders from the IHS headquarters to sterilize women permanently or temporarily. Instead, they considered nationwide concern that welfare mothers needed increased access to contraceptive technologies; they listened to medical colleagues who urged that as physicians, their practice could not only better the lives of patients, but society as well. However, activist groups and individuals such as Uri responded to the behavior by suggesting that physicians abused their authority to restrict the reproductive freedom of Native Americans. The ensuing debate revealed that because Depo-Provera and Norplant were provider-dependent drugs that eliminated users' control over their own reproduction, physicians needed to be especially careful in properly obtaining informed consent from their

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NORPLANT Implants Briefing Sheets," http://www.popcouncil.org/rhpdev/norplantfaq.html (9 September patients. Otherwise, their decision, whether conscious or unconscious, to coerce Native-American women into using Depo-Provera or Norplant, demonstrated misuse of a drug intended to increase female reproductive freedom.

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Justification for investigation of the 1970s sterilizations and Norplant and Depo-Provera as potentially dangerous contraceptive devices lay in the early to mid-20th century eugenics movement, during which sterilization as a form of social control took root. The United States eugenics movement, which advocated race improvement through the control of human reproduction, sought to remedy social ills that "degenerate" citizens created in the rapidly industrializing country.[11] Although the eugenics movement did not rely solely on sterilization to achieve its goal of improving the American gene pool, involuntary sterilization survived and thrived when other strategies—marriage laws, sexual segregation in institutions, and limits on immigration—failed.[12] Between 1907 and 1964, the government mandated the involuntary sterilization of 63,678 Americans.[13] Eugenicists targeted immigrants, the poor, and mentally retarded persons, labeling many sterilization candidates "feeble-minded," "insane," or "imbeciles" in order to justify eliminating their ability to procreate. Eugenicists utilized the term most effectively to arouse fear of "feeble-minded" women whose alleged low intelligence posed a threat to society at large. Although males accounted

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1999).

[11] Allan Chase, *The Legacy of Malthus: The Social Costs of the New Scientific Racism* (New York: Alfred A. Knopf, 1975), 12. European Francis Galton, who coined the word "eugenics," inspired the American eugenics movement. In 1869, he published *Hereditary Genius: An Inquiry into Its Laws and Consequences,* which explained his belief that only parents deemed to have the "most positive" qualities should be allowed to reproduce. The constant inbreeding of talent would gradually eliminate defective genes from the human genepool. Edward J. Larson, *Sex, Race, and Science: Eugenics in the Deep South,* (Baltimore: The Johns Hopkins University Press, 1995), 20. In addition, the rise of evolutionary science and theory of natural selection subtly reinforced white beliefs that the black race was inferior to and had arisen out of degeneration from the white race. Social Darwinist Herbert Spencer first promoted these "scientific" theories on survival of the fit in his 1850 *Social Statistics.* In 1859, Charles Darwin published *Origin of the Species,* forcing society to consider that his "theory of evolution was universal" and that "the human species had evolved under natural selection." Philip R. Reilly, *The Surgical Solution: A History of Involuntary Sterilization in the United States* (Baltimore: Johns Hopkins University Press, 1991), 2 and 4; Chase, 2 and 90.

[12] Larson, *Sex, Race, and Science,* 22. A study of the 1880 census asserted that although an "idiotic population" of 76,895 existed, public institutions only provided for 24, 29. Thus, not only did eugenicists realize that these institutions strained the budgets of state governments, but they did not have the capacity to serve the entire "feeble-minded" population. "Feeble-minded" persons subject to marriage restriction laws simply ignored them. Eugenicists believed they could never fully thwart degeneration of the gene pool through immigration restriction. Reilly, 13.

for 53 percent of the sterilizations prior to the 1930s, increased efforts to secure funding for female sterilizations shifted the gender imbalance during the 1932-1934 period to 60 percent female and 40 percent male.[14]

David Priver M.D.'s 1978 perspective on sterilization echoed the views of earlier physicians who practiced medicine during the eugenics movement and thought that they should use their medical expertise to help remedy social ills. Because the eugenics movement coincided with the rise of Progressivism, it generated many of the same reform impulses aimed at controlling the effects of urbanization, industrialization, and massive immigration.[15] Thus, the response of physicians to cries for reform did not necessarily represent intentional efforts to persecute immigrants, the lower classes, mentally retarded persons, or women. Instead, physicians thought their practice could help maintain societal order; this belief demonstrated that because sexism and racism ran so subtly through medical rhetoric, physicians often viewed their reform efforts not only as innocuous, but *helpful.* One physician urged, "we owe it not only to the adult imbecile herself, *but to humanity and the world at large* to guard in every possible way against the abuse and increase of this class [the low class]."[16] Such statements reflected the belief among physicians that their actions as individuals and agents of modernity could affect the nation as a whole.

Because the eugenics movement never seized the entire nation as an issue of central concern during the early 20th century, physicians exercised significant authority in the debates. Although four different groups promoted the eugenics movement (scientists, non-scientific eugenicists such as judges, scientific eugenicists, and physicians), historians agree that eugenics primarily succeeded due to the role of physicians.[17] Historian Carole McCann theorizes that eugenicists looked to physicians for leadership because they believed that "rational intervention and management of social processes were needed to ensure the order, stability, and efficiency of society. . . . [Americans] had an abiding faith in the value of

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[13] Chase, *The Legacy of Malthus,* 16.

[14] Reilly, *Surgical Solution,* 98. A sample of the trends revealed the striking sexual bias. From 1916-1932, Wisconsin institutions sterilized 364 females and 18 males; from 1927-1937, Virginia sterilized 609 women and 301 men; from 1928-1937, New Hampshire sterilized 364 women and 62 men.

[15] Lewis Gould, *The Progressive Era,* (Syracuse: Syracuse University Press, 1974).

.[16] Reilly, *Surgical Solution,* 98.

[17] *Ibid.,* 89.

scientific methods to identify and eradicate the root causes of social ills."[18] Physicians used their authority on a local level to push for the passage of government legislation and influence court cases, leading many judges to make rulings based on the testimony of physicians who possessed medical expertise.[19] In addition to the ability of physicians to educate the population and influence government, they performed the actual sterilizations and literally translated social rhetoric into medical practice. Physicians had direct contract with patients affected by eugenic theories, and thus accepted personal responsibility for the care of patients who trusted them to exercise their medical discretion sensitively.

The 1927 Supreme Court decision, *Buck v. Bell*, provided the most compelling evidence of the influence physicians exerted in the legal aspects of sterilization. An illegitimate child herself, Virginian Carrie Buck was raped at age 17 and gave birth as a result. A. S. Priddy, M.D., superintendent of the Virginia Colony for Epileptics and Feeble-minded, said that because Buck and her offspring burdened the community, he strongly recommended her sterilization so she could not reproduce again. He effectively demonstrated to the State Board that she should be sterilized; on September 10, 1924, the State Board recognized his authority in the matter and approved his request. Buck appealed. For her appeal, the state named R. G. Shelton her attorney, who had no witnesses for her case. In contrast, state officials secured testimony from J. S. DeJarnett, M.D., superintendent of the largest institution in Indiana, and Arthur Estrabrook, M.D., eugenics advisor to the state of Indiana—both of whom strongly argued that she be rendered unable to reproduce. Ultimately, in a 1927 decision delivered by Justice Oliver Wendell Holmes, Jr., the United States Supreme Court upheld the constitutionality of the sterilization ruling, claiming that the State had already supported "three generations of imbeciles" from which Buck had descended, and could not support anymore. Holmes wrote,

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[18] Carole R. McCann, *Birth Control Politics in the United States 1916-1945* (Ithaca: Cornell University Press, 1994), 8.

[19] Between 1907 and 1913, legislatures in 16 states passed sterilization legislation. Of 12 states that enacted laws, both private care physicians and those who worked in public health voiced some of the strongest pro-sterilization opinions. They single-handedly led the movement in Pennsylvania. In California, Dr. F.W. Hatch drafted the legislative bill himself. The opinions of Dr. B. Owens-Adair of Oregon, who believed only sterilization could prevent the "pollution of germ tissue by alcohol," revealed the concern for social control that ran a dangerous undercurrent in the sterilization movement. Reilly, *Surgical Solution,* 32 and 39.

> The Commonwealth is supporting in various institutions many defective persons who if now discharged would become a menace but if incapable of procreating might be discharged with safety and become self-supporting with benefit to themselves and to society. . . . Carrie Buck is the probably potential parent of socially inadequate offspring. . . . [Thus] she may be sexually sterilized without detriment to her general health and that her welfare and that of society will be promoted by her sterilization.[20]

The testimony of the physicians and Holmes's ensuing decision had far-reaching consequences. Not only did the decision condone the attitude that women posed a danger to society, but it allowed states to pass legislation that violated women's reproductive freedom. Between 1927 and 1942, the number of states with sterilization laws grew from 17 to 30.[21]

Throughout the eugenics movement, physicians responded to conclusions that fervent eugenicist Henry Goddard had reached in his 1912 reports, *The Kallikak Family* and *Feeble-Mindedness: Its Causes and Consequences,* which traced the life of Martin Kallikak and his offspring. These reports helped inspire physicians to sterilize "feeble-minded" females so they could not pass their "defective" genes onto their children. Early in his life, Kallikak had a relationship with a poor girl and fathered her illegitimate son. He later married a "respectable" young woman and produced a successful "line" and family. Mental health experts eventually committed a descendant of Kallikak's illegitimate son to Vineland Training School, which was dedicated to the study of "feeble-mindedness." Goddard determined that the different fates that befell these two offspring of Kallikak correlated to the quality of the two different women with whom he had procreated. Goddard sought to prove that defective genes passed through females, not males. His theories laid the foundation for pushes to control "oversexed" females, which disregarded the reality that males necessarily contributed to procreation as well.[22]

Historians Philip Reilly and Edward Larson have uncovered evidence that reports such as Goddard's influenced the behavior of physicians throughout the United States. At two different New York state hospitals during the 1910s, physicians decided to sterilize nearly fifty mentally ill women. To justify their actions, they claimed that these women could achieve a normal standard of living "without the burdens of pregnancy"; sterilization would also protect them against unintended pregnancy if a nonretarded male raped or seduced

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[20] *Buck v. Bell.* 71 L. Ed. 1000 (1927).

[21] Reilly, *Surgical Solution,* 87.

them.[23] Institutions often temporarily admitted women who were "at the most mildly retarded," solely for the purposes of sterilizing them. Once the institution officials deemed them appropriately unable to reproduce, they discharged them. Both Florida's Children's Home Society and State Prison Farm/State Insane Hospital urged policy makers to focus on admitting females to institutions where they would be sterilized. Representing the institutions, eugenicist Hastings Hart claimed that "feeble-minded" girls posed a "vastly more dangerous" threat to society than boys and represented the "most acute and pressing social problem at the present time."[24] H. H. Ramsey, superintendent of the Mississippi School and Colony for the Feeble-minded, in 1923, seized upon Governor Theodore Bilbo's eugenic interests and earned money for the erection of new institutions. He sought to arouse fear of "feeble-minded" females, claiming that not only would they fail to achieve in life, but they menaced society: "many a young boy is made immoral and his life ruined at the threshold of manhood by the sex advances of feeble-minded girls and women."[25]

At the same time the eugenics movement was finding its niche among groups that wanted to control rapid urbanization, industrialization, and immigration in the United States, the birth control movement was gaining appeal among white, middle-class feminists during the 1920s and 1930s. Drawing inspiration from Progressives who had instituted the ideology of reform in early 20th century society, these women fought to achieve new reproductive freedom for themselves. However, their efforts often resulted in the paradox that poor, minority women experienced a restriction, rather than an increase, in control over their reproduction. As Gwendolyn Mink explains in "The Lady and the Tramp: Gender, Race, and the Origins of the American Welfare State," only white, middle-class women held responsibility for social improvement and legal achievements, particularly regarding labor and maternity legislation. Thus, their goals reflected their desire to engineer reforms that benefited their class and race, rather than their gender as a whole: "Gender interests . . . expressed anxieties about the purity and perpetuity of American democracy. They tied the

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[22] Henry Goodard, *The Kallikak Family* (New York: Macmillan, 1912).

[23] Reilly, *Surgical Solution,* 50.

[24] Larson, *Sex, Race, and Science,* 59 and 68.

[25] *Ibid.*, 92.

future of American democracy to the demographic and political hegemony of the people who founded it."[26]

As Edward Larson discovers, eugenics provided opportunities for developing women's organizations to join in national political discourse and therefore gain credibility. Larson explains how a male physician articulated the attitudes that attracted male eugenicists and female reformers to form a symbiotic relationship in the eugenics movement: "the 'first step' to a comprehensive eugenics reform program was the recognition 'of their [women's] intuitive perception, of their inspiration, of their power, and our solicitation of their active cooperation with us in the work.'"[27] Margaret Sanger, the leader of the birth control movement, published works such as *Pivot of Civilization* that reflected eugenical impulses. In order to advocate increased reproductive freedom, Sanger used eugenics for support and ironically helped restrict the freedom of many low-income and minority women whom eugenicists targeted for sterilization. Historian Carole McCann explains that eugenics gave the birth control movement "an authoritative language through which to legitimate women's right to contraception. By situating birth control within the eugenic terrain of racial betterment, Sanger appropriated the authority and prestige of eugenics to birth control as a tool of racial health.[28] Facing charges that birth control might make the dominant race die out, Sanger argued that birth control would allow the most fit women to produce better offspring. She said that if the most fit women continued to have more children than that for which they could properly care, their offspring would not be given the attention or opportunity needed to maintain their dominance. If fit women could exercise control over the number of children they wanted and the time at which they wanted to have them, they could collectively contribute to the sustainment of their strong race.[29]

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Early debate over the eugenics movement focuses primarily on Mark Haller's *Eugenics* and Kenneth Ludmerer's *Genetics and the American Society*, which represent the

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[26] Gwendolyn Mink, "The Lady and the Tramp: Gender, Race, and the Origins of the American Welfare State," in Linda Gordon, ed., *Women, the State, and Welfare,* (Madison, Wisconsin: University of Wisconsin Press, 1990), 93.

[27] Larson, *Sex, Race, and Science,* 79.

[28] McCann, *Birth Control Politics in the United States 1916-1945,* 100.

first extensive inquiries into how the movement reflected and shaped early 20th century America.[30] Since the mid-1980s, scholars have added contemporary perspectives to the discussion, synthesizing the arguments of Ludmerer and Haller with new research on the rise of federally-funded family planning programs and sterilizations during the 1970s. These historians demonstrate the correlation between the eugenics movement and later events in United States history, suggesting that eugenic impulses never died, but instead gained new strength in different forms under changing scientific, medical, and social circumstances. They have sought to reexamine the eugenics movement by considering issues they believe traditional historiography neglects: the targeting of women for eugenic sterilizations, the role of the medical profession and state-sponsored mental institutions, and regional experiences outside the northeastern United States. Thomas Shapiro's *Population Control Politics*, Philip Reilly's *Surgical Solution,* and Edward Larson's *Sex, Race and Science*, provide context for entering the late 20th century discussion of eugenics and its current implications.

Focusing on women whom eugenicists aimed to sterilize, Shapiro argues in *Population Control Politics* that the transition from early 20th century involuntary sterilizations to voluntary sterilizations under family planning programs during the 1970s did not eliminate potential for abuse. Shapiro views eugenics "as an ideology that was nurtured by prosperous, Anglo-Saxon, Protestant Americans . . . [offering] a robust view of society that would protect their status, prestige, privilege, and property." He believes the 1970s represented a continuation of this pattern.[31] The prosperous upper class used the popularity of family planning to accomplish its goal of preventing "unfit" women from procreating. To justify his claim, Shapiro presents evidence that the rate of minority women sterilized in family planning clinics during the 1970s far surpassed that of white women (all of the women who sought reproductive care at public clinics were poor).[32] Shapiro's argument that elites manipulated the expansion of contraceptive freedom to restrict choices for poor women of color challenges Ludmerer's theory that eugenicists attempted to achieve goals similar to

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[29] *Ibid.*, 107.

[30] Mark H. Haller, *Eugenics: Hereditarian Attitudes in American Thought* (New Jersey: Rutgers University Press, 1963). Kenneth Ludmerer, *Genetics and America Society: A Historical Appraisal* (Baltimore: The Johns Hopkins University Press, 1972).

[31] Shapiro, *Population Control Politics,* 34.

goals of Progressives. This debate raises the question of what motivated eugenicists to sterilize certain groups of people and whether physicians working in family planning clinics during the 1970s reflected similar motivation in sterilizing poor women.[33]

Rather than focusing on females, in *Surgical Solution*, Reilly seeks to understand the experience of institutionalized mentally retarded persons and men in prisons. Although Reilly only examines *in*voluntary sterilization and therefore lacks Shapiro's perspective on why "voluntary" sterilization arguably became more dangerous and insidious than the blatant sterilizations of the early 20th century eugenics movement, he instead offers a more in-depth analysis of how justification for involuntary sterilization developed. Reilly traces the development of the belief that intelligence could determine an individual's value and the impact his or her procreation could have upon society. In doing so, Reilly illustrates how social and medical rhetoric became interconnected during the eugenics movement. He also takes a step back from the situation, theorizing that physicians who supported involuntary sterilization did not subscribe consciously to elitist, sexist, or racist values: "[They] believed that they were acting on behalf of a noble cause that would benefit humanity. They believed that medical and scientific knowledge, combined with new technology, had reached a point in time in which the eradication of inherited defects was possible."[34]

In *Sex, Race, and Science,* Larson reaches many of the same conclusions as Reilly regarding physician motivation during the eugenics movement, but also offers the first extensive examination of sterilization practices through a regional, rather than national, lens. By focusing specifically on the Deep South, Larson determines that eugenicists often were not concerned solely with preventing African Americans from reproducing; they feared that the Caucasian race would not reproduce effectively and therefore lose its strength. Although the eugenics movement rooted itself in an ideology of reproductive control, Larson suggests that another dimension—a rallying cry for whites to procreate freely—existed as well. In addition, Larson looks closely at upper-middle class feminists' efforts throughout the early

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[32] *Ibid.*, 97.

[33] Ludmerer claims that eugenicists, like progressives, "turned their attention and energies toward correcting the social, political, and economic ills they saw in society. . . . they attended to the problems of the poor, the slums, and social injustice." Ludmerer, 15.

[34] Reilly, *Surgical Solution,* xi.

20th century to promote eugenic policies in the South. Using evidence from those studies, Larson introduces the idea that the fledgling feminist movement often scapegoated poor women of color in order to achieve middle- and upper-middle-class goals. Finally, Larson acknowledges the parallels between eugenic sterilization and compulsory Norplant in the 1990s, noting that proponents of both believed medical technology could help solve social problems. Thus, Larson opens questions of how surgical sterilization intersects with non-permanent but potentially coercive forms of modern contraception.

The contradictions and similarities among these historians' arguments raise questions regarding the impact of eugenics' legacy on Native-American experience during the late 20th century. Shapiro's belief that eugenicists sought to further elite goals possibly can coalesce with Reilly and Larson's idea that eugenicists responded to progressive calls for reform. Physicians might have represented the elite class (rather than middle class) which believed it should, out of moral obligation, use its education and technology to raise the living standards of those less fortunate—not protect its own prestige, as Shapiro theorizes. Like the mentally retarded persons and imprisoned males Reilly studies, Native Americans depended on a single institution, the IHS, that possessed sole responsibility for providing them with health care. Because Native-American reservations typically were located in rural areas, potential for abuse similar to that of mental institutions existed. The IHS often functioned as distant regulatory agency, allowing its individual physicians in isolated service areas to act according to their own medical discretion.

Building from the foundation these scholars established, the historiography now can explore the Native-American experience, telling a story that has remained absent from the discussion of eugenics and late-20th century allegations of reproductive control. The intricacies of the Native-American story offer an opportunity to explore *why* Native-American women experienced involuntary sterilization and took Depo-Provera or Norplant without fully understanding the drugs' risks. Research through a Native-American lens also helps understand how IHS physicians developed the belief that they could aid Native Americans as well as society at large by giving Native-American women provider-dependent birth control; the research demonstrates how the beliefs of physicians that they shouldered responsibility for bettering individual women's lives played out in the physician-patient relationship. Giving new voice to Native-American organizations and women's advocates reveals a striking contrast between their perspectives and that of governmental agencies and the medical establishment. These additional components of the debate allow a deeper investigation into the paradox that measures aimed at increasing the reproductive freedom of white, middle-class women often resulted in the reproductive control of poor, minority women.

CHAPTER 2

From Sword to Scalpel: Uncovering Sterilization Abuse

While interviewing over 1000 Native American women during her 1970s investigations, Native American physician Constance Redbird Uri, M.D., uncovered shocking allegations of IHS physicians coercing women into undergoing sterilization procedures. One story involved a Native-American woman who moved to the Los Angeles area in the late 1970s and sought medical treatment at a city clinic. She asked a physician for a "womb transplant," believing that if people could receive kidney transplants, they could also receive womb transplants. An IHS physician had performed a complete hysterectomy on this woman six years earlier, when she was 20, single, and an alcoholic with two children in foster care. When the woman asked for a womb transplant from the Los Angeles clinic, she had recovered from her alcoholism and planned on marrying. Uri claimed that because the woman could not regain her fertility, her marriage disintegrated and left her emotionally devastated. Like many other women who discovered that IHS physicians had coerced them into sterilization, the woman lost her sense of self-worth. Uri explained, "when they [Native-American women] do realize they can't create life, they feel castrated and psychological problems result. It dawns on different women at different times. . . . They often have a total nervous breakdown, try to commit suicide, go into prostitution, or become an alcoholic."[35] Uri labeled such sterilization as "genocidal" because, "as the Cheyenne will tell you, the strength of the Indian nation is in their women. No matter how straight your arrows, no matter how strong your bows, no matter how brave your warriors, no matter is defeated until the hearts of the women are on the ground. When the women give up, you are in trouble."[36]

Uri charged that late 20th century abuses of Native American reproductive freedom stemmed from the federal government's traditionally paternalistic attitude toward her race. She explained, "They have enough pressure on them that they are giving us health care. We prepaid our health care. . . . We paid for it with our land and our lives. We paid for it at a

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[35] Gail Marksjarvis, "The Fate of the Indian," *National Catholic Reporter* 13, no. 31 (27 May 1977): 2.

[36] "Theft of Life."

great cost."[37] While United States policy in mediating problems between white settlers and tribes during the 1800s might have represented efforts to better the lives of Native Americans, governmental reform not only threatened the Native-American way of life, but devastated their health. Of more than 350 treaties the government signed with tribes between 1784 and the late 1800s, none provided tribes with more than five to twenty years of health care. This initial failure to offer Native Americans adequate care established a destructive cycle of poor health that Native Americans would never escape entirely. As whites settled their land, exploited their natural resources, and introduced infectious diseases against which Native Americans had no natural immunity, the Native- American population steadily decreased in strength and size.[38]

After Congress transferred the Bureau of Indian Affairs (BIA) from the War Department to the Department of the Interior in 1849, the government first seriously addressed the issue of poor Native American health. The BIA made physician services available to Native Americans through a "corp of civilian field employees"; then, the newly established Indian Medical Services built the first reservation hospital during the 1880s in Oklahoma, employing 83 physicians and 25 nurses by 1900. In 1908, Congress established a system for supervision of medical activities and made the first appropriation for health services in 1911, though it offered no conditions for long-term funding. Unable to ignore pressure that Native Americans needed continued support to improve their poor health, Congress passed the 1921 Snyder Act, creating a system of regular appropriations for "relief of distress and conservation of health" of Native Americans. The Synder Act also resulted in the development of the IHS and BIA Health Division, designed to monitor the activities of its 12 regional service areas.[39] The 1954 Transfer Act (PL 83-568), which shifted responsibility for Native American health from the BIA to the HEW, established new goals of increasing

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[37] Uri, *Indians and medicine sterilization and genocide.*

[38] Indian Health Service, "Non-Medical Programs," http://www.ihs.gov/NonMedicalPrograms/Profiles/profileIntro.asp and http://www.ihs.gov/NonMedicalPrograms/Profiles/profileChrono.asp and "Comprehensive Health Care Program for American Indians and Alaska Natives, Introduction" (9 September 1999).

[39] *Ibid.*

IHS staff support, facilities, intensive treatment for the seriously ill, and preventative programs.[40]

Despite these legislative efforts, the government still failed to give the IHS the financial assistance it needed, leading Uri to charge that as a "carry-over from the frontier days, the IHS has been underfunded, neglected for years. . . . I think only nine [of 51 hospitals during the early 1970s] meet the minimum specifications for the accreditation of hospitals."[41] Finally, the federal government passed two significant measures aimed at protecting and improving Native-American health. Through the 1975 Indian Self-Determination and Education Assistance Act (PL 93-638), Congress sought to give Native Americans the opportunity to strengthen their roles in the health care delivery system.[42] The 1976 Indian Health Care Improvement Act (PL 94-437) supplemented the Self-Determination Act, as it hoped "to provide the quantity and quality of health services which will permit the health status of Indians to be raised to the highest possible level." Despite these efforts, the government overlooked Native-American *women*. In Title II (Health Services), section (c) of the Act, the government authorized no specific funds for maternal health care, though it did for other services such as dental care, mental health, and treatment of alcoholism.[43]

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Although involuntary sterilization programs faded after World War II due to concerns over Nazi genocide and the declining scientific credibility of eugenics, many laws that authorized them remained intact.[44] Female sterilizations continued to occur under

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[40] Public Law 83-568.

[41] Uri, *Indians and medicine sterilization and genocide.*

[42] Public Law 93-638. Although this law stated that the Secretary of HEW may "make grants to any Indian tribe or tribal organization for the development, construction, operation, provision, or maintenance of adequate health facilities or services," few tribes initially sought to secure a grant. When tribes did seek to establish a contract facility, they simply did not have the man power necessary to maintain adequate facilities. Although tribes have begun to develop more of their own health programs today, this statistic remains largely unchanged. As of October 1, 1996, tribes only operated 12 hospitals and 134 health centers nationwide. United States Department of Health and Human Services, *Trends in Indian Health, 1997* (Washington, D.C.: GPO, 1997), 23.

[43] Public Law 94-437.

[44] Reilly, *Surgical Solution,* 148-149. At the beginning of the 1970s, 21 states still had laws authorizing sterilization. Even as late as 1975, West Virginia enacted a new eugenic sterilization law, arguing that it represented a "tax-saving measure." As an example of how sterilizations continued to occur under these laws, Reilly cites a decision by the Nebraska Supreme Court in 1968 to sterilize Gloria Cavitt, allegedly mildly retarded and the mother of eight illegitimate children. To earn her release from the Beatrice State Home for the retarded,

"voluntary" circumstances, as physicians in the 1970s stressed that voluntary sterilization could raise the living conditions of the poor without violating the rights of patients as involuntary sterilizations had done. Physicians replaced the term "feeble-minded," which had functioned as a justification for involuntary sterilization during the eugenics movement, with a new concern for "poor" women, many of whom were minorities. This shift in rhetoric actually strengthened the ability of sterilization advocates to achieve their goals because it reunited the sterilization movement with the birth control movement and medical establishment, thus reestablishing the validity of sterilization as a medical procedure. Physicians who worked in publicly-funded family planning clinics were able to present sterilization to their patients as a positive procedure, miscommunicating information or neglecting to educate their patients prior to the surgery. Out of the vision of public scrutiny, physicians often did not feel pressured to seek consent whatsoever. Historian Thomas Shapiro theorizes that "the same changed status of sterilization that has benefited so many women may well have left the floodgates to abuse wide open for others," creating an environment in which a new, quieter form of eugenics would thrive.[45]

Influenced by leaders such as President Richard Nixon, who strongly supported population control measures, certain government agencies helped shape the trend that allowed physicians to perform "voluntary" surgical sterilization procedures during the 1970s.[46] Although the Office of Economic Opportunity at the time of its establishment had forbidden that funds be used for family planning services, it accepted a family-planning grant in mid-1960; soon after, lawmakers amended the terms of Aid to Families with Dependent Children (AFDC) so that at least 6 percent of its funds would go to family planning assistance. In addition to new state level efforts to offer family planning services to poor women, the 1970 Congress, aiming to make services available to *all* poor women, passed the Family Planning

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Cavitt needed to agree to sterilization. The court ruled that "the order does not require her sterilization. It does provide, in accordance with the statute, that she shall not be released unless she is sterilized. *The choice is hers* [emphasis by the court]."

[45] Shapiro, *Population Control Politics*, 89.

[46] Curtis H. Wood, "The Changing Trends in Voluntary Sterilization," *Contemporary Obstetrics and Gynecology* (1973): 39. In December 1970, Nixon vetoed $225 million in funds that would support the training of family doctors; on the same day, he authorized $382 million to "control population growth." President Nixon's Commission on Population and the American Future asserted that population growth was no longer in the public interest of the United States and the country should strive toward zero population growth as rapidly as possible.

Services and Population Research Act. These legislative efforts sharply increased the number of women seeking reproductive services from the government, giving them the opportunity to *choose* services such as sterilization rather than being *forced* by the government into receiving them. In 1965, when the government first committed itself to funding family planning clinics, it served 450,000 individuals; in 1975, numbers grew to more than 3.8 million; by 1979, the clinics saw 4.5 million patients.[47]

The Family Planning Services and Population Research Act of 1970 did not establish sterilization regulations, thus allowing physicians to exercise significant freedom in making decisions to sterilize their patients. This lack of regulation proved problematic. In July 1973, when the National Welfare Rights Organization (NWRO) charged that an Alabama physician sterilized teenage sisters Mary Alice and Minnie Relf without their consent, it filed a class action lawsuit to ban the use of federal funds for sterilization. By doing so, the NWRO influenced the HEW to impose a moratorium on sterilizations of mentally retarded persons and minors under 21 and release its first "Notice of Guidelines for Sterilization under HEW Supported Programs" in 1973. When the NWRO attacked the guidelines for still failing to provide adequate safeguards against coercive or involuntary sterilization, the organization ignited a debate over the alleged abusive behavior of physicians.[48] The court eventually declared when delivering its opinion in favor of Relf that physicians, unchecked by legislative guidance, could make "the dividing line between family planning and eugenics . . . murky."[49] When the NWRO filed suit against another party in 1975, United States District Court agreed that the HEW needed to revises its regulations again, stating in *Relf v. Mathews* that "safeguards must be developed to prevent abuse, such as those that might occur through over-zealous physicians."[50] Charging that physicians could act unethically if left to their own discretion when treating poor women, the Court demanded that the HEW institute more stringent regulations to police the behavior of physicians.

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[47] Shapiro, *Population Control Politics,* 113. Title XIX of the Social Security Act ("Medicaid") provides that eligible individuals who desire family planning services may receive them; Title V states that these services "shall be voluntary on the part of the individual to whom such services are offered."

[48] HEW notice of Guidelines for Sterilization Procedures under HEW Supported Programs. 38 Federal Register 20930.

[49] *Relf v. Weinberger.*

[50] *Relf v. Mathews,* 403 F. Supp. 1235 (1975).

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Nationwide, physicians responded to the beliefs of policy makers that poor women needed permanent contraception. Led by medical activists such as Curtis Wood, M.D., physicians articulated their view that they could better the lives of welfare women while helping to control broader social problems. Wood urged physicians that "we have a responsibility in the problems of population control. . . . We have obligations to our individual patients, but we also have obligations to the society of which we are a part."[51] Wood also suggested that physicians had the power to grant a lifelong desire of many women: "Since time began, women have probably wished in their hearts for some kind of sterilization method."[52] In general, Wood hoped physicians could use their authority to persuade women to accept sterilization, thereby achieving permanent birth control in a voluntary manner; he said the most effective strategy would be to offer postpartum sterilization to every woman who gave birth in United States hospitals.[53]

Citing statistics from March 1971, which showed 10 million Americans received AFDC funds—a 50 percent increase since August 1969—Wood asserted, "the welfare mess, as it has been called, cries out for solutions, one of which is fertility control. How many of these children [receiving welfare] were wanted by their mothers, and what chance do they have of developing into happy, useful, self-supporting citizens?" In response to a study which showed 85 percent of Chicago welfare mothers did not want their most recent child, Wood chided, "yet, it is still not unusual for some of these women to have a child every year—year after year."[54] In their 1971 study of a small Southern community, medical researchers Anthony R. Measham, Robert A. Hatcher, and Charles B. Arnold corroborated Wood's claims, concluding that although physicians generally favored voluntary sterilization, they thought the government should mandate compulsory sterilization for welfare mothers with three or more children. Fifty-one percent of physicians favored voluntary sterilization

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[51] Wood, "Changing Trends in Voluntary Sterilization," 39. Wood claimed that overpopulation among welfare recipients contributed to the destruction of the environment, strained marriages, and lowered the quality of life in the United States.

[52] *Ibid.*, 31.

[53] Shapiro, *Population Control Politics,* 55.

[54] Wood, "Changing Trends in Voluntary Sterilization," 39.

for a mother on the AFDC rolls with three illegitimate children; 46 percent favored compulsory sterilization.[55]

Physicians often experienced success in their attempts to convince poor women that they needed permanent contraception. In their 1958 study of physicians and 457 women who had undergone sterilization at the Ohio state MacDonald House, Allan C. Barnes and Frederick P. Zuspan revealed how physicians influenced their patients into accepting a sterilization procedure; they also showed how female patients consequently regretted their decision. In 60 percent of the cases they studied, the physician first had suggested the sterilization procedure; 14 percent of patients who had undergone tubal resection after having had a cesarean section "unequivocally regretted" their decision and felt that physicians 'talked [them] into' the procedure. If the physician had suggested the procedure to a woman, she was twice as likely to regret it and four times as likely to feel ambivalent. In contrast, more than 90 percent of patients who desired sterilization before a physician mentioned the procedure felt happy about their decision.[56] Pedro Poma discovered in his 1980 study of 163 women at the Chicago Mount Sinai Hospital Medical Center that physicians had "adopted an increasingly liberal attitude toward sterilization" due to the new technological ease of the procedure. Poma's results showed that 30 percent of Mount Sinai physicians convinced women to undergo sterilization and 17 percent made the decision without consent from the patient. Poma explored the term "tubal ligation" and concluded that when a patient heard a physician speak optimistically about "tying" her tubes, she assumed the physician could also "untie" her tubes.[57]

Aside from regret, women suffered other emotional and physical consequences because of coercive sterilization. In his 1968 investigation of the emotional reaction of women to abortion at the London Grosvenor Hospital, David R. McCoy also researched

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[55] Anthony R. Measham, Robert A. Hatcher, and Charles B. Arnold, "Physicians and Contraception: A study of Perceptions and Practices in an Urban Southeastern United States Community," *Southern Medical Journal* 64, no. 4 (April 1971): 502.

[56] Allan C. Barnes and Frederick P. Zuspan, "Patient Reaction to Puerperal Surgical Sterilization," *American Journal of Obstetrics and Gynecology* 75, no. 1 (January 1958): 65. During the late 1960s, surgeons perfected puerperal sterilization. This operation, also known as postpartum tubal ligation, increased the acceptance of sterilization because women more eagerly consented to the procedure after a difficult delivery process; it also reduced total hospitalization time.

patient reaction to sterilization. He concluded that sterilization particularly affected the mentally ill, as nine out of 42 mentally ill women who underwent a sterilization procedure at the time of their abortion suffered emotionally; 27 percent expressed varying degrees of regret and 9 percent had "bitter regrets." Researching abortion and contraceptive practices at London Hospital in the late 1970s, Wendy Savage discovered the case of a woman whom a physician sterilized concurrently with her third abortion at the age of 19; the woman finally had to undergo a complete hysterectomy, "as her chronic infection, which appears to date from the combined abortion and sterilization procedure, has made her life a misery."[58] After noting an increased prevalence of menstrual problems following sterilization during the 1970s in Scotland, A.A. Templeton and Susan Cole found that sterilized women had an increased rate of hysterectomy in the four years following their sterilization procedure. Studies released by the Baltimore City Health Department/Johns Hopkins University and *Morbidity and Mortality Weekly Report* reached conclusions that fewer sterilized women than nonsterilized women had ever used condoms and sterilized women reported having had pelvic inflammatory disease more often than nonsterilized women.[59] In a study of women who had been diagnosed with ectopic pregnancies in Puget Sound hospitals during the early 1980s, Victoria Holt concluded that sterilized women had 3.7 times the risk of ectopic pregnancy and a higher incidence of pelvic inflammatory disease or gonorrhea than nonsterilized women.

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In this atmosphere of support for physicians to utilize sterilization as a tool for bettering the lives of individuals and controlling population growth, Constance Redbird Uri,

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[57] Pedro Poma, "Why Women Seek Reversal of Sterilization," *Journal of the National Medical Association,* 72, no. 1 (1980): 41-45.

[58] Wendy Savage, "Taking Liberties with Women: Abortion, Sterilization, and Contraception," *International Journal of Health Services* 12, no. 2 (1982): 293-94. For additional information on the effect of physician behavior on women's choices of contraceptives, see "Staff Influence on Choice of Hormonal Contraceptives in Family Planning Clinics," presented at the National Public Health Association's 123rd Annual Meeting, 29 October-2 November 1995. San Diego, CA. Investigating concerns that physicians could influence young, minority women with limited education into choosing irreversible contraception, the researchers found that indeed, physicians strongly influenced the women's' choices. For more information on secondary side effects of sterilization, including pelvic pain, orgasmic dysfunction, and heavy menstruation, see Poma.

[59] "HIV-Risk Behaviors of Sterilized and Nonsterilized Women in Drug-Treatment Programs—Philadelphia, 1989-1991," *Morbidity and Mortality Weekly Report* 41, no. 9 (6 March 1992). "Surgical Sterilization Among Women and Use of Condoms—Baltimore, 1989-1990," *JAMA* 268, no. 14 (14 October 1992): 1833-34.

M.D., alleged that the IHS sterilized so many Native American women during the 1970s that the agency committed genocide. Until the late 1960s, when the government began investing heavily in family planning programs, the Native American population had been growing. Uri explained, "it's all perfectly logical. They have massacred us in the past. So, this [sterilization] is very clever, very sophisticated, and using the vehicle of health care as a way of [carrying out] genocide. We are not like other minorities. We have no gene pool in Africa or Asia. When we are gone, that's it." When Uri traveled to the Claremore, Oklahoma IHS hospital in August 1974, to assist a protest against employee discrimination practices, she also "uncovered a sterilization factory." Her subsequent investigation yielded evidence that the Claremore physicians had sterilized 132 Native American women of reproductive age—including four teenagers—in 1973. Of those, 32 had undergone complete hysterectomies; assuming that physicians performed the hysterectomies out of medical necessity, Uri said 100 "were purely for the reason of stopping their [the women's] reproduction."[60]

Uri used her discovery to push for a more comprehensive government investigation of IHS sterilization practices. The Government Accounting Office (GAO) eventually responded to her request, probing the records of four Western IHS service areas and publishing its findings in a 1976 report on the *"permanent sterilization of Indians at Indian Health Service facilities and contract facilities.*[61] The GAO reported that IHS physicians targeted women for sterilizations, as only 142 men underwent a vasectomy procedure, while thousands of women had tubal ligations. The GAO placed responsibility for the 3,406 female sterilization procedures, which included 3,001 women of child-bearing age, on the IHS as an agency.[62] Although physicians performed the procedures without obtaining proper consent

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[60] Uri, *Indians and medicine sterilization and genocide.*

[61] GAO, *Letter to Senator James G. Abourezk from the Controller General of the United States presenting findings on medical research involving American Indian subjects, research on the control of trachoma, and permanent sterilization of Indians at Indian Health Service facilities and contract facilities* (Washington, D.C.: Controller General of the United States, 1977).

[62] It is interesting to note that Federal Tort Law protected (and continues to protect) IHS physicians from malpractice suits, transferring responsibility for malpractice charges from individual physicians to the United States government. Because IHS physicians therefore did not suffer direct consequences of their actions as medical professionals, they arguably acted more boldly in their performance of controversial procedures such as sterilization. According to United States Code Title 28, 1346, United States as Defendant, "the district courts . . . shall have exclusive jurisdiction of civil actions on claims against the United States . . . for personal injury or

from patients, the GAO justified the physicians' lack of understanding as the fault of the IHS, which failed to provide direction for area offices when it did not create a consent form to comply with revised HEW standards or properly inform physicians of the new regulations by revising the IHS manual.[63] The GAO also said that because the IHS did not require contract physicians to adhere to the regulations, contract physicians were not at fault. [64] In reaching such conclusions, the GAO elucidated how the IHS established its support for physicians to act according to their individual medical discretion.

The GAO devoted a significant portion of its investigation to reporting on the IHS's lack of proper consent forms for sterilization, focusing on agency policy rather than individual physicians as a cause of the sterilizations (see appendix A). Although the GAO did not condone the behavior of IHS physicians, the GAO offered its tacit pardon by using the explanation of miscommunication and misunderstanding on all structural levels. While the IHS *did* act inappropriately in failing to prepare a form that would comply with HEW regulations, evidence reported by the IHS revealed that physicians acted unethically, as well.[65] The IHS Deputy Director of Program Operations testified that physicians believed they could perform sterilization on minors or mentally retarded persons if they acquired 72-hour informed consent.[66] Despite this argument, the GAO found that 13 involuntary sterilizations occurred precisely because physicians failed to wait the required 72 hours before performing the procedure.[67] Furthermore, the GAO uncovered evidence of IHS physicians simply misusing consent forms (physicians most commonly used consent forms designated for patients undergoing medically required sterilization, rather than voluntary sterilization). When three physicians sterilized three women under the age of 21, the IHS again explained that these physicians misinterpreted HEW policies.[68]

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death caused by the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office or employment, under circumstances where the United States, as a private person, would be liable to the claimant in accordance with the law of the place where the act or omission occurred."

[63] GAO, 25.

[64] *Ibid.*, 18.

[65] *Ibid.*, 24.

[66] *Ibid.*, 22

[67] *Ibid.*, 24.

[68] *Ibid.*,. 22.

Several flaws existed in the GAO report that gave the IHS the opportunity to challenge the credibility of the report.[69] Most obviously, the GAO only probed the records of four areas—Aberdeen, Albuquerque, Oklahoma City, and Phoenix—though the IHS operated (and continues to operate) 12 areas nationwide. The GAO also did not investigate IHS contract facilities, but simply stated that they were under no requirement to adhere to regulations.[70] Second, the GAO did not interview any women or physicians, failing to understand the experience from a patient's perspective and disregarding what motivated physicians to perform the sterilizations.[71] And in preparing the report, the GAO did not demand complete information from the service areas, admitting that the IHS could not supply the GAO with "complete and statistically reliable data" on the ages of the patients and whether the physicians performed voluntary or therapeutic sterilizations.[72] Settling for a record of the *number* of sterilizations procedures physicians performed, the GAO overlooked how details such as age and previous births would have provided critical leads to *why* the sterilizations occurred. The GAO's suggestions for reform also fell short of appropriate, as they focused on preventing future negligence in IHS policy rather than suggesting how physicians should respond as individual federal employees to charges of sterilization abuse. Although the GAO recommended that the HEW assure all IHS facilities were using proper consent forms, training their physicians to understand sterilization of minors and obtaining informed consent, and developing monitoring procedures of both area and contract facilities, the GAO did not explain whether physicians should consult headquarters or colleagues if future confusion arose. This oversight reinforced the idea that the IHS should not threaten the ability of physicians to make autonomous decisions, whether they were based on accurate assumptions or not.

Disappointed and angered by the inadequacies of the 1976 GAO investigation, Uri launched a larger-scale investigation in 1977 and interviewed over 1000 Native American women herself; she wanted to understand the story from the perspective of women rather than

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[69] "Alleged Sterilization of Indians is Denied," *New York Times*, 24 November 1979, sec. A, p. 12.. The *Times* reported in a short newbrief that Frank Clarke, M.D., and Robert Vanderwagon, M.D., denied that physicians had sterilized patients without their knowledge.

[70] GAO, 26.

[71] *Ibid.*, 24.

from the perspective of the IHS. Uri estimated that during the 1970s, IHS physicians sterilized 25,000 women—20 percent of the child-bearing population—at a rate that would have destroyed pure-blooded Native-American races within 15 years.[73] As she did in her localized report which prompted the GAO investigation, Uri examined the idea of physicians attempting to manipulate Native American women not only because of their ethnicity, but because of their class. In 1973, Native Americans living on the Claremore Reservation earned an average income of $300 to $700 per year. Uri believed this environment of "hidden poverty," tucked in a rural setting away from the vision of urban social advocates, posed particular danger to Native Americans. Physicians practicing medicine in isolated areas felt they needed to prevent children from further burdening mothers financially. Uri theorized that physicians' attitudes reflected the disrespect physicians had developed for women of non-Anglo origin while completing their medical training in teaching hospitals that experimented on poverty-stricken minority populations. "It's mixed in with this whole concept of well, my taxes are helping to support this woman's kids and I think she ought to have her tubes tied," she explained. "So, [physicians ask] 'Why should I be paying for her kids?''"[74]

Although Uri often articulated fierce anti-government rhetoric, she believed the sterilizations resulted from the actions of malicious physicians rather than a government-sponsored official extermination plan. She said that "the women have great faith in their doctor—they do as they're told."[75] Of the more than 1,000 women she interviewed, only *one* woman made an independent choice to have the procedure done. Uri said that physicians coerced women into sterilization by threatening to discontinue their welfare benefits or take their children, suggesting sex would be more fun without the threat of pregnancy present, or providing no alternative birth control options. They labeled very young mothers as "polluters" and thus justified performing complete hysterectomies on them. One physician suggested sterilization to a woman who suffered severe headaches; he "said her head hurt because she was afraid of getting pregnant. . . . She later learned she had

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[72] *Ibid.*, 19

[73] Elliott.

[74] Uri, *Indians and medicine sterilization and genocide.*

a brain tumor."[76] Other women signed consent forms just prior to or following childbirth, while under the influence of sedative painkilling drugs. Often, physicians simply did not allow women adequate time to consider their decisions. Uri reflected, "You spend more time deciding whether to buy a house or a car than the mandated 72 hours women have here to mull over permanent sterilization. Confused people can shoot their whole future in a moment. I ask you, what harm is done . . . if you let a woman have more time to think?"[77]

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Uri's objections to the actions of IHS physicians and ensuing investigations coincided with the rise of nationwide social protest and reform impulses. A strain of protest in the Native-American community developed out of attitudes similar to those that characterized the Civil Rights Movement, Women's Liberation, and anti-Vietnam demonstrations. Established by Clyde H. Bellecourt in 1969, the American Indian Movement (AIM) sought to utilize the "connectedness" of Native peoples to "turn the attention . . . toward a renewal of spirituality which would impart the strength of resolve needed to reverse the ruinous policies of the United States government."[78] The movement gained strength during the early to mid-1970s, when members occupied Alcatraz Island and the Washington, D.C., Bureau of Indian Affairs Office (BIA) to symbolize their new fight for "red man's liberation." Red Power, the general term for the insurgent Native-American activism that AIM had inspired, began to adopt more drastic measures for making its voice heard. For 70 days in 1973, 300 Native Americans occupied Wounded Knee, South Dakota, a small village where the United States military had killed several hundred members of the Sioux tribe in 1890. On a less radical front, AIM helped alleviate legal problems for Native Americans, offered culturally-based education services to children, and established adult-education programs. In 1978, Women of All Red Nations (WARN) grew out of AIM and articulated the need for an arena in which to address issues specific to Native-American women and their families.[79]

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[75] Elliott, "Genocide charged by Indian M.D. investigator."

[76] Marksjarvis, "Fate of the Indian," 3.

[77] Uri, *Indians and medicine sterilization and genocide.*

[78] Bellecourt remains the leader of the movement today. American Indian Movement, "A Brief History of the American Indian Movement," http://www.aimovement.org/page3.html (23 November 1999).

[79] *Ibid.* and Terry H. Anderson, *The Movement and the Sixties: Protest in American from Greensboro to Wounded Knee* (New York: Oxford University Press, 1995), 335 and 407.

In 1975, activist physicians founded the Association of American Indian Physicians (AAIP) and along with it, the Association of Native American Medical Students (ANAMS). Because fewer than 75 Native-American physicians practiced medicine in the United States during the 1970s, the AAIP sought to increase Native-American representation and encourage physicians to pursue a career in the IHS. The organization developed a mission statement "to pursue excellence in Native American health care by promoting education in the medical disciplines, honoring traditional healing practices, and restoring the balance of mind, body, and spirit." The groups held regular meetings and a nationwide annual conference; they used newsletters to encourage exchange of information regarding Native-American health issues.[80] Uri supported the efforts of the AAIP, claiming that it could help influence the Bureau of Indian Affairs (BIA) to provide more adequate funding for Native Americans to attend institutions of higher education and increase Native-American representation on minority admissions committees. Uri lamented that in 1973, 25,000 Native Americans applied for BIA scholarships, but only 14,000 received them; she believed that the AAIP could improve this statistic.[81]

Uri used her investigations not only to give voice to women, but to inspire protest both within and beyond the Native American community. Rather than labeling women helpless victims, Uri seized the opportunity to empower women in the role of advocates for their gender and race. "We don't need white interpreters anymore," she said. "We've been to the white men's schools, we know what good medicine is, so we have to be part of the health delivery system for our own people."[82] She called for a renewal of Native American sisterhood, encouraging women to form teams which would speak to tribes about coercive behavior of IHS physicians and file class action lawsuits against the government. She proposed a moratorium on all IHS sterilizations, then insisted that the government address factors contributing to Native American poverty, create jobs for women, and provide daycare.

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[80] Association of American Indian Physicians, "Who We Are," http://www.aaip.com/whoweare/mission.htm (23 November 1999).

[81] Uri, *Indians and medicine sterilization and genocide.*

[82] *Ibid.*

If the government failed to heed her suggestions, Uri warned that "the doctors will continue sterilizing women who just go back to poverty."[83]

Akwesasne Notes, the official publication of the Mohawk Nation at Akwesasne (New York), undertook significant efforts to publicize government abuses and call for reform. Like Uri, *Akwesasne Notes* adopted a radical tone, elucidated in article titles such as "The True Mission of the FBI: A few of the FBI's 'dirty tricks' on the Native people's movement—once again, a definite pattern of subversion" and "Racism: an American ideology—racism is not an overnight phenomenon. Its roots are deeply intertwined in the history of conquest." Continually updating its readers on the progression of Uri's investigations, the publication especially devoted itself to educating Native Americans about coercive sterilization. In 1977, *Akwesasne Notes* attempted to show how the government denied that the GAO's findings regarding Native-American sterilizations were accurate. "Killing Our Future: sterilization and experiments" reported that the U.S. Information Agency sent news releases to foreign countries, asserting that Native-American women had consented to the sterilization procedures. This article illustrated parallels between the Native American experience and the experiences of other minority groups, suggesting that the government had carried out a calculated effort to persecute their populations. A writer of a Native-American journal lamented, "they took our past with a sword and our land with a pen. Now they're trying to take our future with a scalpel."[84]

Although widespread protest did not develop beyond the Native-American community, some publications attempted to spread news of the Native-American sterilizations. Because the *New York Times* only published a short article at the end of a newsbrief section and major magazines such as *Time* and *Newsweek* entirely failed to report on the GAO investigation, only less well-known publications covered the story.[85] The *National Catholic Reporter* used Marksjarvis's *Theft of Life* interview with Uri to make its point that sterilization violated the Catholic church's belief against birth control. In the

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[83] Marksjarvis, "Fate of the Indian," 3.

[84] "Killing Our Future: sterilization and experiments," *Akwesasne Notes* (spring 1977): 4-6; "Sterilization of Young Native Women Alleged at Indian Hospital—48 Operations in July, 1974 Alone," *Akwesasne Notes* (early summer 1974): 22; "The Theft of Life."

medical establishment, the *Medical Tribune* took a strong stance against the HEW hysterectomy handouts released in 1977, running the headline, "HEW 'Sells' Hyster-Sterilization Via Booklet," in response to the HEW's continual revisions of sterilization guidelines. The article also quoted physician John McLean Morris, M.D., Chief of Gynecology at Yale University, as saying that the booklet unethically "advocates, or at least recommends hysterectomy for sterilization." The *Medical Tribune* added that William Ryan, M.D., Chief of Obstetrics and Gynecology at Harvard University, opposed the booklet because it did not present information that tubal ligation often represented a better alternative than hysterectomy for most women.[86]

National advocacy organizations joined the fight against reproductive control, not necessarily concentrating on Native-American women, but seeking to inspire nationwide discussion on the subject. The National Women's Health Network (NWHN), "the only national public-interest membership organization devoted solely to women and health," began providing advocacy for *all* women's health in 1976, focusing its birth control research on Medicaid subsidies for sterilization but not for abortion, sterilization requirements for female workers in high-risk factories and industry, and sterilization of women without their knowledge following childbirth.[87] The NWHN protested the 1977 Hyde Amendment, which forbade the use of federal funding for abortions unless a woman's life was in danger.[88] The gag rule affected the federally-funded IHS, arguably leading to its increased focus on the *prevention* of pregnancy altogether among Native-American women.

During the 1970s, the Public Citizen Health Research Group released a series of three articles documenting sterilization policies of major teaching hospitals. Public Citizen discovered "alarming sterilization abuses" involving physicians sterilizing women without their consent, particularly at Baltimore City Hospital, Boston City Hospital, and Los Angeles County Hospital. Seventy-six percent of 83 hospitals performing sterilizations violated HEW

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[85] "Study Finds Many Indians Sterilized by U.S. Agency Without Full Explanation," *New York Times*, 23 November 1976, sec. A, p. 16.

[86] Allan Barnes, "HEW 'Sells' Hysterilization Via Booklet," *Medical Tribune*, 24 August 24 1977. The *Medical Tribune* printed this article alongside John Elliott's interview with Connie Uri and under a joint heading: "In a continuing series, *Medical Tribune* is reporting on the legitimacy of current sterilization practices among the nation's medically indigent."

[87] Elizabeth Suiter, letter to the author, 6 October 1999.

regulations, and 33 percent reported that they were completely unaware of the regulations. Worried that the 4,000 interns in training at the hospitals would develop the attitude that they had the authority to sterilize poor patients involuntarily, Public Citizen recommended that state Medicaid agencies fully inform physicians about the new regulations, reissue directives yearly, and "develop judicial sanctions for non-compliance with the regulations." If the agencies ignored its recommendations, Public Citizen asserted that it would take legal action against them.[89] Elissa Krauss of the American Civil Liberties Union uncovered the same trends in her survey of teaching hospital policies, and concluded from an ideological perspective that "the doctors and hospitals—and ultimately the federal government—bear the responsibility to assure that no person is denied this fundamental human right to reproductive freedom and voluntary choice."[90]

Despite the advocacy of these organizations and the release of final HEW sterilization guidelines in 1978, which the United States Court of Appeals determined to have established effective safeguards against sterilization abuse, the attitude that minority groups and the lower classes needed to control their fertility remained present.[91] The Center for Disease Control reported in *Surgical Sterilization Surveillance* that although female sterilizations decreased from 12.7 per 1000 women in 1979 to 12.4 per 1000 women in 1980, sterilization rates for black women remained higher than for white women and black women tended to be younger when they underwent sterilization procedures.[92] In its 1983 report, *A Growing Crisis: Disadvantaged Women and Their Children*, the United States Civil Rights Commission insinuated that excessive childbearing contributed to the woes of poor women: "The continuing trend in teenage childbearing out of wedlock is cause for concern. . . . Poverty,

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[88] Public Law 95-205.

[89] Ted Bogue and Daniel W. Sigelman, "Sterilization Report Number 3: Continuing Violations of Federal Sterilization Guidelines By Teaching Hospitals in 1979" (Washington, D.C.: Public Citizen Health Research Group, 1979); Bernard Rosenfeld, Sidney Wolfe and Robert McGarrah, "A Health Research Group Study of Surgical Sterilization: Present Abuses and Proposed Regulations" (Washington, D.C.: Public Citizen Health Research Group:1973); Daniel Sigelman, "Health Research Group Report Number 4 on Sterilization Abuse of the Nation's Poor under Medicaid and Other Federal Programs" (Washington, D.C.: Public Citizen Health Research Group, 1981).

[90] Elissa Krauss, *Hospital Survey on Sterilization Policies* (New York: ACLU, 1975), 28.

[91] *Relf v. Weinberger*, 565 F.2d 722 (1977), Federal Register 43-217, 8 November 1978.

[2] Centers for Disease Control, *Surgical Sterilization Surveillance, 1979-1980,* (Washington, D.C.: U.S. Department of Health and Human Services, 1983). The report stated that its purpose in conducting the report

particularly when linked with single parenthood . . . and the presence of young children, is a major cause of emotional stress."[93]

David Priver, M.D., argued in his 1978 letter to the *Medical Tribune* that "the new HEW guidelines with waiting periods and age requirements are highly discriminatory and represent an overreaction by the government to a single, solitary episode of so-called 'uninformed sterilization.'"[94] His refusal to recognize that *several* "episodes" occurred—the thousands of women represented in *Relf v. Weinberger*, the Native Americans, the teaching hospitals—reflected the attitude among physicians that they needed to continue exercising their own discretion as individual medical experts. Although sterilization would remain a popular contraceptive option during the 1980s and 1990s, physicians increasingly turned to long-term hormonal devices as alternatives to permanent sterilization. Because drugs such as Depo-Provera and Norplant only temporarily sterilized women, physicians did not need to adhere to any federal regulations regarding the administration of the drugs. Freed from the burden of reporting to a federal watchdog, physicians could continue practicing medicine as they individually deemed proper.

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reflected a simple interest in documenting sterilization trends rather than attempting to prevent future sterilization abuse—an interesting focus, considering the rampant abuses of the 1970s.

[93] U.S. Commission on Civil Rights, *A Growing Crisis: Disadvantaged Women and Their Children*, (Washington, D.C.: GPO, 1983), 14 and 52.

[94] Priver, "Letter to the Editor: Sterilization Debate."

CHAPTER 3

A Shot in the Dark: Depo-Provera and Mentally Retarded Native Americans

When Congress conducted its 1987 hearing on the "Use of Drug, Depo-Provera, By the Indian Health Service" witnesses and politicians heatedly debated whether the IHS had misused Depo-Provera on mentally retarded women. Several high-ranking IHS administrators argued as administrators had done during the 1970s that physicians—not the IHS as an agency—had the ultimate right to determine how to treat individual patients. By explaining that the agency did not believe it should order physicians to practice medicine in a certain way and asserting that it trusted the discretion of individual physicians, the IHS simultaneously exonerated itself and its physicians from blame. Because the FDA had not approved Depo-Provera due to evidence of severe side effects and high cancer-causing potential, several politicians questioned whether physicians acted ethically in using the injectable contraceptive on mentally retarded women who could not understand its risks.[95]

Honorable Everett R. Rhoades, M.D., Director of the IHS, and William Haffner, M.D., Senior Clinician for Obstetrics and Gynecology, denied that any abuse of Depo-Provera occurred in the IHS because physicians effectively utilized their own medical expertise when administering the drug. "The IHS does not prescribe the use of Depo-Provera," Rhoades asserted. "This represents a practice of medicine carried out by individual physicians within the responsibility of the physician-patient relationship." The administrators then stated that the IHS only assured that patients received medical care equal to or better than the nationwide standard, not prevented physicians from prescribing certain drugs. Rhoades continued, "They [IHS physicians] . . . bear the same professional responsibility afforded to physicians in non-Indian Health Service private or group practice when deciding or recommending the appropriate use of an approved drug for an unlabeled use for an individual patient." He

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[95] Congress, House, Subcommittee on General Oversight and Investigations of the Committee on Interior and Insular Affairs, *Use of Drug 'Depo-Provera' by the Indian Health Service: Hearing before the Subcommittee on General Oversight and Investigations of the Committee on Interior and Insular Affairs,* 100th Cong., 1st sess., 6 August 1987.

trusted that IHS physicians "decided under what circumstances to use this drug . . . based upon their training and experience."[96]

While the 1970s IHS sterilization controversy occurred alongside similar national events, the 1980s debate over alleged Depo-Provera misuse reflected a series of isolated incidents. Because the FDA had not approved Depo-Provera as a contraceptive, physicians seldom promoted its use among the general population. Instead, they administered it literally "behind the closed doors" of public clinics or institutions that served mentally retarded women. Despite a lack of national context, questions raised over the IHS physicians' administration of Depo-Provera to mentally retarded women represented a critical link between sterilization and more widespread use of Depo-Provera and Norplant during the 1990s. The 1980s revealed that the attitude the IHS had displayed in promoting physician autonomy as a defense against charges of involuntary sterilization did not disappear, but actually *strengthened*, forging an ideology that would perpetuate itself throughout the 1990s. More than any other period in the story of Native-American reproductive control, the 1980s experience with Depo-Provera and mentally retarded women demonstrated a connection to the rhetoric of the eugenics movement; where eugencists had argued for sterilization of dangerously "feeble-minded" women, IHS physicians believed that they could use provider-dependent birth control to better the lives of "mentally retarded" women.

Most significantly, the Depo-Provera controversy elucidated how IHS physicians used—and arguably abused—their power, particularly in a situation where their patients could not understand the risks a drug posed to them. Because the IHS as an agency had adopted a hands-off approach to monitoring the medical practice of individuals, physicians emerged as the sole authority figure in the decision-making process to use the Depo-Provera.. Just as involuntary sterilization allowed physicians to control women's reproductive freedom, a IHS physician could use Depo-Provera to cease a mentally retarded woman's fertility for a period of time *he or she* deemed appropriate. Arguing that this could increase the potential for coercive behavior by physicians, the FDA's Center for Drugs and Biologics asserted, "the mentally retarded cannot themselves appreciate the risks and are unable to give informed

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[96] *Ibid.*, 11.

consent for the use of the drug . . . . This is a threat that people who are in essentially helpless conditions, who are captives, are going to be treated in a way that will make them nicer to look at."[97] The FDA was particularly concerned with the idea that IHS physicians, acting autonomously, could manipulate the term "medical necessity" to mean "hygienic necessity." Mentally retarded women at the mercy of these physicians could not understand or protest their suffering potentially deadly side effects in order to achieve the convenience of amenorrhea (cessation of menstruation) and contraception; instead, they had to trust that physicians carefully would determine the costs and benefits of Depo-Provera before administering it.

During the 1980s, the IHS also experienced a severe reduction in its funding, possibly offering an explanation for why physicians viewed Depo-Provera as a "convenience" that helped eliminate the need for staff supervision of menstruating mentally retarded women. The 1982 Congressional hearing, "Impact of Fiscal Year 1982 Budget Reductions on Indian Health Service," detailed how the government's decision affected IHS areas. Although areas that submitted reports did not solely focus on women's health and reproduction, hospitals most likely sought to reduce complications associated with menstruation and pregnancy that strained budgets. By promoting birth control, hospitals easily could eliminate excessive obstetrical concerns. The Rosebud Sioux Tribe submitted a report that stated how hospitals had to forgo necessary improvements in obstetrics and gynecology in order to address more immediate concerns.[98] The Nez Perce Tribal Executive Committee testified that "since the establishment of this goal, we have not witnessed any clear plan of implementation [to deal with the budget cuts]. We have experienced, on the other hand, only severe reduction in almost all categories on health services." The Chairman of the Hopi Tribe, Ivan Sidney, asserted that the $163,296 loss in the Hopi Health Department would result in a 37 percent reduction in the overall operating budget and the loss of nine filled positions. The reduction in funding for Community Health Representatives (CHRs), who supplemented regular medical staffs, most severely crippled all areas. CHRs focused on maintaining a connection

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[97] *Ibid.*, 3

with communities in order to protect Native American rights and promote awareness of critical health issues. With fewer CHRs to defend and educate their communities, Native American women surely must have been less aware of reproductive issues and the potential for *all* women to be coerced by their physicians into taking a dangerous drug.[99]

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Although Congress did not investigate the Native American experience with Depo-Provera until the late 1980s, the question of proper usage of the drug had roots in another isolated incident from the 1970s. During part of its 1973 *Quality of Health Care—Human Experimentation* hearings, Congress addressed the conflict between FDA regulations and physician autonomy involving Depo-Provera administration, articulating themes that would echo into the 1980s and 1990s. Charles C. Edwards, Commissioner of the FDA at the time, testified that he believed FDA control of medical practice would deteriorate the quality of health care Americans received: "We cannot . . . require that a physician watch a patient's condition worsen because the package insert provides for only a low dose of the drug or contains an applicable warning or contraindication. . . . We must instead increase the physician's sense of professional responsibility and judgment, not place him in a rigid mold."[100] Upjohn assumed a similar view, arguing that "every medicinal agent carries with it some risk. . . . The physician [should] inform his patient of both benefits and risks. . . . There is always a risk that some coercion may be exerted so that the consent is not freely given, so subtle as the patient's confidence in the therapeutic intent of the responsible physician."[101]

Marcia Greenberger of the Center for Law and Social Policy in Washington, D.C., argued that in exercising their autonomy, physicians often demonstrated unethical medical judgment. To explain her argument, Greenberger provided evidence from an investigation her agency had conducted of women who received Depo-Provera injections at the Family Planning Clinic of the Cumberland County Health Department (Tennessee). The Center found that physicians did not obtain informed consent, failing to warn women of Depo-

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Congress, Senate, Select Committee on Indian Affairs, *Impact of Fiscal Year 1982 Budget Reductions on Indian Health Service: Hearing before the Select Committee on Indian Affairs*, 97th Cong., 1st sess., 21 December 1982, 511.

[99] *Ibid.*, 467.

[100] *Quality of Health Care—Human Experimentation*, 16.

Provera's dangers, offer them contraceptive alternatives, or advise them that the FDA had not approved Depo-Provera as a contraceptive. Because these women did not understand Depo-Provera's side effects, they failed to gain proper treatment for the side effects when they occurred. As a result of untreated side effects, two women eventually underwent tubal ligations that resulted in permanent sterilization. Anna Burgess, one of the women forced into accepting Depo-Provera, testified that the welfare department first told her "we would rather feed one youngun than two," then sent her to the family planning clinic. There, a physician gave her Depo-Provera after performing an ordinary pelvic exam. Burgess said "from the impression I got, if I did not take birth control, they would take the [welfare] check."[102]

Greenberger also said that she learned of a similar situation at Arlington Hospital and School, a state-funded institution for mentally retarded persons in Tennessee. Edward Mogan, M.D., a physician associated with Arlington, claimed that 250 female residents were receiving the drug for contraceptive and hygienic purposes (in 1987, IHS physicians would provide identical justification for their use of Depo-Provera). He believed that Depo-Provera was effective and safe, and offered additional information that the Tennessee Public Health Department released statistics saying that the State administered Depo-Provera to between 1,000 and 1,500 women yearly.[103] Leonard Books, M.D., of the New Woman's Clinic in Washington, D.C., expressed his similar perspective that Depo-Provera usage did not represent a problem, but a solution to the "disease" of childbirth: "Tens of thousands of Tennessee women are suffering because they are not in control of their fertility. The disease is a chaotic life—a life disordered by accidental and unwanted pregnancy. . . . Our women are sentenced by inadvertent pregnancy to compulsory motherhood, to a loss of self-esteem, to denial of self-actualization and to instant poverty." When Senator Edward Kennedy questioned whether a physician should be able to place himself above the authority of the FDA, Brooks replied, "if I have the capability to uplift a person's life in some small measure, I will do it

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[101] *Ibid.*, 103. Testimony given by W.N. Hubbard, Jr., M.D., Executive Vice President of Upjohn Company.
[102] *Ibid.*, 57-59.
[103] *Ibid.*, 67

with the agents at hand."[104] Like many other physicians who practiced medicine throughout the late 20th century, Brooks wanted to help women make what he believed were positive changes in their lives. He thought that his responsibility was to determine for certain patients how the benefits of pregnancy prevention outweighed suffering often severe side effects of Depo-Provera.

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The tangled relationship among the federal government, its agencies, and its physicians often obscured accountability for alleged abuses of women who utilized services of the health care delivery system. No situation more clearly demonstrated how unethical medical discretion on the part of individual physicians could endanger women's health than the IHS physicians' administration of Depo-Provera to mentally retarded women during the 1980s. Records showed that in 1987, four service areas—Aberdeen, Alaska, Navajo, and Phoenix—used the drug on up to 80 women at each location. In Phoenix and Navajo, all but one of the women using Depo-Provera were mentally retarded.[105] By asserting that individual physicians lawfully could use their medical discretion to prescribe the drug for unapproved indications, IHS administrators refused to admit that wrongdoing at any level of the IHS had occurred. IHS physicians did not administer Depo-Provera so widely that their actions could be considered genocidal, but the 1980s still represented a critical period in the story of Native-American reproductive control; the same denial that characterized each level of the IHS during the 1970s sterilization epidemic remained present during the 1980s. While the IHS cited communication problems between the agency and its physicians as contributing to sterilizations, the IHS focused even more during the 1980s on protecting physician autonomy in the right to administer Depo-Provera.

Several politicians participating in the IHS Depo-Provera hearing sought to examine the behavior of the IHS and its individual physicians, ultimately reinforcing the belief that the IHS needed to strengthen its role as a supervisory agency and revise its policies regarding informed consent. Just as the 1976 GAO report on sterilizations faulted the IHS for failing to develop and enforce adequate safeguards against abuse, Sam Gejdenson, chairman of the

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[104] *Ibid.*, 78 and 80.

House Subcommittee on General Oversight and Investigations, asserted that he wanted to lead a discussion on the IHS's disregard of the FDA's warnings about potentially carcinogenic effects of Depo-Provera. Gejdenson presented a valid argument that the IHS should have been more active in setting adequate standards of care, but nowhere in his introduction did Gejdenson highlight the negligence of physicians in failing to consider Depo-Provera's dangers. While he suggested that the IHS erred by not properly monitoring the care its patients received, Gejdenson omitted—and arguably excused—the role of individual physicians.[106]

Evidence revealed that IHS physicians used Depo-Provera for two unapproved indications which they loosely defined as medically necessary: contraception and amenorrhea (cessation of menstruation). By arguing that "the principal advantages of Depo-Provera can be summarized in one word: convenience," Gejdenson raised the issue that physicians acted unethically in administering Depo-Provera, seeking expedience without truly considering the needs of their patients.[107] Despite his initial focus on the IHS, Gejdenson also seemed to recognize that misuse of Depo-Provera occurred because individual physicians had the unchallenged authority to determine how to treat their patients. The letter that Alan G. Waxman, M.D., Chief Obstetrician/Gynecologist of the Gallup Indian Medical Center, sent to gynecologists in his service area suggested Gejdenson's charges might have been accurate. In his letter, Waxman asserted that "contraceptive services excluding sterilization may be provided to sexually active mentally incompetent patients. . . . Depo-Provera [is the] treatment of choice when complete suppression of menses is necessary for psychological or hygienic reasons."[108] This statement revealed why Gejdenson and others who joined his side of the debate believed IHS physicians abusively administered Depo-Provera to mentally retarded women. Waxman, without detailing Depo-Provera's dangers or situations in which its use was not appropriate, encouraged physicians to administer the drug simply because it provided an easy alternative to counseling mentally retarded women and providing daily assistance with hygiene.

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[105] *Use of Drug 'Depo-Provera' By the Indian Health Service*, 30 and 36.

[106] *Ibid.*, 1. Ironically, the FDA is a companion agency to the IHS—both being under the jurisdiction of the HEW.

[107] *Ibid.*, 6.

In his testimony, George Morley, M.D., of the American College of Obstetricians and Gynecologists, suggested that ironically, the sterilization guidelines that the federal government had enacted to protect mentally retarded persons actually provided physicians with justification to use Depo-Provera. He believed that Depo-Provera could function as a kind of "temporary sterilization," since federal law forbade any physician from using federal funds to perform permanent surgical sterilization on mentally retarded women: "Depo-Provera . . . provides an alternative for those women who do not wish or cannot be sterilized," Morley testified.[109] With Depo-Provera, physicians could guarantee that a woman would not menstruate up to 31 months after her last injection, sterilizing her for more than two years.[110] Because Depo-Provera provided contraception and eliminated the problem of menstruation in one shot, Morley said he especially approved of the drug being used on mentally retarded women, who could not care for themselves properly.[111] He echoed Waxman's belief that physicians had the authority to determine whether women should suffer the side effects of Depo-Provera in order to achieve the benefit of amenorrhea.

Although Rhoades explained that "strict procedure is followed for obtaining informed consent [for the administration of Depo-Provera]," he also said that "no written policy exists [regarding informed consent for the administration of Depo-Provera]."[112] Rhoades's statement reflected the belief of the IHS administrators that because physicians had the freedom to consider carefully each patient's individual needs and therefore did not need to follow a standard procedure when obtaining informed consent (the consent forms that did exist often failed to educate patients properly; see appendix B).[113] Morley agreed with this view, claiming that although consent could be in written form, it did not *have* to be in written form; he argued that physicians could convey information just as effectively verbally as in writing. To demonstrate that as a practicing physician, he prescribed Depo-Provera for

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[108] *Ibid.*, 226

[109] The 1978 Final HEW Guidelines stated that the federal government would not provide funds to sterilize anyone under the age of 21 or anyone who was mentally incompetent or institutionalized.

[110] Although the Depo-Provera package insert has always cited the range for resumption of menstruation as 5-31 months after a woman's last injection, the Depo-Provera world wide website placed the number at 6-18 months. "About Depo-Provera: Side Effects."

[111] *Use of Drug 'Depo-Provera' by the Indian Health Service*, 145.

[112] *Ibid.*, 30

[113] *Ibid.* Of the 12 IHS service areas, only three developed a formal written consent policy.

contraceptive purposes, Morley described the oral procedure he followed to obtain informed consent. By outlining his methodology, Morley revealed that physicians accidentally or intentionally could fail to provide critical information regarding Depo-Provera. Although Morley said he told female patients about the side effects of Depo-Provera and the fact that the FDA had not approved it as a contraceptive, he did not explain *why* the FDA had not approved the drug. He did not stress that protection against STDs would need to be addressed. He said that the FDA recommended Depo-Provera for "other uses" but did not say that these "other uses" involved treatment—not prevention—of advanced uterine cancer.[114]

Not only did improper administration of Depo-Provera violate Native-American women's right to procreate and right to refuse medical treatment, but once a physician gave a woman the Depo-Provera shot, she would have to suffer devastating, if not deadly, side effects until the hormone left her system.[115] The FDA Center for Drug and Biologics asserted that "never has a drug whose target population is entirely healthy people been shown to be so pervasively carcinogenic in animals as has Depo-Provera."[116] L. Enk and his colleagues' study on Depo-Provera's effect on lipoprotein lipids concluded that Depo-Provera decreased all lipid components of the high density lipoprotein (HDL) and increased low density lipoprotein levels (LDL), which represented "independent risk factors for atherosclerosis and cardiovascular disease."[117] Because heart and liver disease and diabetes mellitus have consistently ranked among the top five causes of death in the Native American population,

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[114] *Ibid.*, 145. Generally, the consent forms that existed did not highlight critical factors that a woman or guardian would need to consider before agreeing to Depo-Provera. The Navajo consent form mentioned that the FDA did not approve Depo-Provera for birth control purposes, but did not explain why. In the same sentence that discussed Depo-Provera's lack of approval as a contraceptive, the consent form said it *had* been approved as a "medicine for treating cancer." Not only did this suggest that Depo-Provera provided cancer protection, but it failed to explain that FDA believed Depo-Provera was not a safe drug for otherwise healthy women.

[115] These side effects could last for an indefinite period of time.

[116] *Use of Drug 'Depo-Provera' by the Indian Health Service*, 2. The decisions of IHS physicians to administer Depo-Provera also violated the Hippocratic Oath, upon which every physician swears, "I will follow that system of regimen which .. . I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous. I will give no deadly medicine to anyone if asked." If Depo-Provera caused cancer, then it *was* deadly medicine.

[117] L. Enk, B.-M. Landgren, Ulla-Beth Lindberg, G. Silfverstolpe, and N. Crona, "A Prospective, One-Year Study on the Effects of Two Long-Lasting Injectable Contraceptives on Serum and Lipoprotein Lipids," *Hormone and Metabolic Research* 24 (1992): 85-89.

Depo-Provera usage presented a serious risk to these users.[118] Tim Cundy and his colleagues showed that Depo-Provera users experienced lower bone density in the lumbar spine and femoral neck than did controls, putting them at an increased lifetime risk of fracture by 30-100 percent.[119] Gary Richwald, M.D., professor at the University of California, Los Angeles School of Public Health, testified that Depo-Provera could cause serious abnormalities in a fetus, providing "strong reasons to have an abortion or otherwise risk the birth of an infant with serious anomalies.[120] Sybil Shainwald of the National Women's Health Network (NWHN) testified that in a study Upjohn conducted, one third of all women bled for more than 10 days each month. Such excessive or irregular bleeding could lead to hysterectomies or prevent diagnosis of uterine or cervical cancer (see appendix C).[121]

Furthermore, the excessive or irregular bleeding patterns women experienced while using Depo-Provera affected women emotionally and disrupted traditional practices of Native-American culture. Many women experienced depression; because their health care providers often did not explain it as a side effect, many women did not understand that the medication caused the depression.[122] Like women of other indigenous groups, Native Americans believed a woman possessed special power during her bleeding cycle, so much that she could alter the outcome of a spiritual ceremony. "Women hold the most powerful power, the life-giving forces. We've always been aware of that," explains Charon Asetoyer, founding member and Executive Director of the Native American Women's Health Education Resource Center (NAWHERC). Excessive bleeding presented a dilemma to Native American women because tradition mandated that they segregate themselves while bleeding and refrain from performing ordinary tasks such as cooking. Asetoyer claims that women

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[118] "Non-Medical Programs."

[119] Tim Cundy, Margaret Evans, Helen Roberts, Diana Wattie, Ruth Ames, and Ian R. Reid, "Bone Density in Women Receiving Depot Medroxyprogesterone Acetate for Contraception," *British Medical Journal* 303 (July 1991): 13-16.

[120] *Use of Drug 'Depo-Provera' by the Indian Health Service*, 211. In addition to these widely documented side effects of Depo-Provera, more dangers exist. In the majority of lawsuits filed against Upjohn in the 80s, the courts found Upjohn liable for damages. Courts based their decisions on the fact that Upjohn failed to warn consumers that "Depo-Provera might cause blood clots, depression, long-term infertility, and cancer...[and that] blood clots caused by Depo-Provera could travel to vital organs in their bodies including their lungs, eyes, or heart". *Use of Drug 'Depo-Provera' by the Indian Health* Service, 179.

[121] *Ibid.*, 159.

[122] *Ibid.*

who experienced excessive bleeding as a result of Depo-Provera often could not participate in certain ceremonies such as sundances or sweats and forbidden to engage in sexual activity.[123]

Testimony given in opposition to the IHS administrators focused on the idea that the behavior of individual physicians represented a greater threat to women's reproductive freedom than a lack of strict IHS guidelines regarding Depo-Provera. Recognizing the dangers inherent in Depo-Provera administration, Richwald revealed that not all physcians agreed Depo-Provera was an appropriate drug for mentally retarded women. In reference to Morley's testimony that he would only give Depo-Provera to women who were unwilling or unable to use other forms of birth control, Richwald said, "I am very concerned with the term 'unwilling', because . . . what does 'unwilling' mean? I know what 'unable' means, where you are medically unable to use something. But 'unwilling' you can basically drive a truck through." He recognized that physicians could coerce women into using Depo-Provera: " I could imagine that with the proper encouragement people who were in the beginning unwilling could certainly become willing to take a drug, and I also think that the impact of physicians in deciding ultimately what patients do . . . needs to be taken into consideration." Richwald believed that physicians needed to be sensitive to the authority they carried in a physician-patient relationship. He reminded physicians that, "we are not talking about an egalitarian relationship. We are talking about a provider and a patient, and usually there is some distance in class, race, and other between the two."[124]

Just as Constance Redbird Uri, M.D. and other women's activists in the 1970s had focused on the role of individual physicians in sterilization, the testimony of Norma Swenson, Boston Women's Health Book Collective member, reinforced the notion that the greatest responsibility for Depo-Provera misuse lay in layers beyond the top-level IHS administration. She presented the results of an international study by British researchers that revealed why physicians recommended Depo-Provera for certain types of women. The researchers found that physicians believed Depo-Provera provided appropriate medical treatment for "women who have refused sterilization, unmotivated women, unreliable or irresponsible women, stupid

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[123] Charon Asetoyer, Executive Director, Native American Women's Health Education Resource Center, interview by author, 18 October 1999.

[124] *Use of Drug 'Depo-Provera' by the Indian Health Service*, 210.

women, incompetent women, retarded women, illiterate women, problem women with problem families . . . [and] to aid in population control."[125] While this evidence reflected international attitudes, it nonetheless elucidated what may have motivated IHS physicians. IHS physicians might not have worked as puppets of the IHS, but simply acted according to their own prejudices against poor minority women, just as these international physicians did.

Television producer Karen Branan, who created the public television documentary, "The Ultimate Test Animal," testified how physicians treated women according to their race and class and presented evidence that Depo-Provera abuse went beyond mentally retarded women. Branan described her experiences in gathering information for her documentary, explaining how she posed as different women seeking information about Depo-Provera from clinics. She called six public health clinics that mainly served poor women of color; then, she called six clinics that served an opposite population—white, middle class women. Every clinic that catered to poor women encouraged her to come in for the shot and assured her that it posed no harmful side effects to her. In contrast, physicians who catered to middle class women expressed shock that "No. 1, I had ever heard of Depo-Provera and No. 2, that I would actually want to take it. My own doctor said, 'I wouldn't put that much hormone in anyone.' Another one said, 'well, it is used primarily on retarded women and women who can't take care of themselves.'" She conducted a more in-depth study in which she sent a Native American woman and a black woman into clinics carrying hidden microphones. The first type of birth control physicians offered them was Depo-Provera, even though one of the women had diabetes. Branan concluded that the "paternalism and racism" of physicians led them to believe that poor women were too ignorant to understand the concept of contraception. She believed their attitudes reflected those of the larger society, particularly the larger society's attitude toward Native Americans: "I cannot keep to myself the fact that a number of doctors who administered Depo-Provera felt the urge to offer political commentary about 'too many Indians on welfare.'"[126]

In addition to calling clinics, Branan had women of color schedule appointments with physicians; she wanted to understand how physicians reacted face-to-face with patients.

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[125] *Ibid.*, 134.

Branan sent a woman with a hidden microphone to St. Paul Ramsey Medical Center, the major provider of Depo-Provera in the Twin Cities. The conversation between a physician and this woman revealed how physicians assumed a convincing tone, creating an atmosphere in which women could not dare challenge his authority. In explaining to this woman that the FDA had not approved Depo-Provera, he asserted that "we [meaning he and his colleagues] think it is stupid. I conversationalize with the people at Upjohn about Depo because we are sort of a mutual admiration society. We both think it is so great for birth control." He and other physicians that women recorded also explained away rumors of cancer in beagle dogs as insignificant and misleading, saying that if a problem really existed, the FDA would have notified them.[127] In making such statements, physicians led women to believe that because the FDA maintained such a close relationship with the medical establishment, physicians functioned as the women's only appropriate source for information. This situation allowed physicians to manipulate facts in order to suit *their* agenda, not meet the needs of the individual women they treated.

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Although the Depo-Provera controversy represented an isolated incident in the nationwide history of reproductive control, attitudes that IHS employees displayed when discussing the drug's use on mentally retarded women remained present in subsequent decades. IHS employees continued to promote the idea that individual physicians—not the IHS as an agency—should have the authority to determine the most therapeutic treatment for individual mentally retarded patients; physicians and nurses strongly believed that their medical expertise allowed them to understand how the benefits of Depo-Provera outweighed potentially dangerous side effects a user may have suffered. Dorothy Meyer, CNM, an IHS employee since the late 1960s, watched the transition in emphasis from sterilization to long-term hormonal contraceptives, and believes that Depo-Provera especially benefited mentally retarded women who used it. Unlike sterilization, Depo-Provera could provide contraception *and* amenorrhea, helping a woman maintain her hygiene. Meyer explains, "women can easily be administered the shot four times a year...[For a mentally retarded woman] who

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[126] *Ibid.*, 199.

wears her pad on her head and runs around with bloody hands while she has her period, Depo-Provera allows the girl freedom to not have her period." Meyer also claims that hormonal contraceptives can protect woman from unwanted pregnancy without rendering her totally infertile. "You haven't lived until you've seen a young [mentally retarded] lady who has been raped," Myer explains. "Her mentality is that of a five year old, you're trying to deliver her baby, and she has no idea what is going on."[128]

Not only did IHS nurses and physicians continue to cite mentally retarded women as appropriate candidates for Depo-Provera, but they also believed that they could use the drug to improve the lives of mentally competent women during the 1990s. Meyer asserts that Depo-Provera helped Native-American women because they were not "being subjected to having more babies than they really want." She also thinks that because Depo-Provera users stopped menstruating and only needed to "walk into a clinic four times a year" to prevent themselves from having an unintended pregnancy, the drug provided an especially good options for often "irresponsible" teenagers. Meyer's comments and the actions of physicians once the FDA approved Depo-Provera for contraceptive purposes raised the same issues present in the debate over Depo-Provera's use on mentally retarded women. Although physicians and nurses such as Meyer acted altruistically in touting the benefits of Depo-Provera, they often failed to recognize that they unintentionally could control the reproductive freedom of Native-American women. Because they held authority as medical professionals, they needed to act particularly sensitively in properly educating their patients about the risks of drugs such as Depo-Provera; they also needed to be aware of their intentions in administering the drugs to mentally retarded women who could not understand potentially adverse side effects. If physicians stopped to reconsider the risk of prescribing Depo-Provera simply for hygienic purposes, they may have realized that better alternatives existed.

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[127] *Ibid.*, 200.

[128] Dorothy Meyer, CNM, interview by the author, 2 November 1999. Meyer is the Maternal Child Health Consultant at the Phoenix Area IHS headquarters.

CHAPTER 4

"It's About Pregnancy Prevention Altogether": Depo-Provera and Norplant in the 1990s

Just as physicians applauded the social benefits of female sterilization techniques in the 1970s, physicians practicing at IHS facilities in the 1990s believed that Depo-Provera and Norplant could enhance the ability of health care providers to offer comprehensive services and better the lives of Native American women.[129] Timothy Ryschon, M.D., Clinical Director of a South Dakota IHS hospital, opposes strict regulation of Depo-Provera and Norplant distribution in the IHS.[130] He argues that Native American patients can rely on the medical discretion of their physicians to assure that they receive proper care. "Only about one percent of medical practice is proven by scientific studies, and therefore only one percent can be driven by some kind of protocol," he claims. Because the other 99 percent of medical practice involves physician judgment and training, Ryschon asserts, "you can't force a physician into a certain way of treating patients or deny their ability to exercise their judgment. IHS physicians practice medicine as though they were in a private office. They all have their own style and relationship with patients, so no one answer is necessarily right."[131]

Ryschon's colleagues echo his perspective that IHS clinic workers could play a central role in expanding Native-American women's reproductive freedom. Dorothy Meyer, CNM, argues that agency-wide monitoring of Depo-Provera and Norplant would depersonalize the way IHS physicians practice medicine. "The more people try to control clinical judgment, the worse things are going to be. Because of technology, we are losing our ability to think. We need to prevent that," she explains. Meyer believes that by "thinking" and responding to the social conditions of Native Americans, physicians can utilize Depo-Provera in a positive manner. "The Chairpeople of different tribes want women to have babies. But when you [an IHS employee] look at a poor mother with five babies, and she's 20 years old, and she doesn't want any more babies, you have to give her options. The poverty cycle makes it hard to remember to take that pill [oral contraceptives] everyday,"

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[129] The FDA approved Norplant in December 1991; after more than 30 years of denying Upjohn's requests, the FDA finally approved Depo-Provera as a contraceptive in October 1992.

[130] The Rosebud Hospital, located in Rosebud, South Dakota, is part of the Rosebud Service Unit in the Aberdeen Service Area. Ryschon is the Clinical Director of the Rosebud PHS Indian Hospital Rosebud Service Unit.

Meyer warns.[132] In an article that documented how Depo-Provera usage had surpassed traditional oral contraceptives in popularity among women on several southwestern reservations, Cheryl Case, R.N., of the Lac du Flambeau service area, articulated her belief that provider-dependent Depo-Provera represented the best contraceptive option for young Native Americans. She claimed that "teenagers make the best candidates for Depo, since they have difficulty taking pills everyday. Very young women are having too many babies, too fast. A baby in a woman's body takes what it needs, including calcium from bones and necessary nutrients."[133]

Prior to the FDA's approval of Depo-Provera as a contraceptive, charges of Depo-Provera misuse surfaced only in isolated incidents such as the 1987 Congressional hearing addressing mentally retarded Native American women. But once physicians openly could promote Depo-Provera, along with Norplant, as birth control for *all* women, the potential for abuse multiplied. The endorsement of these drugs among politicians, government agencies, and physicians often obscured the idea that health care providers such as Ryschon, Meyer, and Case could restrict rather than expand their patients' reproductive freedom. Inevitably, IHS physicians responded to urgings that they could use their authority to better the lives of individual women and the society at large, almost believing that in an era of sky-rocketing welfare costs and increased fascination with technology, Depo-Provera and Norplant represented a panacea for societal ills. And because sterilization remained a popular form of birth control among American women through the 1980s and 90s, physicians quietly administered Depo-Provera and Norplant to their poor patients without drawing widespread criticism.[134]

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[131] Timothy Ryschon, M.D., interview by the author, 29 October 1999.

[132] Meyer, interview.

[133] Julie Buckles, "I Want a New Drug—to Prevent Pregnancy," *Lac du Flambeau News* (December 1994): 16-17.

[134] The Allan Guttmacher Institute reported in 1998 that 27.7 percent of contraceptive users (10,727,000) relied on sterilization as their form of birth control. Nearly that number, 26.9 percent (10,410,000), used birth control pills. Three percent (1,146,000) used the injectable; 1.3 percent (515,000) used the implant. This trend began in the mid-1970s, when use of oral contraceptives declined for the first time ever. Analysts attributed this to the rise in sterilizations. For more information, see *The Depo-Provera Debate*, 369; Congress, Senate, Subcommittee on Aging, of the Committee on Labor and Human Resources *Women's Health Care in the President's Health Care Plan: Hearing before the Subcommittee on Aging*. 103rd Cong., 2nd sess., 9 March 1994, 49. Jeannie Rosoff of the National Women's Health Network (NWHN) testified that 48 percent of women in the United States were sterilized at that time; and Linda J. Piccinino and William D. Mosher, "Trends in Contraceptive Use in the United States: 1982-1995," *Family Planning Perspectives* 30, no. 1 (January/February 1998): 4-10.

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Although long-term hormonal contraceptives appear to pose less of a threat to women than the rampant sterilizations during the 1970s did, feminist historians, legal scholars, and the medical establishment nonetheless have generated a debate over whether the use of these contraceptives represents a continuing trend to restrict reproduction among certain groups of women. Aided by the activism of civil rights organizations, the scholars have sought to explain how Depo-Provera and Norplant can eliminate poor women's ability to exercise control over their own reproduction.[135] While the scholars and activists engaged in the discussion often do not consider the specific role of physicians, they generally argue that measures aimed at preventing overpopulation in third world countries and among African Americans and Mexican Americans represent racist and sexist policies. Their work signals a response to the rhetoric of early feminism, which often failed to consider that advocating unrestricted contraceptive access for middle-class women could harm poor women. The scholars want to prove that birth control proponents cannot push for increased access without simultaneously ensuring that women have the opportunity to make informed choices in an environment free from coercion.

The work of Betsy Hartmann, Barbara Mintzes, and Dorothy Roberts represents the first extensive efforts at explaining why certain groups of women used Depo-Provera and Norplant against their wills. In *Reproductive Rights and Wrongs,* Hartmann approaches the debate from an international perspective, tracing how Depo-Provera and Norplant fit into the population control movement and other reproductive issues such as abortion; she explains how support for reproductive control has grown out of the Western myth that unrestricted procreation among women in densely populated countries will lead the world to self-destruct,

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[135] The National Women's Health Network, the American Civil Liberties Union Reproductive Freedom Project, the National Organization for Women Legal Defense and Education Fund, argued particularly fervently against mandatory Norplant or Depo-Provera for welfare mothers. The ACLU reflected the views of all three organizations when it asserted, "men are not punished for child abuse or substance dependency with vasectomies or mandatory birth control. Nor are vasectomies often proposed as a condition of eligibility for initial or increased public assistance for men." The organization said that using Norplant as a condition of sentencing or welfare benefits was unconstitutional because "it violate[s] the constitutional right to reproductive and bodily autonomy. The incentive plans . . . are coercive. Particularly for low-income women, the offer of money to feed, clothe, and house their families . . . may be difficult to refuse." American Civil Liberties Union, "Norplant: A New Contraceptive with the Potential for Abuse," http://www.choice.org/2.norplant.2.html, 9 September 1999.

as Paul Ehrlich's *Population Bomb* prophesizes.[136] Although reports contained in Mintzes's compilation of field research from several countries, *Norplant: Under Her Skin,* do not explain Norplant in the context of the entire population control movement, they reach the same conclusions as Hartmann about coercive tactics that population control organizations use to restrict women's reproductive rights.[137] Roberts focuses on African Americans, explaining that institutionalized prejudice against their race provides justification for scapegoating poor African-American mothers. She blames the paradox of technology for aiding racists in carrying out their plans: "It is assumed that developing novel reproductive technologies necessarily constitutes progress. . . . But it is not true that every new form of birth control will ultimately benefit women just because it is more effective at preventing pregnancy."[138] Adding a unique dimension to the debates of these feminist historians, legal scholars seek to explain why implanting poor minority women with Norplant violates their constitutional rights. They focus their attention on Norplant's use as a widespread tool of public policy in the intersection between law and medicine.[139]

The *Journal of the American Medical Association* leads the medical establishment's role in the debate over long-term hormonal contraceptives, asserting in its April 1992 Board of Trustees Report that mandatory or coercive use of Depo-Provera or Norplant does not demonstrate an appropriate social response to the problem of child abuse or "excessive child-bearing." It explained that "cultural and other bias" could influence the relationship between physician and patient, forcing women to make decisions "in environments that lack procedural safeguards."[140] Foundations dedicated to examining the health of minority

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[136] Betsy Hartmann, *Reproductive Rights and Wrongs: The Global Politics of Sickness* (Boston: South End Press, 1995); Paul R. Ehrlich, *Population Bomb* (New York: Ballantine Books, 1968).

[137] Barbara Mintzes, Anita Hardon, and Jannemieke Hanhart, eds., *Norplant: Under Her Skin* (The Netherlands: Eburon, 1993).

[138] Dorothy Roberts, *Killing the Black Body: Race, Reproduction, and the Meaning of Liberty* (New York: Vintage Books, 1997), 148.

[139] Sarah Gill, "Discrimination, Historical Abuse, and the New Norplant Problem," *Women's Rights Law Reporter* 16, no.1 (Fall 1994), 43-51; Meredith Blake, "Welfare and Coerced Contraception: Morality Implications of State Sponsored Reproductive Control," *University of Louisville Journal of Family Law* 34, no. 2 (1995-96): 311-344; Wendy Chavkin and Vicki Brietbart, "Reproductive Health and Blurred Professional Boundaries," *Women's Health Issues* 6, no. 2 (1996), 89-96.

[140] Board of Trustees, "Requirements or Incentives by Government for the Use of Long-Acting Contraceptives," *JAMA* 13 (11 Nov 1992): 267. Similar perspectives can be found in M.S. Thomspon, "Contraceptive Implants: Long Acting and Provider Dependent Contraception Raises Concerns about Freedom of Choice," *BMJ* 313 (30

groups have investigated why abuses might occur, but specifically strategize how the medical establishment can prevent or remedy problems. The Kaiser Foundation conducted an international forum on the subject, emphasizing the need to institute clear informed consent guidelines and educate physicians about the needs of poor patients.[141] After a *Philadelphia Inquirer* investigative report sparked controversy when it suggested Norplant could be used to reduce the welfare burden that developed from overpopulation among the lower classes, Sheldon Segal, the Population Council medical researcher who created Norplant, asserted that "Norplant was developed to improve reproductive freedom, not to restrict it. . . . I believe that women should be able to have the number of children they want, when they want to have them. Not just educated and well-to-do women, but all women."[142]

The historiography dealing with coercive use of Depo-Provera and Norplant is developing alongside events themselves, so many dimensions of the debate remain unexplored—particularly how the eugenics movement coalesces with current discussion about forced contraception. Feminist historians, legal scholars, civil rights organizations, and members of the medical establishment effectively argue that debate over Depo-Provera and Norplant needs to look beyond biomedical aspects to the relationships among people and societal attitudes toward poor women of color. However, some theories on *why* and *how* abuses of reproductive rights occur need reconsideration. Roberts argues that white politicians systematically have persecuted African-American women in order to perpetuate the status quo. While this attitude certainly exists at some levels, a careful examination of the physician-patient relationship and how physicians ultimately carry out contraceptive practices reveals a more complicated story. The Native-American women's experiences with physicians, a perspective that the current political and scholarly debate entirely overlooks,

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November 1996), 1393-96; and S.G. Post, "Implantable hormonal contraceptives: emerging controversy," *Obstetrics and Gynecology* 84, no. 6 (December 1994): 1055-7.

[141] Barbara Feringa and Sarah Iden and Allan Rosenfeld, "Norplant: Potential for Coercion." In Samuels, 63.

[142] Sheldon Segal, "Norplant Developed for All Women, Not Just the Well-to-Do," *New York Times,* 6 January 1991, sec. A, p. 18; Donald Kimelman, "Poverty and Norplant: Can Contraception Reduce the Underclass?" *Philadelphia Inquirer,* 12 December 1990, sec. A, p. 18. The Population Council, which developed Norplant, articulated similar opposition to coercive use of Norplant. In its statement of support for informed consent and voluntary contraceptive use, the Population Council affirmed, "the principle that the adoption of contraception should always be a voluntary, informed choice, and with the decision made by the client whether to use contraception, which method to use, when to use it, and when to stop or try another method." Population

elucidates how reproductive control can occur so subtly that physicians actually believe they are helping women by forcing contraception upon them.

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When Congress held its 1994 hearing on the "Impact of the High-Cost of Long-Term Contraceptive Products on Federally Sponsored Family Planning Clinics, Welfare Reform Efforts, and Women's Health Initiatives," it ignored the complicated issue that although poor women needed the same access to birth control as other women, the poor could also fall victim to coercion by physicians. At the time of the hearing, Norplant and Depo-Provera were so expensive that Title X clinics could not provide the drugs to poor women ineligible for welfare.[143] Judith M. DeSarno, President and CEO, National Family Planning and Reproductive Health Association (NFPRHA), testified that Norplant and Depo-Provera were "superior methods" to oral contraceptives, but if clinics offered Depo-Provera and Norplant, then they would have to make a simultaneous reduction in the total number of women to whom they provided services. Because 57 percent of United States births were unplanned in 1993, she wanted to offer these long-term contraceptives to large numbers of women as a way of reversing the trend.[144] Chairman Ron Wyden also promoted the idea that access to contraceptives gave poor women new hope for the future:

Council, "A Population Council Affirmation on Quality: Contraceptive Options and Informed Choice" (December 1990). Available from the Population Council, One Dag Hammarskjold Plaza, New York, New York 10017.

[143] Although Medicaid provided $53 million of the 56.5 million (94%) in federal funds spent for the provision of Norplant in 1992, many clinics could not afford to offer the implant at reduced costs for women who did not qualify for Medicaid. Of the 50 states, District of Columbia, and 12 Indian Health Service Area offices studied, no state Medicaid agency made provisions to cover removal for women who became ineligible for Medicaid. "6 in 10 Family Planning Agencies Did Not Offer the Contraceptive Implant Almost Two Years After FDA Approval," Newsbrief, The Alan Guttmacher Institute (15 February 1994). "Norplant: Opportunities and Perils for Low-Income Women" (New York: Alan Guttmacher Institute, 1993), 2. Available from AGI, 120 Wall Street, New York, New York 10005.

[144] Congress, House, Committee on Small Business, Subcommittee on Regulation, Business Opportunities, and Technology, *Impact of the High-Cost of Long-Term Contraceptive Products on Federally Sponsored Family Planning Clinics, Welfare Reform Efforts, and Women's Health Inititives: Hearing before the Comittee on Small Business, Subcommittee on Regulation, Business Opportunities, and Technology,* 103rd Cong., 2nd sess., 18 March 1994, 67-69. NFPRHA is a nonprofit organization founded to expand and improve on the delivery of voluntary reproductive health care to all women. It represents all the family planning providers in the country, including most Title X grantees. Also see Jacqueline Darroch and Lisa Kaeser, "Questions of Balance: Issues Emerging from the Introduction of the Hormonal Implant," *Family Planning Perspectives* 25, no. 3 (June 1993): 127-132; Stanley K. Henshaw, "Unintended Pregnancy in the United States," *Family Planning Perspectives* 30, no. 1 (January/February 1998): 24-29; and Congress, House, Subcommittee on Regulation, Business Opportunities, and Technology of the Committee on Small Business, *Impact of the High-Cost of Long-Term Contraceptive Products on Federally Sponsored Family Planning Clinics, Welfare Reform Efforts, and Women's*

> Ensuring that women have access to safe, affordable contraceptives can in fact, promote individual responsibility and at the same time ensure that women have the means to succeed. Welfare families get bigger in part because birth control is not available and often fails the mothers of our country. Setting up financial disincentives to having more children won't do the job. Women need health care services that allow them to gain new control over their lives.[145]

Wyden focused on the economic benefits of creating widespread access to contraceptives among poor women. He argued that "one of the most important investments" the government could make would involve providing contraception to young women so they would finish school rather than become pregnant and seek welfare benefits.[146]

The movement to increase access eventually met success, translating political rhetoric into a genuine opportunity for physicians to provide poor women with long-term hormonal contraceptive options. The Norplant Foundation, which Norplant's manufacturer, Wyeth-Ayerst, established in January 1992, largely aided the efforts; the Foundation would provide the implant to women who had no private or public insurance and lived 185 percent below the poverty level. In the late 1990s, after Norplant and Depo-Provera had been on the market for more than five years, the Allan Guttmacher Institute released its findings that women with a household income below 150 percent of the federal poverty level were almost twice as likely to use the injectable contraceptive as those with a higher income, and about three times as likely to use the implant. The government rate for Norplant had dropped from more than $500 per insert at the time of Norplant's FDA approval to $273 per insert in 1999; federal subsidies would enable public clinics to purchase Depo-Provera at $20 per shot. Thus, with little reservation about high costs, clinics could promote these provider-dependent contraceptives as superior methods to user-compliant contraceptives such as birth control pills.[147]

Contributing to the attitude that poor women needed equal contraceptive access, but turning the discussion in a new direction, several politicians expressed their idea that Norplant

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Health Initiatives: Hearing before the Subcommittee on Regulation, Business Opportunities, and Technology of the Committe on Small Business, 103rd Cong., 2nd sess., 18 March 1994.

[145] *Ibid.*, 41.

[146] *Ibid.*, 41-43. Wyden established support for the government to purchase these contraceptives in bulk, fund research to increase the number of contraceptives and therefore spur competition, and use its "bully pulpit and moral suasion" to influence drug companies.

[147] "Contraceptive Use: Facts in Brief."

be mandatory for welfare mothers.[148] In January 1993, Maryland Governor William Schaefer used his seventh annual State of the State address to propose what he admitted was a "extreme" measure that women use Norplant "if they're on welfare and have a certain number of illegitimate children." Just after his election as mayor of Washington, D.C., in November 1994, Marion Barry told the *Washington Post* that he could reduce government spending and "empower" teenage welfare mothers by mandating birth control such as Norplant to prevent future pregnancies: "[If] you want the government to continue to take care of you and those that may be coming, then I think the government ought to impose that [mandatory Norplant]. Now if you don't want the government in your business then you don't have to ask for money." In May 1991, California governor Pete Wilson considered a law that made Norplant mandatory for welfare mothers and made it free for women receiving Aid to Families with Dependent Children (AFDC) benefits.[149] Their opinions had a far-reaching impact; in June 1994, 12 state legislatures had introduced 21 measures involving financial incentives or mandatory use of Norplant. Although no legislature ever enacted the bills, the intensifying debate raised ethical considerations regarding the authority of government to force women into using long-acting contraceptives.[150]

Both activists and ordinary citizens supported the attitude of politicians, proving that many Americans believed reproductive control provided a solution to social problems. After adopting four children from the same drug-addicted mother, Californian Barbara Harris founded the organization CRACK (Children Requiring a Caring Kommunity), which offered

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[148] While President Bill Clinton did not join directly in the Norplant debate, he did contribute to the focus on welfare mothers. Although Congress ultimately failed to approve Clinton's proposals for universal health care in 1994, Clinton did succeed during his first term in eliminating Aid to Families with Dependent Children (AFDC) benefits. While Democrats in opposition to Clinton argued that his "welfare-to-work" reform would put undue stress on mothers already set to lose financial support for their children, Republicans praised Clinton's efforts as a positive step in discouraging poor women from having additional children. Elizabeth Shogren, "Clinton Accepts Broad Welfare Changes as 'Last Best Chance,'" *Los Angeles Times,* 1 August 1996, sec. A., p. 1.

[149] "Reflections of Marion Barry; The DC May-Elect on Welfare, Sex, Hillary Clinton, and Family Values," *The Washington Post*, 20 November 1994, sec. C, p. 4; Charles Babington and Richard Tapscott, "Schaefer Talks Tough on Welfare; Forced Birth Control Measures Suggested," *The Washington Post*, 15 January 1993, sec. A, p. 1; Daniel M. Weintraub and George Skelton, "Wilson Favors Use of Birth Control Implant; Family Planning: Governor Hopes to Make Norplant Device Widely Available to Teen-Agers and Drug Users," *Los Angeles Times*, 17 May 1991, sec. A, p. 1.

[150] Nine states sought to offer a cash bonus to female inmates or women receiving public assistance; five sought to mandate Norplant for pregnant drug users or child abusers. "Norplant: Opportunities and Perils for Low-Income Women, Special Report #3," (New York: Alan Guttmacher Institute, 1994), 4. For more information about state bills on Norplant, see *State Reproductive Health Monitor: Legislative Proposals and Action* 5, no. 2 (May 1994).

cash incentives for drug-addicted mothers to undergo surgical sterilization or take long-term, provider-dependent birth control. Based in Southern California, CRACK generated nationwide publicity through its website, www.cracksterilization.com, and billboard ads ("If you're addicted to drugs, get birth control—get $200 cash"), boasting that women in California, Florida, Illinois, Minnesota, Pennsylvania, New Hampshire, and Michigan had accepted CRACK's financial deal. Harris claimed that she gained inspiration for CRACK from her children's birth mother: "'I thought, 'Here's this irresponsible woman walking around having babies yearly, and she can do that just because she has a right to get pregnant.''"[151] A May 1991 *Los Angeles Times* poll revealed that 60 percent of people surveyed thought that courts should mandate Norplant for drug abusers and make the drug easily available to teens. Other Californians echoed this belief by arguing that Norplant did not infringe on women's rights because it only would be used "to ensure she not have another [child] as long as she and the child are the responsibility of the state." One editorial writer concluded that Norplant could only improve a woman's life: "The required use of Norplant is not a punishment; it is a way to give poor women a chance to break the cycle of poverty for themselves and their children."[152]

Although the medical establishment did not express extensive support of mandatory Norplant and often outright opposed it, some physicians and researchers presented arguments that reflected attitudes similar to those of politicians. Abbey Berenson, M.D., and Constance Wiemann, Ph.D., questioned young women about their satisfaction with Norplant inserts and strongly concluded that adolescents tolerated the implants very well—apparently contradicting their other observations that 71 percent reported irregular bleeding and only 1 percent experienced no side effects at all. Like other proponents of mandatory long-term contraceptives, Berenson and Wiemann believed that the broad social benefits of Norplant outweighed the negative physical side effects individual women suffered. By asserting that "young adolescents were particularly suited for this method because of its long duration of

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[151] Pam Belluck, "Drug Addicts Offered Sterilization Incentive," *Austin American-Statesman,* 24 July 1999, sec. A, p. 4.

[152] Weintraub and Skelton, "The Times Poll: Most Support Norplant for Teens, Drug Addicts," *Los Angeles Times,* 27 May 1991, sec. A, p. 1; Martin Berstein, "Norplant for AFDC Mothers," *Los Angeles Times,* 12 July 1994, sec. B, p. 6; Walter A. Graham, "Norplant Can Aid Mothers," *USA Today,* 16 February 1993, sec. A, p. 10.

action and lack of dependence on patient compliance for efficacy," the authors promoted the idea that physicians could not trust young women to exercise their own control over birth control; adolescents needed to rely on their health care providers to assure that they acted appropriately in preventing unwanted pregnancies that would burden society.[153]

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The IHS world wide web homepage image, which featured a white physician standing over a Native-American woman and her child, illustrates unconsciously that when the IHS attempted to better the lives of Native Americans during the 1990s, its traditionally paternalistic attitude remained insidiously present.[154] IHS physicians continued to believe that they had a responsibility to better the lives of poor Native Americans and help the race escape what they saw as its doomed fate.[155] Despite asserting a new commitment to Native-American health after the 1970s and 1980s controversies, the 1990s ideology of the IHS continued to represent a contradiction between promises and implementation of policy, especially regarding physician autonomy in prescribing Depo-Provera and Norplant. The 1998 Reauthorization of the Indian Health Care Improvement Act stated that two of its goals were to "reduce breast cancer deaths to no more than 20.6 per 100,000 women [and] reduce deaths from cancer of the uterine cervix to no more than 1.3 per 100,000 women"; however, IHS physicians ignored evidence that Norplant and Depo-Provera caused cancer, and they still provided the drugs to Native-American women.[156] Because no national tracking system

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[153] Abbey B. Berenson and Constance M. Wiemann, "Patient Satisfaction and Side Effects with Levonorgestrel Implant (Norplant) Use in Adolescents 18 Years of Age or Younger," *Pediatrics* 92 (1993): 257.

[154] Indian Health Service, http://www.ihs.gov (22 September 1999).

[155] As public and governmental opinion revealed, indigent women faced a greater chance than middle class women to be the subject of reproductive control. This trend meant that IHS physicians often might have viewed Native Americans, of whom 31.6 percent live below the poverty level, as especially appropriate candidates for birth control. This poverty rate contrasts to 13.1 percent for the entire American population. (Today, the median annual family income for Native Americans on tribal lands or reservations is $13,700). Not only was the Native-American birth rate, 25.6 per 1000 population, 65 percent greater than the U.S. all races birth rate and 74 percent greater than the U.S. white rate, but women under the age of 20 produced 45 percent of the births. *Trends in Indian Health*, 35 and 5.

[156] 1998 Reauthorization of PL 93-437. In at least three different human studies, researchers proved that Depo-Provera increased the risk of breast cancer for women under 35. The World Health Organization reported that after four years of Depo-Provera use, a woman's risk doubled (it is interesting to note that in many of the countries where the WHO conducted its studies, the breast cancer rate was significantly lower than that of the United States). In addition, some researchers link Depo-Provera usage to cervical cancer. Ellen Chen and Charon Asetoyer, *A Review of the Use and Effects of Depo-Provera on Native American Women within Indian Health Services and Other Federal Agencies* (Lake Andes, SD: NAWHERC, summer 1995), 8. The Population Council warns that warns that

for the IHS's use of Depo-Provera existed, physicians had the opportunity to administer the drugs without the agency questioning their medical discretion. The *IHS Patient Education Protocols* Family Planning section only coded for discussion of basic anatomy, oral contraceptives, diaphragm, condoms, and sterilization—not for Norplant or Depo-Provera.[157]

The IHS Primary Care Provider, a health newsletter targeted toward IHS health care providers, demonstrated how highly the IHS regarded the opinions of physicians and gave health care providers the opportunities to influence their colleagues regarding contraceptives. The comments that physicians and nurses expressed in strong support of Norplant contradicted the IHS Reproductive Policy which stated, "IHS will neither promote nor discourage sterility or fertility. . . . Its overall policy is geared to the enhancement of life through assuring the availability of legally, ethically, and medically acceptable information and services that afford families and individuals the opportunity to assure that each child is a wanted one."[158] Michael D. Brown, R.N., began the discussion by painting an unrealistically positive picture of Norplant; rather than encouraging dialogue on the drug's strengths and weakness, Brown set a pattern for the continued one-sided praise of Norplant. He touted the drug's effectiveness, "quick reversibility," and continuation rates (patient satisfaction)—but he failed to acknowledge clearly that the research he presented reflected the experiences of women in Third World countries who often had no choice to discontinue use. He highlighted its low failure rate (75-100 times lower than that of oral contraceptives) which made it the most effective reversible method of contraception. But Brown never discussed side effects or the necessity and difficulty of obtaining informed consent.[159]

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women who have known or suspected carcinoma of the breast should not use Norplant. "Population Council NORPLANT Implants Briefing Sheets."

[157] Indian Health Service, "IHS Patient Education Protocols," wysiwyg://347/http://www.ihs.gov?M...re/ClinicalGuidelines/ProvPtEd.asp (9 September 1999). William H.J. Haffner, M.D., Senior Slinician for Ob/Gyn in the IHS told NAWHERC researcher Linda Krust that the IHS abandoned any sort of proposed tracking system for Norplant and Depo-Provera after the drugs gained FDA approval; he said they were like other contraceptives, which the IHS did not track. Linda Krust and Charon Asetoyer, *A Study of the Use of Depo-Provera and Norplant by the Indian Health Services* (Lake Andes, SD: Native American Women's Health Education Resource Center, July 1993), 13.

[158] United States Department of Health and Human Services, *Indian Health Service Manual* (Washington, D.C.: Government Printing Office, 1990), 71.

[159] Michael D. Brown, "Norplant: The Newest Reversible Contraceptive," *The IHS Primary Care Provider* 18, no. 2 (February 1993): 17-18. Brown is the Senior Clinical Nurse Specialist at the Indian School Health Center, Haskell Junior College (Lawrence, Kansas).

While Brown represented localized support for Norplant usage, IHS Senior Clinician for Obstetrics and Gynecology, William J. Haffner, M.D., expressed from an administrative perspective how "personally delighted" the availability of Norplant made him. Although his article in the *Provider* described some very basic potential side effects of Norplant, he dismissed them as "temporary." He emphasized the autonomy of physicians in making decisions about how to educate patients, suggesting that "counseling can be done individually or in a group class setting at virtually any time and the prospective user can be given the manufacturers patient information booklet to take home with her to study at her convenience" (see appendix D). This statement revealed that he failed to consider that women in the Native- American community might not feel comfortable discussing birth control in a group setting. His assumption that a woman might need *no* assistance in understanding the complicated language of the information booklet also revealed how some physicians might dismiss women's right to informed consent. Furthermore, by suggesting that women had the intelligence to comprehend medical terminology without assistance, Haffner entirely contradicted the argument that poor women were "too dumb" and acted too "irresponsibly" to use provider-compliant oral contraceptives.

Citing the high incidence of teenage and unplanned pregnancies in the Native-American population, William L. Dienst, M.D., and Louis Billedeaux, M.D., praised how the 85 women using Norplant in the Crow Service Unit enjoyed their experience. As Brown did, they emphasized Norplant's safety. They cited evidence that just as Depo-Provera had become a phenomenon among the Native-American population, so many women began requesting Norplant that they created a staff position titled "Norplant Coordinator," whose job was to maintain a waiting list and educate patients and practitioners. Dienst and Billedeaux said they gave priority to patients who recently had an abortion; sexually active teenagers with one or more children; nulliparous, sexually active teens with parental consent; females age 18-21 with multiple partners; and females in their 20s not ready for sterilization. Most significantly, the article demonstrated the connection between Norplant and sterilization. The physicians explained that one woman who could not handle the side effects of Norplant opted for a tubal ligation upon removal of Norplant, proving that Norplant could be used in place of sterilization or to achieve a similar effect to sterilization. Dienst and Billedeaux advocated Norplant for alcoholic patients, even though the liver disease present in many alcoholics could lead to toxic accumulation of levonorgestrel, Norplant's hormonal component.[160] By arguing that Native-American patients could not remember to take oral contraceptives, Dienst and Billedeaux implied that physicians should use their authority in such a situation to determine whether the side effects of Norplant would pose less of a danger to an individual than the individual did to society at large.[161]

In response to Dienst and Billedeaux's article, Eric Henley, M.D., wrote a letter to the *Provider* editor in which he advocated even wider use of Norplant. He suggested that the Crow Service Unit might have limited the availability of Norplant to women by "unnecessarily alarming" them about Norplant's side effects. Henley explained that rather than using the "alarming" product insert from Wyeth-Ayerst, the Crow Service Unit issued a consent form that simply described the procedure and confirmed that patients had read a basic fact sheet. Emphasizing that physicians played a critical role in reducing barriers to family planning, he encouraged physicians to "minimize clinic return visits for pill prescriptions by giving out more pill packs at a time; let adolescents who are reluctant to have a first pelvic exam have three months of pills without an exam in order to build a relationship that will allow the completion of the exam at a later date . . . and increase . . . accessibility to the 'morning-after-pill'."[162] Henley's suggestions for liberalizing access to contraception contained an inherent paradox that increasing Native American women's freedom might have also threatened their overall health and relationship with their physicians. If physicians used their authority solely to advocate birth control, then they would seek to achieve one goal—reducing pregnancies—rather than consider potentially dangerous side effects that long-term hormonal contraceptives posed to these women.

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[160] The Population Council warns that women with acute liver disease should not use Norplant. "Population Council NORPLANT Implants Briefing Sheets."

[161] William L. Dienst M.D., and Louis Billedeaux, M.D., "Subdermal Contraceptive Implants in the IHS: The Crow Service Unit Experience," *The IHS Primary Care Provider* 18, no. 2 (February 1993): 20-31; William H.J. Haffner, M.D., "Norplant: Comments from the Senior Physician," *The IHS Primary Care Provider* 18, no. 2 (February 1993): 19. Dienst and Billedeaux practice at the PHS Indian Hospital, Crow Agency (Montana).

[162] Eric Henley, M.D., "Letter to the Editor: Norplant Implants," *The IHS Primary Care Provider* 18, no. 6 (June 1993): 117. Henley is the IHS Albuquerque Area Maternal Child Health Consultant.

Because Depo-Provera and Norplant share the same primary hormonal component, progesterone, they pose similar side effects to users (see appendix E). The specific health concerns of Native-American women, particularly their problems with liver disease and diabetes, make these drugs a particularly inappropriate choice for them. J.C. Konje concluded that one of Norplant's most significant dangers involves its ability to alter carbohydrate metabolism and increase the chances that women predisposed to diabetes eventually could develop the disease.[163] Like Depo-Provera, Norplant severely disrupts bleeding patterns; American Health Consultants reported that almost 75 percent of women who discontinued Norplant did so because of problems with irregular bleeding.[164] Researchers at the Native American Health Education Resource Center (NAWHERC) proved that because women who use Depo-Provera or Norplant do not deal with a threat of pregnancy, they are less likely than other women to use condoms, which provided protection against sexually transmitted diseases (STDs).[165] Condoms provide particularly necessary protection for Depo-Provera users, as studies of the drug have proven that it affects immune system function, making the user less able than a person not using the hormones to fight off the diseases with which they may have come in contact.[166]

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In February 1999, the Native American Women's Health Education Resource Center conducted a focus group of women (ages 18-37) from the Aberdeen area of South Dakota, North Dakota, Iowa, and Nebraska; it represents the most recent commentary on the subject of Native-American reproductive health. The discussion elucidated how Native American women viewed contraception from an entirely different perspective than IHS physicians,

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[163] J.C. Konje, "Effect of Continual Subermal Levonorgestrel on Carbohydrate Metabolism," *American Journal of Obstetrics and Gynecology* 166 (1992): 15-19.

[164] American Health Consultants, "Arrival of Norplant May Be Bittersweet for Clinics," *Contraceptive Technology Update* 12, no. 1 (January 1991): 33-35. In a multi-national study, some Norplant users reported bleeding for twenty days per month; others did not menstruate for the duration of the implant, but menstruated two times per month after discontinuing use. Giselle Garcia and Solange Dacach, "Norplant—five years later [Brazil]," in Mintzes, 73.

[165] Natasha Lewry and Charon Asetoyer, *The Impact of Norplant in the Native American Community* (Lake Andes, SD: Native American Women's Health Education Resource Center, June 1992), 15. Of the women the NAWHERC surveyed in this study, only 54% maintained a monogamous relationship and *no* women—monogamous or not—used condoms.

[166] *Trends in Indian Health,* 122. In Native-American communities, where the AIDS rate in 1994 was 7.8 times the rate in 1987 and STDs reached epidemic levels, women not using condoms faced greater risks than ever.

pointing to breakdowns in communication that threatened their reproductive freedom. Those who had sought care in various service areas found that inconsistencies existed among the personnel of different facilities; some physicians provided thorough examinations without rushing, while most failed to answer women's questions regarding reproductive health to explain birth control options. One woman told of her experience in realizing that an IHS "physician" who had treated her did not even possess a medical degree; another lamented that although she had lived in the same area her entire life, she never saw the same physician because the IHS experienced such rapid turnover in personnel. Three women agreed that IHS staff members continually breached confidentiality issues when they gossiped about pregnancies and left medical charts open on the counter where other patients checked in. One explained, "I went into the clinic. I was 23, and I found out that I was pregnant, and by the next day, so did all of Eagle Butte. That pissed me off. I could not believe it. I was still trying to accept the fact that I was pregnant."[167]

The discussion revealed that physician autonomy in acquiring informed consent often proved troublesome to women who felt their physicians did not properly educate them about Depo-Provera and Norplant. Thirty-two times during the session, women discussed their frustration with the lack of information they received from their providers; about half of the complaints involved birth control. Frequently, women made comments such as: "They gave me pamphlets, but only after I started asking questions. . . . I don't think I've ever gone to one place where they've sat down and told me every option available. It seemed like they've always picked what was the contemporary thing at the time, whether it be the shot . . . or Norplant."[168] Only three women recalled signing a consent form before accepting specific contraceptive treatment, and those who did believed that they did not acquire proper education about dangerous side effects. Although the *Provider* suggested that allowing women to take pamphlets home provided effective counseling, the women expressed their opinion that often, physicians never gave them the pamphlets. One woman asserted, "I've never gotten a pamphlet I could take home and read at my leisure and be on the lookout for

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[167] Native American Women's Health Education Resource Center, *Focus Group Report Examining the Indian Health Service's Reproductive Health Care for Native American Women in the Aberdeen Area,* (South Dakota: NAWHERC, 1999), 13-15.

and be able to say, 'Oh, I am experiencing these side effects . . . so I'm stuck out there in limbo."[169]

Implying that physicians took advantage of the trust placed in them, these Native-American women reported that IHS physicians especially adopted a casual attitude when administering Depo-Provera. Because the Native American custom of respecting Elders and professionals discouraged these females from asking questions, physicians encountered many opportunities to assume unchallenged authority regarding birth control. One woman explained that "growing up in the IHS, you never realize that it's okay to question, that it's okay to be more informed and that more [information] exists." Another agreed, remarking, "They [at the clinic] make it seem like we are inconveniencing them by coming to the doctor or the clinic. . . . It's like they don't care, so you don't care, so they don't care."[170] Often, physicians only gave women a pamphlet that Upjohn developed, not the package insert. One woman said the pamphlet "makes it [Depo-Provera] sound all nice." "*And* convenient," another woman added. She explained that as soon as she suggested that she might want the shot, the physician gave it to her without warning her of the side effects. Twenty five percent of the women said they had never been counseled about side effects of their contraceptive devices.[171] This demonstrated the danger in having no regulations mandating that physicians properly discuss the side effects of Depo-Provera or Norplant or that physicians offer other contraceptive alternatives.

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Throughout the 1980s and 1990s, Native-American activist groups and individuals followed the inspiration of leaders such as Constance Redbird Uri, M.D., in articulating their claims that IHS physicians continued to control female reproduction through Depo-Provera and Norplant. Many of these activists charged that these birth control methods represented a

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[168] *Ibid.*, 10.

[169] *Ibid.* Despite the fact that physicians potentially could coerce poor women of color into using Norplant, Wyeth-Ayerst initially resisted FDA suggestions to mandate consent forms. For four years, Wyeth-Ayerst defended its decision not to require consent by saying that consent forms often triggered women to worry unnecessarily about a "safe" drug. But because the FDA received more than 6,500 reports of adverse side effects from Norplant during its first five years on the United States market, women *did* have good reason to worry; Wyeth-Ayerst eventually complied. Keith Epstein and Bill Sloat, "Norplant distributor agrees to consent forms," *Plain Dealer,* 29 July 1995, sec. A, pp. 1 and 8.

[170] *Ibid.*, 12-13.

new form of IHS sterilization. Charon Asetoyer, Executive Director of the NAWHERC, argues that "family planning for the IHS has meant sterilization, and it has meant various methods in which to reduce a woman's pregnancies. It hasn't necessarily provided services to women who can't have children. It's not about child spacing. It's about pregnancy prevention altogether." Because drug developers did not intend for hormonal contraceptives to sterilize women permanently—though their side effects accidentally may cause infertility—Asetoyer believes that IHS physicians could administer the drugs without facing criticism. "Once a woman uses one of them [Norplant or Depo-Provera], she has no control. She is at the mercy of her health care provider. Sterilization is not just a permanent act. We need to reeducate ourselves about that and broaden the definition to 'interim sterilization.'"[172]

Along with the NAWHERC, the Minnesota Indian Women's Resource Center has led the movement to encourage activism, particularly among Native-American women. The Minnesota center promotes the idea that "the path to recovery is within all women. . . [the Center will] assist American Indian Women so they can enjoy a better quality of life for themselves and their families."[173] Although both resource centers have used group therapy sessions, individual counseling, and community meetings to address issues such alcoholism, domestic violence, and AIDS, they have always focused heavily on reproductive rights.[174] By publishing three reports on Depo-Provera and Norplant, the NAWHERC hopes to inspire more extensive governmental investigation of the alleged abusive behavior of IHS physicians in prescribing the drugs to Native-American women.[175] The NAWHERC and Minnesota Indian Women's Resource Center also wants to use reports to encourage dialogue among Native-American women and establish a modern-day sisterhood that once existed so strongly in traditional culture. Asetoyer believes that giving women voice among their peers would translate into their increased confidence with IHS physicians. She explains that encouraging

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[171] *Ibid.*

[172] Asetoyer.

[173] Minnesota Indian Women's Resource Center, "Homepage," http://www.nnic.com/miwrc/MIWRCprograms.html (9 September 1999).

[174] For more information about NAWHERC programs, see gopher://gopher.igc.apc.org:70/00/orgs/nawherc/about. 57356

[175] Chen, Krust, and Lewry.

women to speak their minds could help destroy the pervasive attitude among IHS physicians that Native-American women simply did not possess the intellectual capacity to make their own decisions regarding contraception.

While some groups such as the NAWHERC maintain a more radical perspective by suggesting that IHS physicians intentionally sought to control the reproduction of Native-American women, the Association of American Indian Physicians (AAIP) continues to focus its efforts on creating dialogue among Native-American physicians and educating them about new developments in health research. In 1999, the AAIP held seminars on diabetes, osteoporosis, and the future of Native-American health. Activities aimed at attracting more young Native Americans to the medical field included a National Native American Youth Initiative rally and Pre-Admission Workshop at the University of Minnesota medical school.[176] According to Rob Hamilton, member of the Association of Native American Medical Students, the organization's efforts met success in convincing him to consider medicine as a career. Raised in rural northwest Oklahoma, Hamilton first joined the military after high school, then eventually found his way to college as a pre-medical student. He heard one speaker from New Mexico giving "a glowing recruitment speech about how much he enjoyed it [the IHS] and how it was not as backward as he had anticipated. It [joining the IHS] is something to which I really give serious consideration. To go where needed most—that's the goal, isn't it?"[177]

IHS employees also responded to charges of reproductive control, asserting that as women's strongest advocates, they never would have allowed involuntary sterilization and coercive use of Depo-Provera and Norplant to occur. Dorothy Meyer, CNM, argues, "it's like people are personally attacking me and my friends who work here for what we've tried to do and tried to facilitate for other people." Meyer explains that she admires the Native-American way of life, and only wants outsiders to allow her to "do her job"—trusting that she and her colleagues have good intentions: "They're [critics of the IHS] not sitting there with the patient, trying to understand what the patient is going through. . . . People who work

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[176] Association of American Indian Physicians, "1999 AAIP Activities," http://www.aaip.com/activities/index.html (22 September 1999).

in the IHS are the same people who go to the barrios or into the Peace Corp. They're not here for the money." She believes that she could not manipulate Native-American women into taking certain types of contraceptives because Native-American women "speak their minds, or show their minds through their actions."[178] Kathy Ray, an IHS Midwife, remains angry at charges Uri brought forth in her sterilization reports. Ray claims the reports were " a bunch of garbage. I don't think there's any force involved here because you don't strap a patient down and take them into surgery fighting." She sees Depo-Provera as an exciting option for women and is "tired of the bad publicity articles. . . . Do you want choices in your reproductive health? I think that says enough right there. Pregnancy affects our lives tremendously."[179]

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Beginning with the eugenics movement, which a small group of activists dominated at the turn of the century, the push for involuntary sterilization and coercive use of Depo-Provera and Norplant occurred quietly alongside major national events. Beyond the concern of mainstream America, certain government agencies, politicians, and physicians encouraged birth control among poor, minority women. While debates over reproductive issues focused on abortion during the 1970s, physicians sterilized hundreds of thousands of poor women in family planning clinics across the country. Because the FDA did not approve Depo-Provera as a contraceptive until 1992 and therefore loosely monitored its use, the IHS was able to give mentally retarded women the drug during the 1980s. Mandatory use of Norplant simply lurked in the background of 1990s debates over "welfare queens" who allegedly were bankrupting the public assistance system. Advocates of sterilization, Depo-Provera, and Norplant for poor, minority women arguably achieved their goals because their intentions appeared altruistic; these advocates believed that because certain groups of women could not make intelligent choices regarding contraception, someone else should make the decisions for them. Although feminist organizations could have generated protest against forced or coercive contraception, white, middle-class leaders often failed throughout the 20th century to

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[177] Rob Hamilton, University of Minnesota School of Medicine student, email correspondence with the author, 8 November 1999.

[178] Meyer, interview.

ensure that the reproductive freedom they desired would exist for *all* members of their gender.

From this investigation of poor, minority women and their experience with reproductive control, a pattern emerges that physicians affected women more directly than government agencies, birth control proponents, or anti-welfare advocates. While the social and legal influence of physicians made them leaders in debates throughout the 20th century, their power arguably lay more in their authority over individual patients. A court could mandate sterilization, and organizations such as CRACK could offer financial incentives for the use of long-term hormonal contraceptives, but physicians had to perform the actual sterilization procedures or administer drugs; their actions either could increase or restrict the reproductive freedom of poor, minority women. As demonstrated in the Native-American experience with IHS physicians, the actions of physicians often have resulted in negative consequences for women. Because the IHS refused to monitor closely the behavior of its employees, physicians had full authority to treat their patients as they deemed proper—not always as their patients desired. Without an agency enforcing strict procedures for educating patients, physicians often failed to consider that ultimately, women themselves should have the choice whether to undergo sterilization procedures or take long-term hormonal contraceptives.

Although many physicians believe that they help women by promoting permanent or long-term contraception, the paradox that physicians also cause harm to their patients must cease to exist. Particularly in the Native-American situation, increased agency surveillance through the use of mandatory consent forms and tracking systems for Depo-Provera and Norplant represents a technical safeguard against problems of reproductive control. However, the real, less immediate solution lies in changing physicians' attitudes toward Native-American women and helping them believe that their patients can make intelligent, responsible decisions regarding contraception. This strategy not only encourages physicians to converse openly with their patients, but it allows the IHS to maintain its hands-off approach to monitoring the medical practice of physicians. Native-American women's advocacy

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[179] Kathy Ray, Chief Midwife at the Rosebud PHS Indian Hospital, interview by the author, 29 October 1999.

groups have the opportunity to seize authority themselves, educating their health care providers about the reproductive needs of their population. Though these groups face a more formidable task than simply advocating informed consent procedures, their efforts to change the attitudes of physicians should have a lasting impact on the way IHS physicians interact with their female patients. Perhaps if physicians become aware of Native-American women's need to make their *own* informed choices, physicians will use sterilization and long-term hormonal contraceptives for their intended purposes: increasing women's reproductive freedom.

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Appendix A

ENCLOSURE IV

ENCLOSURE IV

[illegible] HEALTH AND SOCIAL SERVICES DEPARTMENT
VOLUNTARY STERILIZATION
PATIENT CONSENT FORM

NOTICE: YOUR DECISION AT ANY TIME NOT TO BE STERILIZED WILL NOT RESULT IN THE WITHDRAWAL OR WITHHOLDING OF ANY BENEFITS PROVIDED BY PROGRAMS OR PROJECTS.

A non-therapeutic sterilization may not be performed until at least 72 hours have elapsed after the execution of the consent document.

I, ______________________________ have been counseled by

______________________________, of ____________________

, on the below mentioned items in regard to my request for a voluntary sterilization:

I. PROCEDURES FOR VASECTOMY

I understand that sterilization for men is the surgical procedure called the vasectomy. In a vasectomy a doctor cuts and ties off the vas tube so that the sperm, produced by the testicle, cannot mix with the semen. What the doctor does is very simple. Usually it is done in his office and only takes about a half hour and he usually uses a local anesthesia. The vasectomy is a permanent method of contraception. A doctor will not usually perform a vasectomy unless he is sure that the man who wants it understands that it is permanent.

There are some temporary inconveniences following vasectomy, normal routine may have to be limited in the following 2-3 days and an additional contraception is necessary for the next 3 months, or until the physician is able to determine that there are no sperm present in the ejaculate. Sexual relations are usually not hampered.

Also, with the male vasectomy, as with any other surgical procedure, there are potential-side effects. Any time one makes an incision in the human body, there is a possibility of immediate or delayed bleeding and/or infection. With vasectomy, these side effects are very rare and much less frequent than similar side effects of the sterilization procedure for women. From the physiological point of view, there is no difference in the sexual relationship of a man and a woman before and after vasectomy has been performed. Sexual excitement, sexual intercourse, and orgasm remain totally unaffected. The nature of the ejaculate is thinner and less opaque. The amount is fractionally reduced.

II. PROCEDURE FOR TUBAL LIGATION

I understand this operation is performed to block the path of the reproductive cells so they cannot reach the uterus where fertilization occurs. This operation does not affect either menstrual periods or the age at which change of life occurs. The ovaries and uterus are unchanged by the operation, the ovary continues to release an egg each month and tying the tubes merely prevent the egg from being fertilized by the sperm. Production of female hormones by the ovaries that determine feminity is not interrupted by

Addressograph or I.D.

(PL0111)

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II. PROCEDURE FOR TUBAL LIGATION (CONTD)

cutting and tying the tubes. As with male vasectomy, no reduction of sex drive or function occurs. Also as with the male vasectomy and with any other surgical procedure, there are potential side effects. Any time one makes an incision in the human body, there is a possibility of immediate or delayed bleeding and/or infection.

A. TUBAL LAPAROSCOPY

The physician makes two small incisions about a half inch long in the abdomen. Through one incision is inserted a laparoscope, an instrument that combines a high intensity light and magnifying lenses. Carbon dioxide gas is then pumped in to distend the abdomen, thus allowing the physician to see the Fallopian tubes more clearly. A second instrument, combining a tiny forcep and a cauterizing device, is inserted into the other incision. Grasping the Fallopian tube with the forceps, the physician fuses the tube shut with a brief burst of electricity. This procedure is done on both tubes. Laparoscopy is ordinarily performed under general anesthesia. In many cases the woman is able to leave the hospital the same day, although an overnight stay may be necessary. As with any surgical procedure, there are some potential side effects; however, with this operation, they are minimal. Recovery only takes a few days with some slight discomfort in the abdominal area.

B. ABDOMINAL TUBAL LIGATION

The physician makes an incision just above the pubic hair line about 4-5 inches long. The physician will expose the Fallopian tubes and cut a small piece out of both tubes, tying and cauterizing the ends of the tubes. The abdominal tubal ligation is usually performed under general anesthesia and frequently in conjunction with other abdominal surgery. The woman usually remains in the hospital for 2-3 days. The abdominal muscles will feel sore, and it may take a few days to walk easily. Normal activity may be resumed after 10 days, or whenever the physician advises.

C. VAGINAL TUBAL LIGATION

This procedure is performed through an incision about one inch long in the vaginal wall. The patient is in the same position as when having a pap smear, and generally has had a general or spinal anesthetic.

The physician inserts an instrument called culdoscope through the incision to locate the tubes. The culdoscope has a tiny forcep attachment and cauterizing device which cuts and cauterizes both Fallopian tubes. After he has cut and cauterized the tubes, the physician closes the incision with suture which dissolve in about 10 days. The procedure usually lasts about a half hour, but the woman usually remains in the hospital overnight. This procedure has a slightly higher risk of infection, and the patient may feel discomfort in the lower abdomen for a few days. After 5 days she may resume normal activities, but the physician should be consulted as to when she may resume intercourse. Tampons should not be used for at least 4 weeks after surgery.

Appendix A

III. I UNDERSTAND THAT THE INTENT OF THIS PROCEDURE is to make me sterile and unable to have additional children. I have been informed that this procedure is non-reversible and that it must be considered as such prior to my consent. I am aware that on occasion some people have psychological depression after tubal ligation or vasectomy. It was pointed out that the intense counseling performed prior to surgery is an effort to minimize this depression. I understand that this procedure will in no way interfere with my normal sex habits after recovery and may decrease sexual tensions caused by the fear of unplanned pregnancy.

IV. METHODS OF FAMILY PLANNING

During the counseling session(s) prior to my surgery I have been instructed in other methods of family planning:

1. PILLS: I was told how the pill works and that the effective rate was the highest available among non-surgical methods. I was informed that many pills were available, some more acceptable than others depending upon the needs of the individual.

2. IUD: The intrauterine device was explained and demonstrated including appropriate effective rates and the fact that this method requires no daily pills or other function to be remembered daily. The discomforts which sometimes accompany insertion were explained as were the numerous types of IUD's.

3. DIAPHRAGM: This method was explained to me starting with the method of measurement. I was instructed on how to insert the device properly and the absolute requirement to use proper lubricants. I was informed that the diaphragm must be used each time intercourse occurs.

4. CONDOM: Condoms were explained as an effective method, especially when used in conjunction with spermacidal foam. I was told that when used according to directions, these two methods in combination should be considered as effective as the birth control pill with fewer side effects. I was also informed that some pregnancies occur when only one of these methods is used, and that an interruption in the lovemaking process is necessary to insure proper contraceptive protection which some individuals deem undesirable.

5. FOAM: Foam and other chemical spermacides such as jellies and creams were explained as an effective method, especially when used with a condom. I was told that when used according to directions, these two methods in combination should be considered as effective as the birth control pill with fewer side effects. I was also told that pregnancies may result when foam, cream or jelly is used by itself. I understand that to use foam there may be an interruption in the lovemaking process which some people find undesirable.

6. NATURAL: Natural family planning was explained as a method involving selective abstinence. I was told that only on certain days could I get pregnant and was told how to predict when these days were. I was informed that this was a highly participatory method and cooperation (from sex partner) was an absolute necessity before any contraceptive protection was available.

Appendix A

ENCLOSURE IV

ENCLOSURE IV

IV. METHODS OF FAMILY PLANNING (CONT'D)

7. STERILIZATION: This surgical procedure was explained to me as a method to make my body incapable of becoming pregnant/or making a woman pregnant. I was informed that some individuals accidentally become pregnant/impregnate after this procedure because the canal which is cut during the operation grows back. I was told that this is rare. I was also informed that some individuals have periods of depression following this procedure. I am fully aware that I may, at any time before surgery, retract my consent to have this procedure performed. I am also aware that my decision will not in any way affect any other benefits or privileges which are available to me or my family from this or any other organization.

I have received counseling as described above and have been given an opportunity to ask additional questions about any and all methods, procedures, risks, benefits, or other concerns which I may have.

I understand that there must be a 72 hour waiting period between the time I receive counseling and sign this consent form, and the time my sterilization surgery is actually performed.

I now hereby voluntarily consent to a ______________________ surgical sterilization procedure.

____
(SIGNATURE OF PATIENT)

____
(SIGNATURE OF PERSON OBTAINING THE CONSENT)

____
(SIGNATURE OF SPOUSE) - (IF MARRIED)

__________ (TIME) __________ (DATE)

I, ______________________, was designated by __________ ______________________ as her/his auditor-witness, and was present when she/he received her/his counseling and information on sterilization surgery and birth control methods. Everything described by this consent form was discussed and there were opportunities for additional questions.

____
(Signature of auditor-witness designated by patient)

__________ (Time) __________ (Date)

CONSENT FOR USE OF DEPOMEDROXYPROGESTERONE ACETATE

The doctors at Gallup Indian Medical Center or Tohatchi clinic have recommended a medicine called Depo Provera (Depomedroxyprogestrone acetate) for [redacted] medicine that the doctor feels will help her by stopping her menstrual periods (monthly bleeding). It will also keep her from getting pregnant. Because you are her parent or guardian your approval is necessary for us to give her this medicine.

Depo Provera is given as a shot every three months. Like any medicine it may have some side effects. She may have heavy or irregular bleeding during the first several months while her body is getting used to the medicine. After that she should not have any bleeding until after the medicine is stopped. During this time she will have over 99% effective protection against pregnancy. After stopping the medicine most women will be able to become pregnant again although it may take up to a year before her periods become regular and pregnancy can occur. Some people also have headaches, dizziness, weight gain, allergic reactions or feel depressed when this medicine is given.

The Food and Drug administration of the federal government has approved the use of this medicine for other purposes but has not approved its use for birth control. They have not approved it because of tests showing a risk of breast tumors in beagle dogs. So far this has not been shown to be a problem in humans. Also if a woman using this medicine gets pregnant during the first few months after the medicine is stopped the baby has a small risk of birth defects. Another type of birth control should be used for several months after the medicine is stopped.

The doctors at Gallup Indian Medical Center and Tohatchi Clinic have evaluated [redacted] carefully and feel that this medicine is the safest and most effective way to control her monthly periods and keep her from having an unwanted pregnancy. Because of the concerns mentioned in this paper your permission is required. Be sure that any questions you may have are answered before signing this.

[redacted] 1-5-86
Signature of Parent or Guardian Date

[redacted] 1-5-86
Witness Date

Draft
1/22/86

Appendix B

CONSENT FOR USE OF DEPOMEDROXYPROGESTERONE ACETATE

The doctors at Gallup Indian Medical Center or Tohatchi clinic have recommended a medicine called Depo Provera (Depomedroxyprogestrone acetate) for ______________________. This is a medicine that the doctor feels will help her by stopping her menstrual periods (monthly bleeding). It will also keep her from getting pregnant. Because you are her parent or guardian your approval is necessary for us to give her this medicine.

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The doctors at Gallup Indian Medical Center and Tohatchi Clinic have evaluated ______________________ carefully and feel that this medicine is the safest and most effective way to control her monthly periods and keep her from having an unwanted pregnancy. Because of the concerns mentioned in this paper your permission is required. Be sure that any questions you may have are answered before signing this.

______________________________ ______________
Signature of Parent or Guardian Date

______________________________ ______________
Witness Date

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
HEALTH SERVICES ADMINISTRATION
INDIAN HEALTH SERVICE

TO: CLINIC Physicians, Nurses
Pharmacists, Community Health Nurses
DATE: 02-04-85

FROM: Carl R. Olden, M.D., Yakima PHS

SUBJECT: Depo-Provera

A number of Yakima obstetricians and gynecologists have prescribed Depo-Provera to individuals in our patient populatin. Because of its apparent recent popularity in the local community I felt it was important to review the medication and its indications and contraindication for our clinic staff.

Depo-Provera is an oil based form of progesterone that is given as an intramuscular injection. It requires six to eight months for the drug to totally clear from the average woman and the effective contraception level is maintained for four months. Giving 150 mgms intramuscularly every three months assures 100% contraception. Depo-Provera may be useful as a contraceptive in restricted groups of women. It has no advantages over oral contraceptives other than ease of administration and should not be represented as a preferred method of contraception or as a means of avoiding the side effects of birth control pills.

Some specific groups of women who may be candidates for Depo-Provera include:

<u>#1</u> Women for whom estrogen is contraindicated such as women with congenital heart disease, women with previous history of thromboembolism and women over 30 especialy those who smoke or have other cardiovascular risk factors.

<u>#2</u> Mentally retarded females for whom the added advantage of suppression of the menstruation may also aid in their care.

<u>#3</u> Women who desire temporary but effective contraception and have medical contraindications to the use of IUDs and who cannot or will not take birth control pills on a daily basis. Depo-Provera should not be represented to patients as an easy way to avoid having to remember to take a pill every day as this will inevitably attract women who would be good candidates for other methods which are less costly and have fewer long lasting effects.

The major disadvantages to the use of Depo-Provera are:

1.) Because of the long duration of action and the six to eight months period of time necessary to clear the drug from the average woman, any side effects directly related

FEB 25 1987

Previous consent form did not state that the operation was not [illegible]

Appendix B

to the medication are quite prolonged. Where is a 5% incidence of significant weight gain and/or depression which will persist for six to eight months at least after a single dosage of Depo-Provera. In addition, the long term suppression of ovulation also means that it may take up to 12 months to restore fertility in normal women after a single injection. There have been no studies which have indicated an increase in rates of infertility after the use of Depo-Provera, however the longer period of wait is important to keep in mind when counseling patients. There is also approximately a 30% incidence of breakthrough bleeding during the first year of usage and approximately 10% per year after that. This can be treated with supplemental estrogens if necessary however is not usually a particularly harmful or serious condition and may not require treatment at all.

Documentation of Consent:

Part I.

If the indication for usage of Depo-Provera is mental retardation an attempt should be made to document this and the severity of the problem by getting school records if at all available or psychological evaluations. Use of Depo-Provera should be discussed with the individual's responsible parent or adult guardian, ~~or~~ trusted and reliable family member or friend and this person should also sign the consent form as a witness. The patient's own reproductive plans should be elicited and documented in the medical record when possible.

Part II.

If the indication for use of Depo-Provera is the patient's inability or refusal to take birth control pills regularly it should be carefully documented in the medical record that this is the patient's own decision. It should be made clear in the record and to the patient that it is clinic policy to discourage use for this particular reason, and care should be taken that Depo-Provera is never represented as a preferred method of birth control or as a way to avoid the inconvenience of taking birth control pills.

Follow-up of patients on Depo-Provera:

1. It would be ideal to have the pharmacy keep a computerized record of all patients on Depo-Provera and if at all possible keep a reminder file which can indicate when patients are due for their injection, so that CHN's can remind them by mail/visit to return to clinic.

2. All patients on Depo-Provera should have regular contact with the Community Health Nurses to evaluate patient and family satisfaction and side effects. Particularly for those patients for whom mental retardation or other compliance problems are the indication for use of

Depo-Provera the Community Health Nurses may be requested to offer injections every three months at the patient's home. If it has been more than four months since the patient's last injection they must return to the clinic for evaluation and to exclude possibility of pregnancy before Depo-Provera injections will be resumed. Regular home visits by the Community Health Nurses will in no way substitute for an annual gynecologic examination, pap smear, and screening for sexually transmitted disease, and these should be required of all patients on a yearly basis. If the patient has had health care in facilities other than Yakima Indian Health Center, medical records must be obtained to document this prior to continuation of the Depo-Provera.

Recommended therapy: Depo-Provera 150 mgm. intramuscularly every three months should provide 100% contraception to all women regardless of body habitus or metabolism. A 400 mg vial of Depo-Provera costs approximately $__ which at this point must be charged to Contract Care monies.

Thank you very much for reading through this memo. Please put your comments in the margin or on the back and sign them. I will review all comments, revise the draft and recirculate it to interested parties prior to our clinic adopting this new policy.

CARL R. OLDEN, M.D.

(10 2 83)

ient Information for Depo-Provera:

o-Provera ("the shot") has only one advantage when compared to th control pills; it does not need to be taken every day. cause the medicine in the shot is so long lasting, it does have veral disadvantages:

1. Prolonged infertility, up to one year after an injection.

2. Irregular menstrual bleeding.

3. Occasional weight gain and/or depression.

herefore, it is the policy of the Yakima Indian Health Center to scourage the use of Depo Provera except for women who:

(1) Urgently desire complete contraceptive protection and do not wish to begin pregnancy for an entire year.

(2) May be unable to remember to take birth control pills regularly each day or use barrier methods (foam and condoms, diaphragm) every time.

(3). Are not medical candidates for an IUD.

CONSENT

1. I understand that Depo-Provera shots will prevent pregnancy three months.

2. I understand that after three months it cannot be predicted hen I will be able to become pregnant but it may not be for a whole ar.

3. I understand that Depo-Provera has not been shown to crease infertility after one year.

4. I understand that after taking the shot my periods will obably stop completely; breakthrough bleeding sometimes occurs but not dangerous.

5. I understand that there is approximately a 1 in 20 chance at the shot will cause unpleasant side effects of weight gain or pression.

6. I understand that once I begin taking the shots I must keep with regular appointments every three months and that I must have yearly pap smear and examination. If I do not do so further shots y be denied.

7. I have made the decision to start Depo-Provera shots of my n free will because of my wish to avoid pregnancy and under no ercion or fear of loss of benefits from any Federal or State ogram or Agency.

____
tness Date
HS Provider)

____
Patient Date
or Guardian if patient is a
minor

Appendix B

CONSENT FOR CONTRACEPTION

(Depo Provera)

I, ______________________________ have requested the doctors at ______________________________ to prescribe a method of birth control which will protect ______________________________ from pregnancy. If this request is for other than myself, I certify that I am the parent or the legal guardian of the individual noted for whom the request is being made.

I understand that the following methods of birth control are available, including birth control pills, condoms, diaphragm, contraceptive foam, and surgical sterilization. For each of these, the doctor has discussed with me how each is used, precautions for individuals with certain health conditions, side effects of the methods as they are currently known, and how well the method could be expected to prevent pregnancy for ______________. These methods of preventing pregnancy have not been chosen for the reason(s) noted in the medical record.

I have selected Depo Provera shots every three months as the method which will be most effective in preventing pregnancy. It has been explained to me that the United States Food and Drug Administration (FDA) has approved this medicine for treating cancer but has not approved it for birth control purposes.

The most common side effect experienced immediately by many women with Depo Provera is irregular bleeding for several months. An estrogen medication may be used if the bleeding becomes excessive. Once the body gets used to the medicine, a woman will usually have no menstrual bleeding until the medicine is stopped. While the shots are being given, a woman will have 99% protection against getting pregnant. Once the shots are stopped, most women will be able to become pregnant again although it may take up to a year before periods are regular and pregnancy is possible.

Some women experience other side effects of Depo Provera including dizziness, weight gain, allergic reactions or a feeling of depression. Since Depo Provera is like one of the chemicals which makes up birth control pills, some of the birth control pill side effects which have been explained to me could also occur with the Depo Provera shots.

I understand that the major FDA concern over the use of Depo Provera for birth control purposes is based upon studies in which dogs receiving Depo Provera showed an increased risk of breast tumors. The studies on cancer in humans receiving Depo Provera have not been conclusive.

The most recent review of all available data including an international study still underway was reported in the Bulletin of the World Health Organization, 64(3):375-382(1986). This review included all previous studies in humans as well as the preliminary findings from the WHO Collaborative Study. The findings as reported are: "The preliminary data concerning cancers of the endometrium, ovary, liver and breast suggest that there is no risk to users". Some people think that there may be a relationship between Depo Provera and cervical cancer but this has not yet been resolved. There is still only limited information on long term users of Depo Provera and further studies will

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CONSENT FOR CONTRACEPTION
(Depo Provera)

need to be carried out in the future.

I have been given an opportunity to ask questions on this matter and also understand that I do not have to sign this consent form immediately. I have had time to think about this decision and give permission for the use of Depo Provera for ______________________________.

This consent is only good for one year. I understand if I change my mind before the year is over, that the medicine will be stopped if I request it.

______________________________ ______________
Signature of Patient, Parent, Guardian Date

______________________________ ______________
Physician Date

______________________________ ______________
Witness Date

(Revised 1986)

Appendix B

Appendix C

DEPO-PROVERA® Contraceptive Injection

medroxyprogesterone acetate injectable suspension, USP

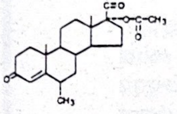
Pharmacia
& Upjohn

Patients should be counseled that this product does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

DESCRIPTION

DEPO-PROVERA Contraceptive Injection contains medroxyprogesterone acetate, a derivative of progesterone, as its active ingredient. Medroxyprogesterone acetate is active by the parenteral and oral routes of administration. It is a white to off-white, odorless crystalline powder that is stable in air and that melts between 200° C and 210° C. It is freely soluble in chloroform, soluble in acetone and dioxane, sparingly soluble in alcohol and methanol, slightly soluble in ether, and insoluble in water.

The chemical name for medroxyprogesterone acetate is pregn-4-ene-3,20-dione, 17-(acetyloxy)-6-methyl-, (6α)-. The structural formula is as follows:



medroxyprogesterone acetate

DEPO-PROVERA Contraceptive Injection for intramuscular (IM) injection is available in vials and prefilled syringes, each containing 1 mL of medroxyprogesterone acetate sterile aqueous suspension 150 mg/mL.

Each mL contains	
Medroxyprogesterone acetate	150 mg
Polyethylene glycol 3350	28.9 mg
Polysorbate 80	2.41 mg
Sodium chloride	8.68 mg
Methylparaben	1.37 mg
Propylparaben	0.150 mg
Water for injection	qs

When necessary, pH is adjusted with sodium hydroxide or hydrochloric acid, or both.

CLINICAL PHARMACOLOGY

DEPO-PROVERA Contraceptive Injection (medroxyprogesterone acetate), when administered at the recommended dose to women every 3 months, inhibits the secretion of gonadotropins which, in turn, prevents follicular maturation and ovulation and results in endometrial thinning. These actions produce its contraceptive effect.

Following a single 150 mg IM dose of DEPO-PROVERA Contraceptive Injection, medroxyprogesterone acetate concentrations, measured by an extracted radioimmunoassay procedure, increase for approximately 3 weeks to reach peak plasma concentrations of 1 to 7 ng/mL. The levels then decrease exponentially until they become undetectable (<100 pg/mL) between 120 to 200 days following injection. Using an unextracted radioimmunoassay procedure for the assay of medroxyprogesterone acetate in serum, the apparent half-life for medroxyprogesterone acetate following IM administration of DEPO-PROVERA Contraceptive Injection is approximately 50 days.

Women with lower body weights conceive sooner than women with higher body weights after discontinuing DEPO-PROVERA Contraceptive Injection.

The effect of hepatic and/or renal disease on the pharmacokinetics of DEPO-PROVERA Contraceptive Injection is unknown.

INDICATIONS AND USAGE

DEPO-PROVERA Contraceptive Injection is indicated only for the prevention of pregnancy. To ensure that DEPO-PROVERA Contraceptive Injection is not administered inadvertently to a pregnant woman, the first injection must be given **ONLY** during the first 5 days of a normal menstrual period; **ONLY** within the first 5-days postpartum if not breast-feeding, and if exclusively breast-feeding, **ONLY** at the sixth postpartum week. The efficacy of DEPO-PROVERA Contraceptive Injection depends on adherence to the recommended dosage schedule (see DOSAGE AND ADMINISTRATION). It is a long-term injectable contraceptive in women when administered at 3-month (13-week) intervals. Dosage does not need to be adjusted for body weight.

In five clinical studies using DEPO-PROVERA Contraceptive Injection, the 12-month failure rate for the group of women treated with DEPO-PROVERA Contraceptive Injection was zero (no pregnancies reported) to 0.7 by Life-Table method. Pregnancy rates with contraceptive measures are typically reported for only the first year of use as shown in Table 1. Except for intrauterine devices (IUD), implants, sterilization, and DEPO-PROVERA Contraceptive Injection, the efficacy of these contraceptive measures depends in part on the reliability of use. The effectiveness of DEPO-PROVERA Contraceptive Injection is dependent on the patient returning every 3 months (13 weeks) for reinjection.

Table 1
Lowest Expected and Typical Failure Rates*
Expressed as Percent of Women Experiencing an Accidental Pregnancy
in the First Year of Continuous Use

Method	Lowest Expected	Typical
Injectable progestogen		
DEPO-PROVERA	0.3	0.3
Implants		
Norplant (6 capsules)	0.2†	0.2†
Female sterilization	0.2	0.4
Male sterilization	0.1	0.15
Pill		3
Combined	0.1	
Progestogen only	0.5	
IUD		3
Progestasert	2	
Copper T 380A	0.8	
Condom	2	12
Diaphragm	6	18
Cap	6	18
Spermicides	3	21
Sponge		
Parous women	9	28
Nulliparous women	6	18
Periodic abstinence	1-9	20
Withdrawal	4	18
No method	85	85

Source: Trussell et al[1]

* Lowest expected - when used exactly as directed.
Typical - includes those not following directions exactly.

† from Norplant® package insert.

CONTRAINDICATIONS

1. Known or suspected pregnancy or as a diagnostic test for pregnancy.
2. Undiagnosed vaginal bleeding.
3. Known or suspected malignancy of breast.
4. Active thrombophlebitis, or current or past history of thromboembolic disorders, or cerebral vascular disease.
5. Liver dysfunction or disease.
6. Known hypersensitivity to DEPO-PROVERA Contraceptive Injection (medroxyprogesterone acetate or any of its other ingredients).

WARNINGS

1. Bleeding Irregularities

Most women using DEPO-PROVERA Contraceptive Injection experience disruption of menstrual bleeding patterns. Altered menstrual bleeding patterns include irregular or unpredictable bleeding or spotting, or rarely, heavy or continuous bleeding. If abnormal bleeding persists or is severe, appropriate investigation should be instituted to rule out the possibility of organic pathology, and appropriate treatment should be instituted when necessary.

As women continue using DEPO-PROVERA Contraceptive Injection, fewer experience irregular bleeding and more experience amenorrhea. By month 12 amenorrhea was reported by 55% of women, and by month 24 amenorrhea was reported by 68% of women using DEPO-PROVERA Contraceptive Injection.

2. Bone Mineral Density Changes

Use of DEPO-PROVERA Contraceptive Injection may be considered among the risk factors for development of osteoporosis. The rate of bone loss is greatest in the early years of use and then subsequently approaches the normal rate of age related fall.

3. Cancer Risks

Long-term case-controlled surveillance of users of DEPO-PROVERA Contraceptive Injection found slight or no increased overall risk of breast cancer[2] and no overall increased risk of ovarian,[3] liver,[4] or cervical[5] cancer and a prolonged, protective effect of reducing the risk of endometrial[6] cancer in the population of users.

A pooled analysis[7] from two case-control studies, the World Health Organization Study[2] and the New Zealand Study[8], reported the relative risk (RR) of breast cancer for women who had ever used DEPO-PROVERA Contraceptive Injection as 1.1 (95% confidence interval (CI) 0.97 to 1.4). Overall, there was no increase in risk with increasing duration of use of DEPO-PROVERA Contraceptive Injection. The RR of breast cancer for women of all ages who had initiated use of DEPO-PROVERA Contraceptive Injection within the previous 5 years was estimated to be 2.0 (95% CI 1.5 to 2.8).

The World Health Organization Study[2], a component of the pooled analysis[7] described above, showed an increased RR of 2.19 (95% CI 1.23 to 3.89) of breast cancer associated with use of DEPO-PROVERA Contraceptive Injection in women whose first exposure to drug was within the previous 4 years and who were under 35 years of age. However, the overall RR for ever-users of DEPO-PROVERA Contraceptive Injection was only 1.2 (95% CI 0.96 to 1.52).

[NOTE: A RR of 1.0 indicates neither an increased nor a decreased risk of cancer associated with the use of the drug, relative to no use of the drug. In the case of the subpopulation with a RR of 2.19, the 95% CI is fairly wide and does not include the value of 1.0, thus inferring an increased risk of breast cancer in the defined subgroup relative to nonusers. The value of 2.19 means that women whose first exposure to drug was within the previous 4 years and who are under 35 years of age have a 2.19-fold (95% CI 1.23 to 3.89-fold) increased risk of breast cancer relative to nonusers. The National Cancer Institute[9] reports an average annual incidence rate for breast cancer for US women, all races, age 30 to 34 years of 26.7 per 100,000. A RR of 2.19, thus, increases the possible risk from 26.7 to 58.5 cases per 100,000 women. The attributable risk, thus, is 31.8 per 100,000 women per year.]

A statistically insignificant increase in RR estimates of invasive squamous-cell cervical cancer has been associated with the use of DEPO-PROVERA Contraceptive Injection in women who were first exposed before the age of 35 years (RR 1.22 to 1.28 and 95% CI 0.93 to 1.70). The overall, nonsignificant relative rate of invasive squamous-cell cervical cancer in women who ever used DEPO-PROVERA Contraceptive Injection was estimated to be 1.11 (95% CI 0.96 to 1.29). No trends in risk with duration of use or times since initial or most recent exposure were observed.

4. Thromboembolic Disorders

The physician should be alert to the earliest manifestations of thrombotic disorders (thrombophlebitis, pulmonary embolism, cerebrovascular disorders, and retinal thrombosis). Should any of these occur or be suspected, the drug should not be readministered.

5. Ocular Disorders

Medication should not be readministered pending examination if there is a sudden partial or complete loss of vision or if there is a sudden onset of proptosis, diplopia, or migraine. If examination reveals papilledema or retinal vascular lesions, medication should not be readministered.

6. Unexpected Pregnancies

To ensure that DEPO-PROVERA Contraceptive Injection is not administered inadvertently to a pregnant woman, the first injection must be given **ONLY** during the first 5 days of a normal menstrual period; **ONLY** within the first 5-days postpartum if not breast-feeding, and if exclusively breast-feeding, **ONLY** at the sixth postpartum week (see DOSAGE AND ADMINISTRATION).

Neonates from unexpected pregnancies that occur 1 to 2 months after injection of DEPO-PROVERA Contraceptive Injection may be at an increased risk of low birth weight, which, in turn, is associated with an increased risk of neonatal death. The attributable risk is low because such pregnancies are uncommon.[10,11]

A significant increase in incidence of polysyndactyly and chromosomal anomalies was observed among infants of users of DEPO-PROVERA Contraceptive Injection, the former being most pronounced in women under 30 years of age. The unrelated nature of these defects, the lack of confirmation from other studies, the distant preconceptual exposure to DEPO-PROVERA Contraceptive Injection, and the chance effects due to multiple statistical comparisons, make a causal association unlikely.

Neonates exposed to medroxyprogesterone acetate in utero and followed to adolescence, showed no evidence of any adverse effects on their health including their physical, intellectual, sexual, or social development.

Several reports suggest an association between intrauterine exposure to progestational drugs in the first trimester of pregnancy and genital abnormalities in male and female fetuses. The risk of hypospadias (five to eight per 1,000 male births in the general population) may be approximately doubled with exposure to these drugs. There are insufficient data to quantify the risk to exposed female fetuses, but because some of these drugs induce mild virilization of the external genitalia of the female fetus and because of the increased association of hypospadias in the male fetus, it is prudent to avoid the use of these drugs during the first trimester of pregnancy.

To ensure that DEPO-PROVERA Contraceptive Injection is not administered inadvertently to a pregnant woman, it is important that the first injection be given only during the first 5 days after the onset of a normal menstrual period within 5 days postpartum if not breast-feeding and if breast-feeding, at the sixth week postpartum (see DOSAGE AND ADMINISTRATION).

7. Ectopic Pregnancy

Health-care providers should be alert to the possibility of an ectopic pregnancy among women using DEPO-PROVERA Contraceptive Injection who become pregnant or complain of severe abdominal pain.

8. Lactation

Detectable amounts of drug have been identified in the milk of mothers receiving DEPO-PROVERA Contraceptive Injection. In nursing mothers treated with DEPO-PROVERA Contraceptive Injection, milk composition, quality, and amount are not adversely affected. Neonates and infants exposed to medroxyprogesterone from breast milk have been studied for developmental and behavioral effects through puberty. No adverse effects have been noted.

9. Anaphylaxis and Anaphylactoid Reaction

Anaphylaxis and anaphylactoid reaction have been reported with the use of DEPO-PROVERA Contraceptive Injection. If an anaphylactic reaction occurs appropriate therapy should be instituted. Serious anaphylactic reactions require emergency medical treatment.

PRECAUTIONS

GENERAL

1. Physical Examination

It is good medical practice for all women to have annual history and physical examinations, including women using DEPO-PROVERA Contraceptive Injection. The physical examination, however, may be deferred until after initiation of DEPO-PROVERA if requested by the woman and judged appropriate by the clinician. The physical examination should include special reference to blood pressure, breasts, abdomen and pelvic organs, including cervical cytology and relevant laboratory tests. In case of undiagnosed, persistent or recurrent abnormal vaginal bleeding, appropriate measures should be conducted to rule out malignancy. Women with a strong family history of breast cancer or who have breast nodules should be monitored with particular care.

2. Fluid Retention

Because progestational drugs may cause some degree of fluid retention, conditions that might be influenced by this condition, such as epilepsy, migraine, asthma, and cardiac or renal dysfunction, require careful observation.

3. Weight Changes

There is a tendency for women to gain weight while on therapy with DEPO-PROVERA Contraceptive Injection. From an initial average body weight of 136 lb, women who completed 1 year of therapy with DEPO-PROVERA Contraceptive Injection gained an average of 5.4 lb. Women who completed 2 years of therapy gained an average of 8.1 lb.

Women who completed 4 years gained an average of 13.8 lb. Women who completed 6 years gained an average of 16.5 lb. Two percent of women withdrew from a large-scale clinical trial because of excessive weight gain.

4. Return of Fertility

DEPO-PROVERA Contraceptive Injection has a prolonged contraceptive effect. In a large US study of women who discontinued use of DEPO-PROVERA Contraceptive Injection to become pregnant, data are available for 61% of them. Based on Life-Table analysis of these data, it is expected that 68% of women who do become pregnant may conceive within 12 months, 83% may conceive within 15 months, and 93% may conceive within 18 months from the last injection. The median time to conception for those who do conceive is 10 months following the last injection with a range of 4 to 31 months, and is unrelated to the duration of use. No data are available for 39% of the patients who discontinued DEPO-PROVERA Contraceptive Injection to become pregnant and who were lost to follow-up or changed their mind.

5. CNS Disorders and Convulsions

Patients who have a history of psychic depression should be carefully observed and the drug not be readministered if the depression recurs.

There have been a few reported cases of convulsions in patients who were treated with DEPO-PROVERA Contraceptive Injection. Association with drug use or pre-existing conditions is not clear.

6. Carbohydrate Metabolism

A decrease in glucose tolerance has been observed in some patients on DEPO-PROVERA Contraceptive Injection treatment. The mechanism of this decrease is obscure. For this reason, diabetic patients should be carefully observed while receiving such therapy.

7. Liver Function

If jaundice develops, consideration should be given to not readministering the drug.

8. Protection Against Sexually Transmitted Diseases

Patients should be counseled that this product does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

DRUG INTERACTIONS

Aminoglutethimide administered concomitantly with the DEPO-PROVERA Contraceptive Injection may significantly depress the serum concentrations of medroxyprogesterone acetate. Users of DEPO-PROVERA Contraceptive Injection should be warned of the possibility of decreased efficacy with the use of this or any related drugs.

LABORATORY TEST INTERACTIONS

The pathologist should be advised of progestin therapy when relevant specimens are submitted.

The following laboratory tests may be affected by progestins including DEPO-PROVERA Contraceptive Injection:

(a) Plasma and urinary steroid levels are decreased (eg, progesterone, estradiol, pregnanediol, testosterone, cortisol).
(b) Gonadotropin levels are decreased.
(c) Sex-hormone-binding-globulin concentrations are decreased.
(d) Protein-bound iodine and butanol extractable protein-bound iodine may increase.
T3-uptake values may decrease.
(e) Coagulation test values for prothrombin (Factor II), and Factors VII, VIII, IX, and X may increase.
(f) Sulfobromophthalein and other liver function test values may be increased.
(g) The effects of medroxyprogesterone acetate on lipid metabolism are inconsistent. Both increases and decreases in total cholesterol, triglycerides, low-density lipoprotein (LDL) cholesterol, and high-density lipoprotein (HDL) cholesterol have been observed in studies.

CARCINOGENESIS

See "WARNINGS" section 3

PREGNANCY

Pregnancy Category X. See "WARNINGS" section 6

NURSING MOTHERS

See "WARNINGS" section 8

PEDIATRIC USE

Safety and effectiveness in pediatric patients have not been established. See "WARNINGS" section 6

INFORMATION FOR THE PATIENT

See Patient Labeling.

Patient labeling is included with each single-dose vial and prefilled syringe of DEPO-PROVERA Contraceptive Injection to help describe its characteristics to the patient. It is recommended that prospective users be given this labeling and be informed about the risks and benefits associated with the use of DEPO-PROVERA Contraceptive Injection, as compared with other forms of contraception or with no contraception at all. It is recommended that physicians or other health-care providers responsible for those patients advise them at the beginning of treatment that their menstrual cycle may be disrupted and that irregular and unpredictable bleeding or spotting results, and that this usually decreases to the point of amenorrhea as treatment with DEPO-PROVERA Contraceptive Injection continues, without other therapy being required.

ADVERSE REACTIONS

In the largest clinical trial with DEPO-PROVERA Contraceptive Injection, over 3,900 women, who were treated for up to 7 years, reported the following adverse reactions, which may or may not be related to the use of DEPO-PROVERA Contraceptive Injection.

The following adverse reactions were reported by more than 5% of subjects:

Menstrual irregularities
(bleeding or amenorrhea, or both)
Weight changes

Headache
Nervousness
Abdominal pain or discomfort

Dizziness
Asthenia (weakness or fatigue)

Adverse reactions reported by 1% to 5% of subjects using DEPO-PROVERA Contraceptive Injection were:

Decreased libido or anorgasmia
Backache
Leg cramps
Depression
Nausea
Insomnia

Leukorrhea
Acne
Vaginitis
Pelvic pain
Breast pain
No hair growth or alopecia

Bloating
Rash
Edema
Hot flashes
Arthralgia

Events reported by fewer than 1% of subjects included: galactorrhea, melasma, chloasma, convulsions, changes in appetite, gastrointestinal disturbances, jaundice, genitourinary infections, vaginal cysts, dyspareunia, paresthesia, chest pain, pulmonary embolus, allergic reactions, anemia, drowsiness, syncope, dyspnea and asthma, tachycardia, fever, excessive sweating and body odor, dry skin, chills, increased libido, excessive thirst, hoarseness, pain at injection site, blood dyscrasia, rectal bleeding, changes in breast size, breast lumps or nipple bleeding, axillary swelling, breast cancer, prevention of lactation, sensation of pregnancy, lack of return to fertility, paralysis, facial palsy, scleroderma, osteoporosis, uterine hyperplasia, cervical cancer, varicose veins, dysmenorrhea, hirsutism, unexpected pregnancy, thrombophlebitis, deep vein thrombosis.

In addition, voluntary reports have been received of anaphylaxis and anaphylactoid reaction with use of DEPO-PROVERA Contraceptive Injection.

Appendix

Patient Information

Provided by your family physician and the American Academy of Family Physicians.

Norplant Birth Control: Questions and Answers

What is Norplant?

Norplant is a new form of birth control that lasts up to five years at a time. Six small capsules filled with the female hormone levonorgestrel are placed under the skin in the upper arm. A small amount of hormone is released at a steady rate into the body, preventing pregnancy. Levonorgestrel is a synthetic progestin (female hormone) used in many birth control pills. Norplant can be removed at any time if pregnancy is desired or another form of birth control is preferred.

Who can use Norplant?

Anyone who wants a long lasting but not permanent method of birth control may use Norplant. Unlike birth control pills that contain the hormone estrogen, Norplant is safe in older women, women who smoke and women who have high blood pressure.

Who should not use Norplant?

Norplant should not be used in women who may be pregnant. Women who have abnormal vaginal bleeding or women who may be pregnant should not use Norplant until further examination by their physician. Women with liver disease, breast cancer or blood clots (such as in the leg, lung or eye) should not use Norplant.

How does Norplant work?

Norplant prevents ovulation (the release of an egg by an ovary). The mucus at the opening of the uterus (womb) also becomes thicker, preventing sperm from entering the uterus. In addition, the lining of the uterus becomes thinner, making it less receptive to implantation of an egg.

How effective is Norplant?

Norplant is the most effective method of birth control available today. If pregnancy is desired, Norplant can be removed at any time.

How soon is Norplant effective?

Norplant is usually inserted within the first seven days of the menstrual cycle, allowing Norplant to become effective within 24 hours.

Does insertion of Norplant cause pain?

Although there is some pain from the needle used to inject local anesthesia, the procedure itself is usually painless. Insertion of Norplant takes about 10 to 15 minutes, and removal takes about 20 minutes. An incision about 1/8 inch in length is required for insertion.

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Appendix D

Can Norplant be seen in the arm?

Since Norplant is placed in the inner part of the upper arm, it is barely detectable. The capsules may look like small veins, and they may be felt below the surface of the skin.

What can be expected immediately after Norplant has been inserted?

After Norplant is inserted, the arm will appear bruised for about seven to 10 days. However, the arm will not be very sore and all regular activities can be resumed. The bandage should be left on for two to three days, and the arm should be kept dry. Nonprescription pain relievers like acetaminophen are usually all that is required for any discomfort. If there is any redness, swelling or drainage, contact your doctor immediately.

What side effects may occur?

Most women will have irregular menstrual periods for several months. Periods may last longer than usual, and bleeding or spotting may occur between periods. Some women go several months without a period. Others may have a combination of these changes. However, these changes are not serious. Periods usually return to normal within six months to one year. Less common effects include weight gain or weight loss, headaches, depression, acne, excessive hair growth or, occasionally, mild pain or itching at the site of the implant. Ovarian cysts may occur but usually do not require treatment.

Is any special medical care needed after Norplant has been inserted?

Three months after Norplant is inserted, a follow-up visit to the physician's office is required to have the blood pressure checked and to discuss any problems with menstrual periods. After that, a check-up once a year is necessary.

What if a woman who uses Norplant wants to become pregnant?

Ability to become pregnant returns quickly after Norplant has been removed. About half of women desiring pregnancy become pregnant within three months, and 86 percent are pregnant by one year after Norplant removal.

Can a woman continue to nurse her infant if she uses Norplant?

If Norplant is inserted six weeks after delivery, it does not affect the mother's milk or the baby's growth.

For more information, contact your family physician.