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RECENT DEVELOPMENTS

COMPELLED ANTIVIRAL TREATMENT OF HIV POSITIVE PREGNANT WOMEN

Michael A. Grizzi*

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INTRODUCTION

A widely publicized medical breakthrough, giving new hope to HIV (human immunodeficiency virus) positive pregnant women, revives a thorny issue of bioethics with which legislators and judges have been struggling in recent decades. Scientific evidence now indicates that the perinatal administration of the antiviral drug Zidovudine (commonly known as AZT)¹ to HIV positive pregnant women sharply reduces the rate at which infants born to such women are themselves HIV infected.² Such an advance has been appropriately greeted by commentators with much praise,³ for the tragedy of one million infected children worldwide serves as a continuing reminder of the ceaseless

1. Zidovudine is the name of the drug formerly known as Azidothymidine, and is commonly referred to as AZT. The brand name for Zidovudine, for which the Burroughs Wellcome Company owns the patent, is Retrovir. See PHYSICIAN'S DESK REFERENCE 802 *et seq.* (49th ed. 1995). This paper will use the common name, AZT, to refer to the drug.

2. Edward M. Connor et al., *Reduction of Maternal-Infant Transmission of Human Immunodeficiency Virus Type 1 with Zidovudine Treatment*, 331 NEW ENG. J. MED. 1173 (1994).

3. See, e.g., *Zidovudine for Mother, Fetus and Child: Hope or Poison?*, 344 LANCET 207, 207-09 (1994) (noting that the discovery "could have far greater implications for children born to HIV-positive women than any treatment for HIV-infected children themselves in the foreseeable future").

advance of the HIV pandemic and the need for a quick solution.⁴ Yet amidst the relief at the medical breakthrough, there remains a deceptively simple question: now that we have this information, what do we do with it?

Our response is likely to be immediate and intuitive. Society will want to make sure that all pregnant women know that this treatment is available. Yet upon reflection we find that this simple prescription ignores the unique reality of HIV disease and its manifestations. We first must confront the fact that the majority of people in the world, including those in the United States, who are infected with HIV are unaware of their status.⁵ We must also confront the fact that it is possible for an HIV positive woman to conceive and bear a child without becoming aware of her own status, or that of her child.⁶ Perhaps most troubling, we must acknowledge that even if a pregnant woman became aware of both her own status and the possible benefits to her child of perinatal AZT therapy, the woman might, for a variety of reasons, decide not to initiate the therapy.

News of the AZT study⁷ has revived the debate over whether government intervention into the decision-making process of an HIV positive pregnant woman is appropriate. Most of the current proposals in response to the study have been for legislation mandating HIV testing of pregnant women, and some municipalities are contemplating such testing.⁸ A growing voice, however, recognizes that mandatory testing provides a means for the government to initiate a coercive approach requiring pregnant women who test positive to begin AZT therapy.⁹ Dr. Har-

4. See, e.g., *A Gain Against AIDS that Carries Ethical Questions*, L.A. TIMES, Nov. 14, 1994, at B6.

5. A person infected with HIV may look and feel healthy for many years. TRACEY HOOKER & LUCINDA BRYANT, NATIONAL CONFERENCE OF STATE LEGISLATORS, HIV/AIDS FACTS TO CONSIDER: April 1993 Update 1 (1993). Only 50% of HIV infected persons develop AIDS within 10 years after infection. *Id.*

6. See *supra* note 5.

7. See *infra* part I.C.

8. See, e.g., *Success of 076 Spurs Bills for HIV Testing of Pregnant Women*, 9 AIDS ALERT 82 (1994), available in LEXIS, Nexis Library, ASAPII File; Christine Gorman, *Moms, Kids and AIDS: Can Testing and Treatment Before and After Birth Help Thousands of Youngsters Threatened by HIV?*, TIME, July 4, 1994, at 60; Carla Rivera, *County Weighs HIV Tests of Pregnant Women*, L.A. TIMES, Dec. 20, 1994, at B1; Pamela Warrick, *Whose Life Is It?: Weighing the Ethics of Keeping Unborn Babies Safe From HIV*, L.A. TIMES, Feb. 7, 1995, at E1.

9. See, e.g., Arthur Caplan, *Make These HIV Tests Mandatory*, ALB. TIMES-UNION, Mar. 8, 1995, at A12; Gorman, *supra* note 8, at 61 (quoting Theresa Klimko, a North Carolina epidemiologist: "We have no reason to mandate testing [of mothers] unless we mandate treatment."); Gina Kolata, *Discovery that AIDS Can*

vey Fineberg, dean of the Harvard School of Public Health, was quoted in a recent *Time* magazine article on the subject: "[The debate over mandatory testing and treatment of HIV positive pregnant women] is a very deep ethical and social dilemma, and fraught with all manner of emotional responses."¹⁰

This paper will explore the potential legal responses to the newly demonstrated efficacy of perinatal AZT therapy in reducing vertical transmission¹¹ of HIV. Part I examines the medical facts behind HIV disease, with particular emphasis on the vertical transmission of HIV from mother to child, the efficacy and effects of antiviral medications for HIV, and the medical implications of the new AZT study. Part II examines the legal and ethical doctrines under which any proposal to mandate that HIV positive pregnant women initiate AZT therapy must be assessed. It considers the justifications for (1) direct legislation requiring HIV positive pregnant women to initiate AZT therapy at the time medically indicated for the greatest potential protection of the fetus, (2) legislation that would require the woman's physician to direct her to begin AZT therapy, and (3) allowing an HIV infected child to bring an action against a mother who did not initiate the therapy. Part II concludes that there is little ethical justification for any coercive governmental action directed against the HIV positive pregnant woman.

I. THE MEDICAL BACKGROUND

A. *Manifestations of HIV Infection in Pregnant Women and Fetuses*

1. Effect of Pregnancy on HIV Positive Women

HIV infection generally leads to a weakening of the immune system and an accompanying series of diseases and infections which a normally functioning immune system would easily fend off.¹² For the majority of people, infection with HIV leads to a

Be Prevented in Babies Raises Debate on Mandatory Testing, N.Y. TIMES, Nov. 3, 1994, at B14; Rivera, *supra* note 8.

Other justifications advanced by proponents of mandatory testing and notification include the ability of HIV positive pregnant women to make a better informed decision regarding their reproductive and treatment options, to reduce the monetary costs to society of caring for babies with AIDS, and to make discussion of HIV a "vital component of the doctor-patient dialogue." *Id.*

10. Gorman, *supra* note 8, at 60.

11. See *infra* part I.A.2 for a discussion of vertical transmission.

12. For a relatively small percentage of persons living with HIV, infection does not lead to a decline in the traditional measures by which the medical community

clinical diagnosis of AIDS.¹³ However, the time period for a typical progression from HIV seroconversion (change in infection status from HIV negative to HIV positive) to an AIDS diagnosis varies widely.¹⁴ Once diagnosed with AIDS, the infected person generally undergoes periods of serious illness of increasing severity and length, leading almost always to the person's death.¹⁵

evaluates the health of a person's immune system, such as a count of a person's "T-cells." These persons are generally termed "asymptomatic," for members of this group typically do not experience the types of health problems which are usually associated with HIV infection. At the time of this writing, there have been verified cases of asymptomatic persons living with HIV infection for 15 years without experiencing any demonstrable decline in the health of their immune system. See, e.g., Don Colburn, *Long-Term AIDS Survivors Puzzle Scientists*, WASH. POST, Jan. 31, 1995, at HM7. Although the reason for the ability of such persons to escape the decrease in immune functioning which typifies the majority of persons with HIV infection is largely unknown, increasing medical evidence points to either one or a combination of the following possibilities: a genetic component to their bodies' abilities to hold the replication of HIV in check; particularly strong immune systems; and the presence of milder strains of HIV. *Id.*

For purposes of this paper, I do not differentiate between HIV positive pregnant women who may have this genetic capacity to ward off immune system decline and those who do not. I refrain from doing so for two reasons. First, women with such genetic capacity are believed to be in the clear minority of all such women. Second, there has not as yet been any medical study to indicate the degree to which (if any) infants born to women with genetic resistance to HIV inherit that same resistance. Thus, it is possible that mother-to-child transmission of HIV may occur in which the mother would not experience demonstrable ill effects from HIV infection (at least in a defined time span) while the infant born to such a woman might well experience the symptoms traditionally associated with such infection.

13. The clinical diagnosis of AIDS, as defined by the Centers for Disease Control and Prevention, is as follows: (1) a positive test for antibodies to HIV, and (2) one of the following: *either* a T-cell count of 200 or below *or* at least one of a long list of opportunistic infections that occur in humans only when their immune systems have been severely weakened. Such opportunistic infections include but are not limited to Kaposi's Sarcoma and pneumocystis pneumonia. In women, such infections are also likely to include esophagitis and persistent and recurring vaginal yeast infections. Charles C.J. Carpenter M.D. et al., *Natural History of Acquired Immunodeficiency Syndrome in Women in Rhode Island*, 86 AM. J. MED. 771, 771-75 (1989). It should be noted that the study of the unique manifestations of HIV and AIDS in women has begun only in the past few years, as women have begun to constitute the majority of new HIV infections worldwide. See, e.g., Laurie Jones, *AIDS Focus Slowly Turning Toward Women*, AM. MED. NEWS, Mar. 21, 1994, at 3; *Worldwide They Face the Greatest Risk*, AIDS WKLY., Dec. 12, 1994, at 19.

14. It is now no longer assumed that the majority of persons who seroconvert will progress to AIDS within a few years, as was assumed at the start of the pandemic. A typical estimate now is that progression to AIDS after seroconversion takes between 2 to 15 years, although the majority of those HIV infected who do advance to AIDS generally do so within an 8 to 11 year period after seroconversion. See HOOKER & BRYANT, *supra* note 5. The results of a multicenter AIDS cohort study suggest that between 9% and 17% of HIV positive people will remain AIDS-free up to 20 years after infection. See Colburn, *supra* note 12.

15. See HOOKER & BRYANT, *supra* note 5.

Most studies have recognized that HIV positive women generally experience a decreased length of survival after a diagnosis of AIDS relative to HIV positive men.¹⁶ Possible reasons for this survival difference include less use of health care resources and relatively less use of antiviral therapy by women as compared to men.¹⁷

For HIV positive women who are pregnant,¹⁸ the ravages of HIV infection may be even more pronounced and serious. In all women, regardless of HIV status, pregnancy takes a notable toll on the immune system.¹⁹ The immune system of an HIV positive pregnant woman is doubly taxed; it fights the impairments caused both by HIV and the pregnancy. Studies have demonstrated that HIV infection influences both the course and outcome of pregnancy, as indicated by elevated levels of premature

16. See, e.g., S. Blum et al., *Trends in Survival Among Persons with Acquired Immunodeficiency Syndrome in New York City*, 4 AM. J. EPIDEMIOLOGY 351 (1994); G.H. Friedland et al., *Survival Differences in Patients with AIDS*, 4 J. ACQUIRED IMMUNE DEFICIENCY SYNDROMES 144 (1991); G.F. Lemp et al., *Survival for Women and Men With AIDS*, 1 J. INFECTIOUS DISEASES 74 (1992); S.L. Melnick, *Survival and Disease Progression According to Gender of Patients with HIV Infection*, 24 JAMA 1915 (1994); R. Rothenberg et al., *Survival with the Acquired Immunodeficiency Syndrome*, 21 NEW ENG. J. MED. 1297 (1987). But see Barbara J. Turner et al., *Health Care Delivery, Zidovudine Use, and Survival of Women and Men with AIDS*, 7 J. ACQUIRED IMMUNE DEFICIENCY SYNDROME 1250 (1994) (reporting a study failing to find a difference in survival rates between non-AZT using men and women).

17. See Richard D. Moore et al., *Zidovudine and the Natural History of the Acquired Immunodeficiency Syndrome*, 324 NEW ENG. J. MED. 1412, 1412-16 (1991); B.J. Turner et al., *Women and HIV Infection Part XV*, AIDS INFO. NEWSL. (AIDS Information Center, U.S. Dept. of Veterans Affairs, San Francisco, Cal.), Dec. 16, 1994, at 1.

18. Since 1992, AIDS has been the fourth leading cause of death among women aged 25-44 in the United States. See *Facts About Women and HIV/AIDS*, FACT SHEET (Centers for Disease Control and Prevention Nat'l AIDS Clearinghouse, U.S. Dep't of Health and Hum. Services, Rockville, Md.), Feb. 1993, at 1.

19. It is not uncommon for HIV negative women who are pregnant to experience a decline in the measures by which doctors evaluate the strength of a person's immune system. The extent of immune suppression increases over the duration of the pregnancy. See Eugene D. Weinberg, *Pregnancy-Associated Immune Suppression: Risks and Mechanisms*, 3 MICROBIAL PATHOGENESIS 393, 393-97 (1987). An HIV negative person with a normal functioning immune system typically has a T-cell count per cubic milliliter of blood in excess of 800. Pregnancy, a tax on a woman's immune system, may cause this indicator to dip below 800. See NANCY BREWER, HOLLYWOOD SUPPORTS, AIDS IN THE WORKPLACE: FACILITATOR'S MANUAL 5.3 (1993) (on file with author). An HIV positive person qualifies for a clinical diagnosis of AIDS, according to the Centers for Disease Control and Prevention, when her T-cells dip to 200. See Centers for Disease Control and Prevention, *1993 Revised Classification System for HIV Infection and Expanded Surveillance Case Definition for AIDS Among Adolescents and Adults*, 41 MORBIDITY & MORTALITY WKLY. REP. 961 (1992).

labor and low birthweight infants.²⁰ Although the evidence remains inconclusive, some studies indicate that HIV positive pregnant women may experience a quicker than average acceleration of their HIV infection to a clinical diagnosis of AIDS, especially women whose HIV infection has already caused significant damage to their immune systems.²¹

2. Mechanics of Vertical Transmission

Transmission of HIV may occur when one of four infectious bodily fluids from an HIV positive person²² comes into contact with a mucous membrane of another person. By far the most common method of transmission is when an infectious fluid comes into contact with a mucous membrane during sexual intercourse. However, injectable drug use also causes a substantial number of transmissions because the unique protective container of a hypodermic needle can permit blood from an HIV positive person to directly enter the bloodstream of another person.²³

There are three methods of HIV transmission which are unique to mother and child — such methods are termed “vertical transmission.” HIV can be present in breast milk,²⁴ and studies have confirmed transmission of HIV solely through an infant’s ingestion of milk from its mother.²⁵ A second method is *in utero* transmission — transmission while the fetus is in the womb and has not yet begun the birthing process. Although the mother and fetus do not share the same blood stream, the fetus is capable nonetheless of receiving HIV from the mother. The mechanics

20. Daniel J. DeNoon & Mike Cooper, *Effects of HIV Infection on Pregnancy: A Clinical and Immunologic Evaluation*, AIDS WKLY., Jan. 29, 1990, at 13.

21. See, e.g., Catherine A. Hankins & Margaret A. Handley, *HIV Disease and AIDS in Women: Current Knowledge and a Research Agenda*, 5 J. ACQUIRED IMMUNE DEFICIENCY SYNDROMES 957 (1992).

22. The four infectious fluids are blood, semen, vaginal secretions, and breast milk. No other bodily fluids are capable of transmitting the virus. See *Facts About the Immunodeficiency Virus and its Transmission*, FACT SHEET (Centers for Disease Control and Prevention Nat’l AIDS Clearinghouse, U.S. Dept. of Health and Human Services, Rockville, Md.), Feb. 1994, at 1.

23. See *Facts About Drug Use and HIV/AIDS*, FACT SHEET (Centers for Disease Control and Prevention Nat’l AIDS Clearinghouse, U.S. Dep’t of Health and Human Services, Rockville, Md.), Sept. 1993, at 1.

24. See, e.g., Sally A. Lederman, *Estimating Infant Mortality from Human Immunodeficiency Virus and Other Causes in Breast-Feeding and Bottle-Feeding Populations*, 89 PEDIATRICS 290, 290–96 (1992).

25. The risk of transmission is greatest when mothers become infected during the breast-feeding period. See World Health Organization, *Global Programme on AIDS - Consensus from the WHO/UNICEF Consultation on HIV Transmission*, WKLY. EPIDEMIOLOGICAL REC., June 12, 1992, at 117.

of *in utero* transmission are not well understood, and methods to prevent such transmission are still being studied. As a result of *in utero* transmission, there have been infants born who are not only HIV positive, but who also have a clinical diagnosis of AIDS upon birth.²⁶

Researchers believe that the most common means of vertical transmission is transmission during delivery.²⁷ During delivery, mucous membranes of the emerging infant's eyes, ears, and nose inevitably come into sustained contact with substantial amounts of the mother's blood. For this reason, the majority of vertical transmissions occur during delivery.²⁸ Recent studies indicate that this risk of vertical transmission rises with the amount of HIV present in a pregnant woman's blood.²⁹

3. Effect of HIV on the Fetus and Newborn Infant

Approximately 75% of HIV positive children acquire the infection perinatally.³⁰ HIV disease ravages the immune systems of fetuses and newborn infants in an even more devastating fashion than those of infected adults. The immune system of a fetus or newborn infected with HIV often never achieves a significant degree of healthy functioning.³¹ Thus, HIV infected fetuses and HIV infected newborns frequently exhibit characteristics of in-

26. See NAT'L COMM'N TO PREVENT INFANT MORTALITY, FACT SHEET (1992).

27. See European Collaborative Study, *Risk Factors for Mother-to-Child Transmission of HIV-1*, 339 LANCET 1007 (1992).

28. Studies indicate that the risk of vertical transmission can be reduced by up to 50% if the HIV infected mother delivers her baby by Caesarean section rather than vaginally. M.L. Newell et al., *Caesarean Section and Risk of Vertical Transmission of HIV-1 Infection*, 343 LANCET 1464, 1466 (1994). A Caesarean section greatly reduces the amount of infected blood with which the newborn infant comes into contact during the birth. *Id.* A preliminary study indicates that Caesarean sections may have their most beneficial impact if performed before the onset of labor, and that some obstetrical indications for Caesarean sections, such as placental abruptions, may themselves increase the risk of infection. *Id.* The authors conclude that "more detailed information on the circumstances of delivery . . . could help clarify the timing of transmission." *Id.*

29. See Lawrence K. Altman, *High H.I.V. Levels Raise Risk to Newborns*, 2 *Studies Show*, N.Y. TIMES, Aug. 17, 1994, at C8.

30. Marshall H. Becker & Jill G. Joseph, *AIDS and Behavioral Change to Reduce Risk: A Review*, 78 AM. J. PUB. HEALTH 394 (1988).

31. See, e.g., S. Blanche et al., *A Prospective Study of Infants Born to Women Seropositive for Human Immunodeficiency Virus Type 1*, 320 NEW ENG. J. MED. 1637, 1643-48 (1989); Italian Multicentre Study, *Epidemiology, Clinical Features, and Prognostic Factors of Pediatric HIV Infection*, 2 LANCET 1043, 1043-45 (1988); H. Minkoff et al., *Pregnancies Resulting in Infants with Acquired Immunodeficiency Syndrome AIDS-Related Complex: Follow Up of Mothers, Children, and Subsequent Born Siblings*, 69 OBSTETRICS & GYNECOLOGY 288, 289-91 (1987).

fection which would likely occur in an adult only after years of HIV infection. The result is yet another disturbing aspect of the pandemic: a newborn infant with HIV typically faces an extremely short and painful life.³²

B. *Antiviral Treatments for HIV: Effectiveness, Risks, and Resistance*

Antivirals are a class of drugs which slow the replication of HIV within an infected person by blocking the ability of the virus to replicate itself within the DNA of a host cell. Antiviral drugs have not demonstrated the ability to kill completely all HIV in an infected person's body, nor have antiviral drugs shown the ability to stop replication of the virus entirely. For these reasons, antiviral drugs are of limited efficacy in treating HIV infection. Their use is generally initiated to slow down the destruction of an infected person's immune system, the goal being to provide either an increased life span to an HIV infected person, to extend the period of time during which an infected person's life is free from severe episodes of illness, or both.

AZT was the first antiviral drug approved by the FDA for the treatment of HIV disease. All of the subsequent antiviral drugs approved by the FDA for the treatment of HIV disease³³ work in generally the same manner as AZT — interrupting the cycle of replication of HIV within the DNA of a host cell at roughly the same stage in the cycle. As of this writing, the only approved class of drugs for use in treating HIV infection is antivirals.³⁴

32. The average age of an HIV-infected infant at death is 18 months. NAT'L COMM'N TO PREVENT INFANT MORTALITY, *supra* note 26.

33. The other antiviral drugs approved by the FDA for common use as of this writing are DDI, DDC, and D4T. See *Step By Step*, THE ECONOMIST, Nov. 26, 1994, at 93. These drugs, along with AZT, are also referred to as nucleoside analogs. 3TC, another nucleoside analog, is currently classified by the Food and Drug Administration as an experimental drug but is widely available under an expanded access program. When administered in conjunction with AZT to an HIV positive patient, 3TC appears to significantly enhance the effectiveness of AZT. This drug combination continues to be closely studied. See John S. James, *3TC Plus AZT: Important Treatment Advance?*, AIDS TREATMENT NEWS, Dec. 2, 1994, at 1.

34. It is widely expected that other nucleoside analogs (such as 3TC) will be approved for use soon. James, *supra* note 33. A particularly promising new class of drugs, protease inhibitors, that interrupt the cycle of replication of HIV inside a cell at a different stage than that of nucleoside analogs is expected to be approved and available soon. See Marlene Cimon & Thomas H. Maugh II, *New Drugs Offer Hope in Battle Against AIDS*, L.A. TIMES, Feb. 1, 1995, at A1, A13. Preliminary results indicate that protease inhibitors may be 10 to 20 times as effective as AZT in

Antiviral drugs have undesirable side effects, including anemia, peripheral neuropathy, and severe headaches.³⁵ In addition, because the use of these antiviral drugs is relatively new, potential long-term side effects of these drugs are unknown. Research into these side effects continues even as the drugs are administered to persons with HIV infections.³⁶ Some physicians, however, do not recommend AZT treatment to their HIV infected patients, citing the drug's toxicity and side effects.³⁷

In addition to those side effects indicated above, growing medical literature indicates that persons treated with an antiviral drug often begin to develop a resistance to the drug which may be permanent. Such resistance reduces or eliminates the drug's ability to slow down the replication of the virus and the subsequent destruction of the immune system.³⁸ For this reason, HIV positive persons who are being treated with an antiviral drug often take the drug only for limited periods of time, switch to a different antiviral drug, or use the various drugs in different combinations.³⁹

1. Effect of Antiviral Treatment on Pregnant Women

There is limited information available about the specific effects of antiviral treatment on pregnant women.⁴⁰ Preliminary studies indicate that the use of AZT does not appear to cause effects on pregnant women different from the general side effects

stopping HIV replication inside the body. *Id.* Researchers now believe that a combination therapy of both protease inhibitors and antiviral drugs may create a vastly improved weapon against HIV replication. *Id.* Because the effects of the new class of drugs on vertical transmission are unknown and will likely be so for some time, this paper will not discuss these other drugs. It is likely, however, that the analysis of this paper would similarly apply to any proposed compelled treatment of HIV positive pregnant women with these new drugs.

35. See, e.g., PHYSICIAN'S DESK REFERENCE, *supra* note 1 (side effects of AZT). Such side effects occur because antiviral drugs interfere with cellular enzymes similar to the viral enzyme they target. See Cimons & Maugh, *supra* note 34, at A13.

36. Because of the terminal nature of HIV disease in most patients, the antiviral drugs were and continue to be approved by the FDA on an expedited basis, on the theory that the immediate benefits to a patient's health outweigh the longer term and unknown risks from extended use.

37. See *Zidovudine for Mother, Fetus, and Child: Hope or Poison?*, 344 LANCET 207 (1994).

38. See, e.g., Marilyn S. Smith, *Zidovudine Resistance Persists After Therapy Discontinued*, AIDS WKLY., Feb. 14, 1994, at 5.

39. See *Step By Step*, *supra* note 33.

40. Rhoda Sperling et al., *A Survey of Zidovudine Use in Pregnant Women with Human Immunodeficiency Virus Infection*, 326 NEW ENG. J. MED. 857, 857-61 (1992).

experienced by the entire population of AZT users. AZT appears to be well-tolerated by pregnant women and has not been associated with malformations in newborns, premature birth, or fetal distress.⁴¹

2. Effect of Antiviral Treatment on Fetuses and Newborn Infants

Researchers continue to study the effects of antiviral therapy on fetuses and newborn infants. There is some preliminary data indicating that the use of AZT by pregnant women does not increase the risk of birth defects in their children.⁴² The current position of the Centers for Disease Control and Prevention is that the benefits of taking AZT in reducing vertical transmission of HIV outweigh potential side effects to the infants.⁴³ There has, however, been some concern expressed by researchers that the long-term effects of a pregnant mother's use of AZT on her infant are unknown and research on this issue will take years.⁴⁴

C. AZT and Reduced Risk of Vertical Transmission of HIV

Protocol 076 (the AZT study), a clinical trial conducted in the United States and France,⁴⁵ was the first study to illustrate the effect of antiviral treatment on reducing the risk of vertical transmission of HIV. The study concluded that the risk of seroconversion by an infant born to a woman with mildly sympto-

41. *Id.*

42. See *Birth Outcomes Following Zidovudine Therapy in Pregnant Women*, MORBIDITY & MORTALITY WKLY. REP., June 10, 1994, at 409; see also *Zidovudine Therapy of HIV-1 Infection During Pregnancy: Assessment of the Effect on the Newborns*, AIDS WKLY., May 17, 1993, at 25 (reporting that infants of women treated with AZT during pregnancy were of normal height, weight, and neurological growth).

43. See Public Health Service, U.S. Department of Health and Human Services, Draft Recommendations for HIV Counseling and Testing for Pregnant Women (Feb. 23, 1995) [hereinafter Draft Recommendations]; see also *Birth Defects in AZT Users Mirror General Population*, 9 AIDS ALERT 116 (1994), available in LEXIS, Nexis Library, ASAPII File.

44. See Liz Hunt & Philippa Bourke, *Caution over Use of AZT to Protect Fetus*, THE INDEPENDENT (London), Aug. 10, 1994, at 6; Ursula Ardnt, *More Research Needed on AZT Fetal Effects*, L.A. TIMES, Mar. 12, 1995, at E6 (letter to the editor).

Should AZT or other antiviral drugs be found to have severe effects on the fetus, the impetus for coercive treatment of pregnant women with the drugs would be expected to subside. For purposes of this paper, I will assume that the current findings of the Centers for Disease Control and Prevention will remain in force, and that treatment of fetuses with AZT is medically justified, taking into consideration the risks to the fetus.

45. Connor et al., *supra* note 2.

matic HIV disease who had no prior treatment with antiviral drugs during the pregnancy could be reduced by two-thirds if doctors administered AZT ante partum and intra partum to the mother, as well as to the newborn for six weeks.⁴⁶ AZT treatment would effectively reduce the risk of seroconversion by an infant born to an HIV positive woman from 25.5% to 8.3%.⁴⁷ It should be noted that the study was of a particular subcategory of all HIV positive pregnant women, namely those who were relatively healthy.⁴⁸ In August 1994, after preliminary results of the study had been published, the U.S. Food and Drug Administration Antiviral Drugs Advisory Committee unanimously recommended approval of the use of AZT to prevent vertical transmission.⁴⁹ The U.S. Public Health Service published recommendations for the administration of AZT to pregnant women and their babies, but noted that "the long-term effects of [AZT] therapy for both treated mothers and infants are unknown, and HIV-infected pregnant women must consider both the benefits and potential risks when making decisions to receive such therapy."⁵⁰

II. THE LEGAL AND ETHICAL ISSUES

A considerable consensus exists within the medical community that women who are HIV infected should be informed of all of their options for contraception and reproduction, including abortion.⁵¹ The presumption behind such a recommendation is that when a woman receives counseling about the potential risk to her infant of acquiring HIV, the woman will choose not to become pregnant.⁵² One study has indicated that a higher proportion of women who are aware of their own HIV positive sta-

46. *Id.*

47. *A Gain Against AIDS that Carries Ethical Questions*, *supra* note 4.

48. Connor et al., *supra* note 2.

49. *Approval for New Use of AZT*, AIDS WKLY., Aug. 8, 1994, at 19.

50. *See Draft Recommendations*, *supra* note 43.

51. *See, e.g., Human Immune Deficiency Virus Infections* AM. C. OF OBSTETRICS & GYNECOLOGISTS TECH. BULL., Dec. 1988, at 1. The U.S. Health Service explicitly acknowledged this consensus in the Draft Recommendations. *See Draft Recommendations*, *supra* note 43.

52. Sunderland et al., *The Impact of Human Immunodeficiency Status on Reproductive Decisions of Women*, 79 OBSTETRICS & GYNECOLOGY 1027, 1027-31 (1992). Note, however, that in 1993 an estimated 7000 HIV infected women delivered infants in the United States. *See Centers for Disease Control and Prevention, Update: AIDS Among Women — United States 1994*, MORBIDITY & MORTALITY WKLY. REP., Feb. 10, 1995, at 81.

tus choose to abort their fetuses than women who are aware that they are HIV negative.⁵³ There have been a number of studies, however, which indicate that a sizable percentage of women aware both of their own HIV positive status *and* the risk of infecting their infants through vertical transmission nonetheless decide to become pregnant.⁵⁴

The reasons behind the decision of an HIV positive woman to bear a child are complex.⁵⁵ Many women may feel pressure from the great value society places upon women to reproduce, and may feel that bearing a child can improve their community status. Some commentators have observed that this pressure may be especially strong in minority cultures.⁵⁶ Women who are HIV infected and chemically dependent may experience child-rearing as a boost to their fractured self-esteem.⁵⁷ Some HIV infected women, cognizant of the heightened risk that their own life spans may be shortened, choose to become pregnant in order to leave behind a legacy.⁵⁸ Still other women, especially those who are asymptomatic, may experience denial about their own condition and its possible implications,⁵⁹ an experience which is

53. Frank D. Johnstone et al., *Women's Knowledge of Their HIV Antibody State: Its Effect on Their Decision Whether to Continue the Pregnancy*, 300 BRIT. MED. J. 23 (1990). The authors of the study, however, characterize this difference as not statistically significant and conclude that "many women with HIV infection do not see this as a reason to terminate a wanted pregnancy." *Id.*

54. See, e.g., *id.*; Selwyn et al., *Prospective Study of Human Immunodeficiency Virus Infection and Pregnancy Outcomes in Intravenous Drug Users*, 261 JAMA 1289, 1289-94 (1989).

55. For a discussion of the variety of reasons which may inform an HIV positive woman's decision to become pregnant, see Richard Beck et al., *Understanding and Counseling Special Populations with HIV Seropositive Disease*, AM. REHABILITATION, Autumn 1993, at 24.

This paper contemplates potential legal responses to the decision of an HIV positive woman to choose to bear a child without initiating antiviral therapy. In limiting my discussion in this manner, I do not intend to dismiss the situation of a woman who unintentionally becomes pregnant and, not wishing to remain pregnant, cannot afford an abortion or will not have one for moral or religious reasons. With the publication of the AZT study, much of the current debate (at present, over mandatory testing and counseling) appears to presuppose that no HIV positive woman would ever choose to carry a fetus to term without taking AZT if she were aware of her own HIV positive status and the risks to the fetus. For this reason, I address the situation of such women in this paper, since I believe they will be the most immediate focus of any attempt to legislate restrictions on their reproductive choices.

56. *Id.* at 24-25.

57. *Id.* at 25.

58. C. Levine & N. Dubler, *Uncertain Risks and Bitter Realities: The Reproductive Choices of HIV-Infected Women*, 68 MILBANK Q. 321, 334-35 (1990).

59. AIDS THE SECOND DECADE 101 (Heather G. Miller et al. eds., 1990).

typical in many HIV infected persons and which may play a useful role in maintaining both physical and psychological health following an HIV positive diagnosis.

The decision of an HIV positive pregnant woman to bear a child is ethically troubling to a significant percentage of our society. Some members of the medical community, citizen activists, and politicians, justifiably concerned over the quality and length of life of an HIV infected infant, have begun to call for legislation that would require HIV testing of all pregnant women.⁶⁰ Such legislation would require that women be notified of their HIV positive status in order to make an informed decision about whether or not to initiate therapy to protect the health of their fetus.⁶¹

It is entirely possible that the same concerns which drive the push for mandatory HIV testing of pregnant women will lead to calls for mandating that the mother "do the right thing" with the information — where "the right thing" would be defined as the initiation of every possible medical treatment, including AZT therapy, to protect the health of the fetus.⁶² Because of the like-

60. See, e.g., *HIV Testing is a Help, Not Punishment*, CHI. SUN-TIMES, Mar. 3, 1995, at 39 (discussing a proposed Illinois HIV Pregnancy Screening Act). For a summary of the ethical considerations behind screening pregnant women for HIV, see Edmund G. Howe, *Societal and Clinical Approaches to Preventing Pediatric AIDS: Some Psychological Aspects and Their Ethical Considerations*, 5 AIDS & PUB. POL'Y. J. 9 (1990). For an economic analysis of the benefits of screening, see Abdolazim Houshyr, *Screening Pregnant Women for HIV Antibody: Cost-Benefit Analysis*, 6 AIDS & PUB. POL'Y J. 2 (1991).

At the time of this writing, there was some concern among AIDS activists that the United States Congress might require mandatory testing of all pregnant women getting care at facilities funded under the Ryan White Act. See Anne Rochell, *HIV Test Urged For All Pregnant Women*, ATLANTA J. & CONST., Feb. 23, 1995, at A9.

In addition to mandating the testing of pregnant women, some jurisdictions are contemplating mandatory testing of newborn infants. For a discussion of one such bill, see Kevin J. Currin, Note, *Newborn HIV Screening and New York Assembly Bill No. 6747-B: Privacy and Equal Protection of Pregnant Women*, 21 FORDHAM URB. L.J. 857 (1994). See also Linda F. Post, Note, *Unblinded Mandatory HIV Screening of Newborns: Care or Coercion?*, 16 CARDOZO L. REV. 169 (1994).

61. The issue of whether a pregnant woman has the "right not to know" her HIV status is a hotly debated topic which will undoubtedly be invigorated by the AZT study. As previously mentioned, for purposes of bringing the ethical issues to light in the sharpest manner, this paper contemplates the situation of a hypothetical woman who, despite knowing of her own HIV positive status, decides not to initiate AZT therapy. I do not, by simplifying the issue for the purpose described above, intend to presume that forced HIV testing and notification is either legally or ethically justified.

62. See, e.g., Kolata *supra* note 9, at B14 (Dr. Arthur Caplan, director of the Center for Bioethics at the University of Pennsylvania, is quoted as follows: "It seems to me that despite all the verbiage, this isn't such a complicated moral call

likelihood of such a scenario, it is important to examine the legal and ethical basis for compelling the initiation of antiviral therapy for HIV positive pregnant women.⁶³ I conclude, based on current medical understanding of antiviral treatment, that mandated antiviral treatment cannot be justified legally or ethically.

A. *Compelled Medical Treatment of HIV Positive Pregnant Women with Antiviral Therapy*

Governmental efforts to coerce HIV positive pregnant women to initiate AZT therapy could take a number of subtle and not so subtle forms. First, direct legislation could require such women to initiate and continue therapy as medically indicated. Accompanying penalties could enforce such legislation. Second, legislation could coerce the woman through her physician,⁶⁴ by requiring the physician to direct the woman to initiate therapy. The physician, then, would be subject to penalties for failure to do so. Lastly, the government might coerce women into AZT therapy less directly, by permitting an HIV infected child to maintain an action against a mother who chose not to initiate AZT therapy. An examination of the legal and ethical validity of these coercive methods follows.

1. *Direct Legislation Requiring HIV Positive Pregnant Women to Initiate Antiviral Therapy*

Any direct legislation requiring HIV positive pregnant women to initiate antiviral therapy at the time medically indicated to protect the health of their fetus must first address difficulties presented by the established legal right of patients to refuse medical treatment for themselves, as well as the established legal right of parents to refuse medical treatment for their children.

... If you can prevent a young child from being infected, it would seem to me that you are under an *obligation to take the steps necessary to prevent that harm.*") (emphasis added).

63. The conclusion that compelled antiviral therapy cannot be legally or ethically justified may well illuminate some of the ethical issues in the debate over the right not to know one's own HIV status, for a justifiable distinction between a pregnant woman and other members of society may not be sustainable if the pregnant woman cannot be forced to act in any particular manner on the knowledge of her own status.

64. By the use of the term physician, I mean to indicate any medically trained personnel to whom a pregnant woman would turn for advice on her medical condition.

a. *Right of a Pregnant Woman to Refuse Medical Treatment for Herself*

Because any mandated antiviral therapy necessarily involves administration of medical treatment to the pregnant woman, the government would first have to demonstrate that there are sufficient state interests overriding the right of the patient to refuse treatment for herself.⁶⁵ Competent adults have the right to refuse any medical intervention.⁶⁶ However, the following state interests have been asserted as overriding a patient's refusal to be treated: (1) the preservation of life, (2) the prevention of suicide, (3) the integrity of the medical profession, and (4) the protection of innocent third parties.⁶⁷

The first three asserted state interests are clearly not served by the compelled initiation of antiviral therapy. AZT therapy has not been proven to preserve the life of an HIV infected pregnant woman,⁶⁸ the right of a mother to take her own life is not at issue, and medical ethics do not require the forcible treatment of nonconsenting competent patients.⁶⁹ It may be argued, however, that state-compelled antiviral treatment is necessary for the protection of an innocent third party, namely the fetus. Yet courts have been wary of requiring a competent adult to undergo a medical procedure for the benefit of another person,⁷⁰ accepting

65. See, e.g., PRESIDENT'S COMM'N FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, MAKING HEALTH CARE DECISIONS 2-3 (1982).

66. The right of competent patients to refuse treatment originated in the common law, but is also constitutionally protected as a liberty interest under the Due Process Clause of the Fourteenth Amendment. *Cruzan v. Director, Mo. Dep't of Health*, 497 U.S. 261, 269-79 & n.7 (1990). See generally David C. Blickenstaff, Comment, *Defining the Boundaries of Personal Privacy: Is There a Paternal Interest in Compelling Therapeutic Fetal Surgery?*, 88 Nw. U. L. REV. 1157, 1160 n.16 (1994).

67. See, e.g., *In re A.C.*, 573 A.2d 1235, 1246 (D.C. 1990); *Public Health Trust v. Wons*, 541 So. 2d 96, 97 (Fla. 1989).

68. See *supra* part I.B.

69. See GEORGE J. ANNAS, *THE RIGHTS OF PATIENTS: THE BASIC ACLU GUIDE TO PATIENT RIGHTS* 204 (1989) (discussing the following position of the American Medical Association: "The social commitment of the physician is to sustain life and relieve suffering. Where the performance of one duty conflicts with the other, the choice of the patient . . . should prevail.") (citation omitted).

70. The reluctance of courts to order medical procedures to be conducted on one person for the benefit of another was perhaps best articulated in *McFall v. Shimp*, a Pennsylvania case in which a man in need of bone marrow sought to force a donation from a relative: "For a society which respects the rights of one individual, to sink its teeth into the jugular vein or neck of one of its members and suck from it sustenance for another member, is revolting to our hard-wrought concepts of jurisprudence." *McFall v. Shimp*, 10 Pa. D. & C.3d 90, 92 (C.P. 1978) (emphasis omitted).

arguendo that the fetus could appropriately be characterized as a person in this context.⁷¹

b. *Right of the Mother to Refuse Medical Treatment of Her Fetus*

In *Prince v. Massachusetts*,⁷² the U.S. Supreme Court stated that the exercise of a fundamental right by a parent, in that case, the exercise of the free practice of religion, did not include the "liberty to expose . . . the child . . . to ill health."⁷³ The *Prince* Court added that: "Parents may be free to become martyrs themselves. But it does not follow that they are free . . . to make martyrs of their children."⁷⁴ Thus as a preliminary matter, it may be insufficient for a mother to seek to withhold her consent to the administration of AZT by claiming that her fundamental right to refuse medical treatment precludes any legal responsibility for failing to provide her fetus with necessary medical treatment. When various modes of treatment, each consistent with generally accepted medical practice, are available, parents may legally choose among them. When, however, the only choice is between one mode of treatment and nontreatment, parents may legally choose nontreatment only if it is in the child's best interest.⁷⁵ The state's traditional obligation, under its *parens patriae* power, to protect children from child neglect caused by nontreatment, arises only in situations where it is clear that the best interest of the child demands that the child be treated.⁷⁶

It would be difficult for a court to conclude that the child's best interest is clearly served by treatment with AZT therapy as opposed to nontreatment. Because the risk of HIV infection to the child, absent antiviral treatment, is approximately one in

A few courts have, however, ordered pregnant women to submit to surgical procedures for the benefit of their fetuses — in fact, there are a number of cases involving such obstetrical interventions as Caesarean sections. See generally Veronika E.B. Kolder, M.D. et al., *Court Ordered Obstetrical Interventions*, 316 *NEW ENG. J. MED.* 1192 (1987).

71. Indeed the determination of whether the fetus is a person for purposes of medical treatment is an issue on which volumes have been written. Without implying agreement with the characterization of a fetus as a person, this paper seeks to avoid that debate by engaging in analysis generally applicable regardless of the characterization of the fetus.

72. 321 U.S. 158 (1994).

73. *Id.* at 166–67.

74. *Id.* at 170.

75. See ANNAS, *supra* note 69, at 211.

76. *Id.*

four,⁷⁷ a decision by a mother to "play the odds" cannot clearly be characterized as not in the child's best interest. Nonetheless, a court might be tempted to second-guess the mother's assessment of the child's best interest in this situation. However, the doctrine of override would carefully circumscribe the court's ability to do so.

Under the doctrine of override, which allows courts to override parental withholding of consent to medical treatment of a minor child, state courts have been more willing to permit override when the child's life is significantly endangered, the treatment does not present significant risks, and the treatment is likely to cure the underlying condition.⁷⁸ In cases where the danger to the child's life is not imminent, the decisions of state courts are less uniform.⁷⁹ For example, where a mother refused to permit blood transfusions for her son during an operation to correct a spinal deformity which may have shortened his life span, the Pennsylvania Supreme Court refused to allow an override of the mother's withholding of consent.⁸⁰ In contrast, a Pennsylvania lower court permitted the override of a parental refusal to provide consent to blood transfusions to treat a medical condition which presented a 16 to 18% risk of death within one year to the child and an 80% chance of severely disabling the child without the transfusions.⁸¹ In characterizing this override doctrine, one commentator concluded that "the greater the harm to the child to be averted, and the more lasting protection the treatment will provide, the more likely the override becomes."⁸²

The AZT study has demonstrated a sharply reduced risk to the fetus of even *acquiring* HIV disease. Therefore, at first glance, there appears to be a strong case for a future court to permit the override of a mother's refusal to accept administration of AZT in order to reduce the fetus's chance of seroconverting during birth. The harm to the fetus to be averted is extremely grave⁸³ and the increased protection to the fetus would amount to permanent freedom from seroconversion barring subsequent

77. *A Gain Against AIDS that Carries Ethical Questions*, *supra* note 4.

78. See Suzanne Sangree, *Control of Childbearing by HIV-Positive Women: Some Responses to Emerging Legal Policies*, 41 BUFF. L. REV. 309, 375 (1993).

79. *Id.* at 376-77.

80. *In re Green*, 292 A.2d 387 (Pa. 1972).

81. *In re Cabrera*, 552 A.2d 1114 (Pa. Super. Ct. 1989).

82. Sangree, *supra* note 78, at 377.

83. See *supra* text accompanying note 32.

HIV exposure.⁸⁴ The case is strengthened if we indulge the presumption, as indicated by early medical studies, that the fetus would not suffer any long-term medical risk from AZT administration, or at least that any such risk would be commonly considered minor relative to the risk resulting from seroconversion.⁸⁵ Even those legal analysts strictly opposed to any compelled testing or treatment of HIV positive pregnant women have described this scenario, in which seroconversion is not treated but rather prevented, as a “complex case for analysis under the override doctrine.”⁸⁶

Yet upon closer analysis the case may not be so complex. Any compelled administration of AZT to HIV positive pregnant women would clearly fall outside the parameters of the override doctrine, and only a court which sought greatly to expand the scope of that doctrine could order such compelled treatment. There are substantial obstacles to the applicability of the override doctrine. First and perhaps most significantly, application of the doctrine to the case of pregnancy requires the characterization of the fetus as a child. The rationale for the doctrine — that the state interest in protecting a child’s life may outweigh, in extraordinary circumstances, the parent’s right to withhold consent for medical treatment of that child — may not be mechanically asserted to justify an override in the context of a pregnancy. However, one need not resolve this issue in order to conclude that the doctrine is inapplicable in this context.

It is impossible to divorce the right to withhold consent to the treatment of the fetus from the right of the pregnant woman to withhold treatment for herself. Administration of AZT to the fetus to prevent seroconversion cannot, at present, occur in a surgically precise manner, delivering the drug solely to the fetus. Rather, for the fetus to receive the increased protection from AZT, the mother must embark on a regime of AZT therapy, at least for the limited period of time required to provide protection to the fetus.

The consequences of the AZT therapy for the mother are great and cannot be ignored. First, there are well-established side effects to AZT, which may greatly impair the mother’s health and the quality of her life.⁸⁷ Recall that the side effects of

84. See *supra* notes 46–47 and accompanying text.

85. See Sperling et al., *supra* note 40 and accompanying text.

86. Sangree, *supra* note 78, at 380–81.

87. See *Step by Step*, *supra* note 33 and accompanying text.

AZT are so well-known, feared, and documented that some physicians treating HIV positive patients, even when faced with the likely progression of their patients' HIV disease into AIDS and its accompanying manifestations, nonetheless choose not to recommend AZT therapy in order to preserve their patients' existing quality of life.⁸⁸ As we enter into our second decade of experience with AZT, AZT (and indeed the entire class of antiviral drugs of which AZT was the first) is at best considered a mere help in the management of HIV disease. AZT has never been demonstrated to rid the body of HIV permanently, and there is conflicting medical evidence as to whether AZT extends the life span of persons infected with HIV.⁸⁹

Second, there is a substantial body of medical evidence that suggests that once a person initiates AZT therapy, such therapy loses its effectiveness over time as the virus adapts to the presence of AZT in the bloodstream.⁹⁰ Therefore, for many people living with HIV, the timing of the decision to initiate AZT therapy is of major importance. While some patients and their physicians recommend the initiation of AZT therapy immediately upon learning that the patient is HIV positive, the majority of such doctors and patients initiate therapy only after the immune system has begun a very clear and precipitous decline.⁹¹ A legally compelled requirement to initiate AZT therapy at the time at which such therapy might sharply reduce the risk of perinatal transmission of HIV would infrequently coincide with the point in the progression of the mother's HIV disease when treatment would otherwise be medically indicated. Thus there are two potential side effects to the compelled AZT treatment of an HIV positive pregnant woman: the "direct" side effects which the AZT frequently causes in many HIV positive patients, and the "indirect" side effect caused by the resistance to the drug which the mother may develop.

It is important not to ignore the fact that the drug resistance which the HIV positive mother may develop has serious conse-

88. See *supra* note 37. Additionally, a minority of physicians and HIV infected patients subscribe to the belief that AZT (or other antiviral) treatment is itself a cofactor in the progression of HIV disease into AIDS. See, e.g., Michael Jones, *Why Do Doctors Hate This Man?*, *GENRE*, June 1994, at 43.

89. See *Step By Step*, *supra* note 33.

90. See *supra* note 38.

91. See, e.g., *PHYSICIAN'S DESK REFERENCE*, *supra* note 1 (The medically indicated time for initiation of AZT therapy is when an HIV-infected person's T-cell count has declined to under 500.).

quences for the infant born without seroconverting. Should the resistance which the mother develops make it more difficult for doctors effectively to slow down the progression of HIV within the mother, her health might deteriorate more rapidly than might otherwise be the case. The possibility exists, therefore, that an infant born to such a mother would experience less time with her, or experience less quality time with her, than if AZT therapy had not been initiated. Consequently, in the case of an HIV positive pregnant woman, application of the override doctrine could well force a pregnant mother to choose between her life and the life of her fetus. This choice has already been directly confronted by courts in several contexts. In *Thornburgh v. American College of Obstetricians & Gynecologists*,⁹² the U.S. Supreme Court concluded that statutes that require a trade-off between the woman's life and fetal survival are unconstitutional.⁹³

Even if the life of the mother is not directly at stake, there is a dearth of legal authority for the proposition that the government can compel a mother to submit to any medically risky intrusion of her body to save the life of her fetus. Indeed, much of the existing case law concludes just the opposite. For example, in *Colautti v. Franklin*,⁹⁴ the Supreme Court struck down a Pennsylvania statute requiring the use of whatever abortion technique provided "the best opportunity for the fetus to be aborted alive," because the statute did not clearly specify that "the woman's health must always prevail over the fetus' life and health when they conflict."⁹⁵ Commentators have concluded that courts are unlikely to compel conduct to protect the life of a fetus, for "the burden that would be placed upon the parents by compelling particular conduct in order to protect the fetus is far more substantial than the burden of avoiding negligent conduct that entails unreasonable risks to the fetus."⁹⁶

Ultimately, direct legislation requiring HIV positive pregnant women to initiate AZT therapy would be impractical to enforce. As one commentator has noted, "[E]ven if one sought to mandate the use of an intravenous dose of zidovudine during delivery, how could one enforce a daily regimen of five doses of

92. 476 U.S. 747 (1986), *overruled in part* by *Planned Parenthood v. Casey*, 112 S. Ct. 2791 (1992).

93. *Id.* at 769.

94. 439 U.S. 379 (1979).

95. *Id.*

96. Carol A. Simon, Note, *Parental Liability for Prenatal Injury*, 14 COLUM. J.L. & SOC. PROBS. 47, 87 (1978).

zidovudine during the second and third trimesters of pregnancy? Would anything short of incarceration make such treatment possible?"⁹⁷ The prospect of the incarceration of HIV positive women who have just given birth to HIV positive infants seems very unpalatable indeed.⁹⁸ The nonenforcement of such legislation mandating compelled treatment would then raise complicated issues of the moral legitimacy of unenforced statutes.

2. Requirement That Doctors Direct HIV Positive Pregnant Women to Initiate Antiviral Therapy

Courts have rejected civil or criminal liability for a physician's decision to honor a patient's refusal of lifesaving treatment.⁹⁹ On the other hand, serious legal consequences threaten a physician who forces a woman to undergo treatment in the absence of a court order.¹⁰⁰ Legislation requiring the physician to encourage the HIV positive pregnant woman to initiate AZT therapy might be proposed as a way to coerce the woman into AZT therapy without violating the dictates of existing case law regarding physician liability. Similar legislation limiting physician freedom to explore all reproductive options with a pregnant woman has been upheld in other contexts.¹⁰¹ The moral arguments against enacting such legislation in the first instance might serve to dissuade legislators from taking such action. An examination of these arguments follows.

Because infants with AIDS suffer more than similarly situated adults, physicians may feel justified in urging HIV positive pregnant women to initiate AZT therapy. Nonetheless, medical

97. Ronald Bayer, *Ethical Challenges Posed by Zidovudine Treatment to Reduce Vertical Transmission of HIV*, 331 NEW ENG. J. MED. 1223, 1223-25 (1994).

98. But perhaps such incarceration is not inconceivable. Certain local municipalities have enacted legislation authorizing the incarceration of tuberculosis patients who do not faithfully adhere to the medically indicated drug therapy. See, e.g., *TB Patients Who Reject Pills Face a Dose of Jail*, CHI. SUN-TIMES, Nov. 26, 1994, at 15. In addition, one national survey found that 46% of physicians interviewed thought that mothers who refused medical advice and thereby endangered the life of the fetus should be detained in hospitals or other facilities so that compliance could be ensured. See Kolder, *supra* note 70.

99. See, e.g., Lawrence J. Nelson & Nancy Milliken, *Compelled Medical Treatment of Pregnant Women: Life, Liberty and Law in Conflict*, 259 JAMA 1060 (1988).

100. *Id.*

101. See, e.g., *Rust v. Sullivan*, 500 U.S. 173 (1991). Professor Sangree argues that the use of directive counseling to discourage HIV positive women from bearing children would [also] violate the principle articulated in *Skinner v. Oklahoma*. See Sangree, *supra* note 78. (*Skinner*, 316 U.S. 535 (1942), invalidated a state statute which sought to prevent the birth of socially undesirable offspring.)

ethics present a compelling case for physicians not to do so. Edmund Howe has suggested an analogy to physician counseling of parents contemplating whether to have a baby where there is a substantial chance that the baby will have a severe genetic ailment.¹⁰² In both situations, physicians encounter particularly vulnerable potential parents: parents making life and death decisions about their future children. By expressing a moral position, physicians would be exploiting the vulnerability of a person who may, under the circumstances, give undue weight to the opinion of a medical professional, when such decisions properly involve considerations beyond the merely medical.¹⁰³ HIV positive pregnant women are likely to be even more vulnerable than parents facing genetic risk assessments, because the women making the decisions must confront not only their child's mortality but their own mortality as well.¹⁰⁴

In addition, the number and variety of HIV treatments which have been developed in the past twelve years suggest that HIV infected offspring will be less symptomatic and will live longer, as will their HIV infected parents. As the severity of the consequences of HIV infection diminish, there is less of a case for physicians to be directive in their treatment recommendations.¹⁰⁵

3. Permitting Actions by a Perinatally HIV Infected Child Against His or Her Mother for Negligent Infliction of Prenatal Injury

Courts have increasingly permitted children to bring personal injury actions against their mothers for harm resulting from the mother's conduct during her pregnancy.¹⁰⁶ Such actions face a substantial proximate causation problem in the case of the perinatally infected child. Because there remains an 8% risk to an infant of contracting HIV even if the HIV positive mother does initiate the AZT therapy at the medically indicated time, how does an HIV positive child establish that the mother's failure to do so is a sufficiently proximate cause of its injury? Even assuming, *arguendo*, that such a proximate cause requirement could be

102. See Howe, *supra* note 60.

103. *Id.*

104. *Id.* at 12.

105. *Id.*

106. See Thomas M. Fleming, Annotation, *Right of Child to Action Against Mother for Infliction of Prenatal Injuries*, 78 A.L.R. 4th, § 2[a], at 1084 (1990).

satisfied, no such action may be legally justified in the context of an HIV positive mother's refusal to initiate antiviral therapy.

Courts have only recently begun to determine whether a child may bring an action against its mother for negligent infliction of prenatal injuries. The two prominent cases in this emerging area reach strikingly different conclusions, illustrating both the difficulties inherent in such an action as well as the differing philosophies behind permitting such actions at all. In *Grodin v. Grodin*,¹⁰⁷ a Michigan appellate court held that a mother could be held liable for her decision to take tetracycline during her pregnancy, a drug which the child claimed caused his teeth to be discolored.¹⁰⁸ The court ruled that a child has a legal right to begin life with a sound mind and body, and that if the child could demonstrate a causal connection between the mother's unreasonable conduct and the harm to the child, the child might recover damages from the mother.¹⁰⁹ The court added an important qualification, that the doctrine of parent-child tort immunity would apply where the mother's negligence involved a "reasonable exercise of parental discretion" regarding the provision of medical care, among other things.¹¹⁰ The court implied that where difference of opinion on the issue is possible, the reasonableness of the mother's conduct would be determined by a factfinder assessing the utility of the mother's conduct in relation to the magnitude of the resulting risk to her unborn child.¹¹¹

In sharp contrast, the Illinois Supreme Court held in *Stallman v. Youngquist*¹¹² that a child does not have a cause of action against its mother for prenatal injury that the mother unintentionally inflicts upon the child during pregnancy.¹¹³ The court reasoned that since any act or omission by the mother may affect her developing fetus, liability would make the mother a guarantor of the child's condition at birth.¹¹⁴ The court was troubled by the implications of imposing this type of liability: the legal adver-

107. 301 N.W.2d 869 (Mich. Ct. App. 1980).

108. *Id.* at 869.

109. *Id.* at 870-71.

110. *Id.* at 871.

111. *Id.* The implication that the reasonableness of an exercise of parental discretion would be determined by a factfinder was disagreed with in *Mayberry v. Pryor*, 352 N.W.2d 322 (Mich. Ct. App. 1984), *rev'd on other grounds*, 374 N.W.2d 683 (Mich. Ct. App. 1985), and *Thelen v. Thelen*, 435 N.W.2d 495 (Mich. Ct. App. 1989).

112. 125 Ill. 2d 267 (1988).

113. *Id.*

114. *Id.* at 276.

serial relationship between mother and child from conception to birth and the fact that the law does not require any other defendant to endure "biological changes of the most profound type, in order to bring forth an adversary into the world."¹¹⁵

Even if future courts were to adopt the more liability-friendly view of the *Grodin* court, the unique situation of an HIV positive pregnant mother and her fetus suggests that an action by the child against the mother for negligent infliction of prenatal injury would be unsuccessful. There are two primary hurdles which an action by a child claiming negligent infliction of prenatal injury by a mother who did not initiate antiviral therapy must overcome: the doctrine of parental immunity recognized in *Grodin*, and the establishment of a duty on the part of the mother to initiate antiviral therapy.

The decision whether to initiate drug therapy to protect the health of the fetus fits squarely within the parental tort immunity rule which the *Grodin* court recognized. The decision of a parent to provide medical services or not is a decision traditionally immunized from tort liability. In addition, it is highly unlikely that a factfinder would conclude that the mother's evaluation of the resulting risk to the child from a highly toxic substance with unknown long-term side effects was clearly unreasonable, especially under circumstances in which an untreated fetus stands a 75% chance of not seroconverting.¹¹⁶ Also, the *Stallman* court's concern over the extension of liability to a mother who subjects herself personally to extensive medical risk would likely weigh equally heavily on future courts facing this scenario. The doctrine of parental tort immunity, however, has widely varying vitality among the states.¹¹⁷ The state of flux of the doctrine raises at least the possibility that a future court may not apply the parental tort immunity doctrine and might allow a future action by a child for the mother's failure to initiate antiviral therapy.

The existence of a duty of the mother to protect a fetus from harm resulting from her own negligent conduct has been debated for many years.¹¹⁸ I pause here only to comment that any attempt to demonstrate the existence of a duty of an HIV positive

115. *Id.* at 278.

116. *See supra* note 4.

117. For a comprehensive review of the state of the doctrine of parental tort immunity in the fifty states, see Ron Beal, "Can I Sue Mommy?" *An Analysis of a Woman's Tort Liability for Prenatal Injuries to Her Child Born Alive*, 21 SAN DIEGO L. REV. 325, 333-57 (1984).

118. *See, e.g., id.* at 357-70 (discussing attempts to establish this duty).

mother to initiate antiviral therapy would face insurmountable obstacles. Unlike the traditional concept of a duty to refrain from negligent actions that might harm the fetus, the decision not to undergo antiviral therapy is most appropriately characterized as a decision not to engage in an action which might reduce the odds of harm to the fetus, odds which are already in the fetus's favor.¹¹⁹ Given that antiviral therapy has at least the potential for unknown long-term side effects, a mother defending against such an action would surely have a strong argument that she was in fact acting to protect the fetus by *not* taking the omitted action of which the child is complaining. A court attempting to establish a violation of a duty of the mother in this context would face an exceedingly difficult task in attempting to ground a pronounced extension of duty principles in prior case law.

B. *The Justifiability of Governmental Coercion*

In defense of the governmental ability to mandate protection of the health of the fetus, some commentators have suggested that having chosen to carry her fetus to term, the mother subjects her interests in privacy and autonomy to limitation under the state *parens patriae* power to protect child welfare.¹²⁰ This argument has significant rhetorical force. Once a mother has made the free choice to carry a pregnancy to term, the argument goes, doesn't the mother freely assume limitations upon her own freedom of choice in matters of medical treatment?

Although this argument has significant visceral appeal, there is, however, a chasm between the conclusion that the mother has assumed these limitations and the right of the government to coerce her to accept such limitations. Governmental authority to coerce an HIV positive pregnant woman into AZT therapy would undoubtedly be justified by the traditional governmental authority to secure public health and safety. But where there is no threat to a person other than the fetus, the abortion debate demonstrates that the government must also justify intrusions of the mother's right to personal autonomy and bodily integrity. Without revisiting that debate, I would only suggest that there are several additional unique considerations which make such a justification particularly unwieldy and troubling.

119. See *supra* note 4 and accompanying text.

120. See, e.g., John A. Robertson, *Procreative Liberty and the Control of Conception, Pregnancy, and Childbirth*, 69 VA. L. REV. 405 (1983); Simon, *supra* note 96.

It must be remembered that one effect of treatment of HIV positive pregnant women with AZT during pregnancy will likely be a greater percentage of healthy babies born to mothers who may become very ill and die shortly after the birth of the baby. Already the plight of "AIDS orphans," children who have been left motherless as a result of maternal death from HIV infection, has reached staggering proportions. By the year 2000, it is estimated that there will be between 72,000 and 125,000 AIDS orphans in the United States alone.¹²¹ Additionally, 93,000 to 112,000 children will be born to HIV infected mothers.¹²² A government which institutes coercive antiviral treatment of HIV positive mothers must necessarily be braced to absorb an increase in the number of orphaned children that such a policy would create.

An additional question is how one would justify the distinctive treatment of AZT therapy in this context, as opposed to other actions or omissions of the mother which similarly affect the health or indeed the HIV status of the fetus. A few months before the publication of the official results of the AZT study, another published study indicated that maternal vitamin A deficiency appears to increase the risk of vertical transmission.¹²³ Should we mandate, therefore, that an HIV positive mother take a daily vitamin pill? Perhaps we would not be troubled by such a seemingly innocuous requirement, especially given the ease and safety with which vitamins can be administered. But how then do we draw a principled line between that mandate and, for example, a further mandate that HIV positive pregnant women stay in bed in order to reduce stress on their bodies? We may begin to grow troubled by the compounding intrusions into the sphere of the woman's personal autonomy, but on what basis do we justify drawing an arbitrary line in the sand?¹²⁴

121. Deborah Pinkney, *Motherless Child: The AIDS Epidemic Is Creating the Largest Orphan Crisis Since the Influenza Outbreak of 1918; How Can Physicians Help?*, AM. MED. NEWS, Apr. 18, 1994, at 13.

122. *Id.* In 1993, approximately 1000 to 2000 infants were perinatally infected with HIV. See Centers for Disease Control and Prevention, *Update: AIDS Among Women — United States, 1994*, MORBIDITY & MORTALITY WKLY. REPORT, Feb. 10, 1995, at 81, 82.

123. Richard D. Semba et al., *Maternal Vitamin A Deficiency and Mother-to-Child Transmission of HIV-1*, 343 LANCET 1593 (1994); see Lawrence K. Altman, *Vitamin A Deficiency Linked to Transmission of AIDS Virus From Mothers to Infants*, N.Y. TIMES, Feb. 3, 1995, at A17.

124. See, e.g., Lawrence J. Nelson, *Compelled Medical Treatment of Pregnant Women: Life, Liberty, and Law in Conflict*, 259 J. AM. MED. ASSOC. 1060-66 (1988)

The variables inherent in the process of giving birth to a healthy baby are incapable of external control, and at some point the mother must be trusted to make the decisions regarding appropriate levels of care. The relationship of mother and child is one unlike any other legal relation between members of society, and that status justifies the assertion that society must treat the mother-child relationship with great deference and care.

CONCLUSION

The crisis of HIV infection may be most sadly reflected in the misery suffered by its youngest victims. The news of the AZT study has brought new hope to the fight to eliminate pediatric AIDS, and has encouraged women who desire to bear a child despite their own HIV positive status. Yet it is imperative that the decisions arising out of the AZT study be treated with the same reasoned deliberation that has generally marked many of the other public health policy decisions made in response to the HIV pandemic. There may develop a societal consensus that treatment of pregnant women with AZT so as to reduce the risk of vertical transmission is a moral imperative. The risks of transforming that moral imperative into governmentally coercive action are many and would likely in the long run exacerbate the suffering of some of our most vulnerable citizens, HIV infected pregnant women and their children.

("Every action a pregnant woman takes has a potential impact on her fetus, including the simplest and most common activities of daily living: eating, drinking, sexual intercourse, and physical activity . . .").